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TUESDAY, AUGUST 17, 1976

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NOTE: There were no items eligible for inclusion in the list of RULES GOING INTO EFFECT TODAY.

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List of Public Laws

This is a continuing numerical listing of public bills which have become law, together with the law number, the title, the date of approval, and the U.S. Statutes citation. The list is kept current in the FEDERAL REGISTER and copies of the laws may be obtained from the U.S. Government Printing Office.

S. 3735..... Pub. Law 94–380
"National Swine Flu Immunization Program of 1976".
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S. 537..... Pub. Law 94–381
To improve judicial machinery by amending the requirement for a three-judge court in certain cases and for other purposes.
(Aug. 12, 1976; 90 Stat. 1119)

S. 3589..... Pub. Law 94–382
To designate the Federal office building located in Manchester, New Hampshire, as the "Norris Cotton Building".
(Aug. 12, 1976; 90 Stat. 1121)

H.R. 5360..... Pub. Law 94–383
To increase benefits provided to American civilian internees in Southeast Asia.
(Aug. 12, 1976; 90 Stat. 1122)

AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The six-month trial period ended August 6. The program is being continued on a voluntary basis (see OFR notice, 41 FR 32914, August 6, 1976). The following agencies have agreed to remain in the program:

Monday	Tuesday	Wednesday	Thursday	Friday
NRC	USDA/ASCS		NRC	USDA/ASCS
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Documents normally scheduled on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

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rules and regulations

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

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Community Services Administration

Section 213.3373 is amended to show that one position of Confidential Secretary (Stenography) to the Deputy Director is excepted under Schedule C.

Effective on publication August 17, 1976, § 213.3373(a)(7) is added as set out below:

§ 213.3373 Community Services Administration.

(a) *Office of the Director.* * * *

(7) One Confidential Secretary (Stenography) to the Deputy Director.

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

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.76-24136 Filed 8-16-76;8:45 am]

Title 9—Animals and Animal Products

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

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

PART 73—SCABIES IN CATTLE

Release of Area Quarantined

This amendment releases a portion of Filmore County in Nebraska from the areas quarantined because of cattle scabies. Therefore, the restrictions pertaining to the interstate movement of cattle from quarantined areas contained in 9 CFR Part 73, as amended, will not apply to the excluded area, but the restrictions pertaining to the interstate movement of cattle from nonquarantined areas contained in said Part 73 will apply to the excluded area. No areas in Nebraska remain under quarantine.

Accordingly, Part 73, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of cattle because of scabies is hereby amended as follows:

§ 731.1a [Amended]

In § 73.1a, paragraph (b) relating to the State of Nebraska is deleted.

(Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; (21 U.S.C. 111–113, 115, 117, 120, 121, 123–126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

Effective date: The foregoing amendment shall become effective August 11, 1976.

The amendment relieves restrictions no longer deemed necessary to prevent the spread of cattle scabies and should be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

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

Done at Washington, D.C., this 11th day of August 1976.

F. W. HANSEN, Jr.,
Acting Deputy Administrator, Veterinary Services.

[FR Doc.76-23849 Filed 8-16-76;8:45 am]

Title 10—Energy

CHAPTER III—ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION

PART 700—CONDUCT OF EMPLOYEES

PART 735—CONDUCT OF EMPLOYEES

These regulations on Conduct of Employees for the Energy Research and Development Administration (ERDA) are revised and redesignated as Part 735, Title 10, CFR.

On January 19, 1975, the former Atomic Energy Commission (AEC) was abolished and ERDA was established as one of two successor agencies pursuant to the provisions of the Energy Reorganization Act of 1974, Pub. L. 93–438; (42 U.S.C. 5801); 88 Stat. 1233. By section 301(b) of that Act the regulations of the AEC which were in effect on that date continued in effect until modified, terminated, superseded, set aside, or revoked by appropriate action or operation of law. On March 3, 1975, notice was given in the FEDERAL REGISTER (40 FR 8794), of ERDA's intent to republish and recodify all regulations applicable to ERDA; and as an interim measure, the regulations of the ABC codified as Parts 0–170 of Title 10, CFR, were redesignated as Parts 700 through 870 of a new Chapter III of Title 10, CFR. 10 CFR Part 700 contains the existing ERDA regulations on Conduct of Employees, which are hereby revised in their entirety and redesignated as Part 735. The current Part 735, Human Uses of Byproduct Material, has no applicability to ERDA, and the material contained therein is hereby removed from 10 CFR, Chapter III.

The establishment of ERDA and its different organizational structure from that of the AEC have rendered obsolete many of the procedural aspects of the existing Conduct of Employees regulations. The expanded program responsibilities of ERDA have also made changes desirable in certain substantive aspects of the revised regulations.

The new Part 735 reflects this change in agency name, organizational structure and functions. It includes a number of language changes designed to achieve greater clarity and employee understanding of the regulations. Substantive changes include:

1. Reducing the level of stock and bond interests determined to be "too remote or too inconsequential to affect the integrity of government officers' or employees' services" under 18 U.S.C. section 208;

2. Enlarging the scope of financial interests required to be reported to include such "remote" or "inconsequential" interests; and

3. Broadening the criteria for determining positions which require the filing of employment and financial interest statements.

Because this revision relates solely to matters of agency management or personnel, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon as unnecessary and for making this revision effective on August 17, 1976.

In consideration of the foregoing, Part 735 is removed, and Part 700 is revised and redesignated as Part 735 as set forth below. This Part 735, Conduct of Employees, has been approved by the Civil Service Commission.

Although these regulations become effective on August 17, 1976, interested persons who desire to submit written comments or suggestions for consideration in connection with such regulation should send them on or before November 1, 1976, to the General Counsel, Energy Research and Development Administration, Washington, D.C. 20545.

Effective date: August 17, 1976.

ROBERT C. SEAMANS, Jr.,
Administrator.

Therefore 10 CFR Part 700 is revised and redesignated Part 735 as set forth

below and the material contained in the present Part 735 is revoked:

Subpart A—General

Sec.
735.1 Policy.
735.2 Program objective.
735.3 Responsibilities and authorities.
735.4 Definitions.
735.5 Basic requirements.
735.6 National emergency application.

Subpart B—Conflict of Interest Restrictions

735.20 General.
735.21 Acts affecting a personal financial interest (based on 18 U.S.C. 208).
735.22 Future employment (based on 18 U.S.C. 208).
735.23 Activities of officers and employees in claims against and other matters affecting the Government (based on 18 U.S.C. 205).
735.24 Receiving salary from source other than the United States Government (based on 18 U.S.C. 209).
735.25 Compensation to employees in matters affecting the Government (based on 18 U.S.C. 203).
735.26 Disqualification of former officers and employees in matters connected with former duties or official responsibilities (based on 18 U.S.C. 207).
735.27 Appearances by former employees before ERDA.
735.28 Confidential statements of employment and financial interests.

Subpart C—Other Restrictions Imposed by Statute on Conduct of Employees

735.30 Description of statutory provisions.

Subpart D—Other Restrictions Imposed by ERDA on Conduct of Employees

735.40 Outside employment and other outside activity.
735.41 Misuse of information.
735.42 Gifts, entertainment, and favors.
735.43 Use of Government property.
735.44 Scandalous conduct.
735.45 Employee indebtedness.
735.46 Gambling, betting, and lotteries.
735.47 Handling of funds entrusted by fellow employees.
735.48 Ex parte contacts.
735.49 Employment under professional term appointments of persons on extended leave of absence from a previous employer with reemployment rights or other benefits with the previous employer.
735.49a Other proscribed actions.

Subpart E—Ethical and Other Conduct Responsibilities of Special Government Employees

735.50 Use of Government employment.
735.51 Use of inside information.
735.52 Coercion.
735.53 Gifts, entertainment, and favors.
735.54 Miscellaneous statutory provisions.
735.55 Applicable standards of conduct.
Appendix A Concurrent Resolution.
Appendix B Position Categories Requiring Statements of Employment and Financial Interests By Incumbents.
Appendix C Criteria for Determining Positions or Categories of Positions Listed in Appendix B.

AUTHORITY: Pub. L. 94-438, sec. 105(a), 88 Stat. 1238 (42 U.S.C. 5815).

Subpart A—General

§ 735.1 Policy.

(a) The personnel policy of the U.S. Energy Research and Development Administration states in ERDA Manual 4101, in part, that:

> Conduct and self-discipline of ERDA employees, both on and off the job, must measure up to unusual standards * * *. (ERDA Manual Appendix 4101, Personnel Policy—Foreword, paragraph 3.)

(b) Section 735.101 of the Civil Service Commission regulations (5 CFR 735.101), issued pursuant to Executive Order 11222, "Prescribing Standards of Ethical Conduct for Government Officers and Employees," May 8, 1965, states that:

> The maintenance of unusually high standards of honesty, integrity, impartiality, and conduct by Government employees and special Government employees is essential to assure the proper performance of the Government business and the maintenance of confidence by citizens in their Government. The avoidance of misconduct and conflicts of interest on the part of Government employees and special Government employees through informed judgment is indispensable to the maintenance of these standards * * *.

§ 735.2 Program objective.

(a) The program objective is to protect the interests of the public and employees by setting forth principles, practices, and standards governing conduct of employees in such a manner that they may be readily understood by the individuals involved and practicably administered by ERDA.

(b) It is expected that the provisions of this part will be observed and administered in a manner which is consistent with both their spirit and their letter.

(c) Of necessity, because of the nature of the criminal statutes and the subject matter involved, this part cannot deal with all of the problems which may arise with regard to the conduct, including conflicts of interest, of employees and former employees.

§ 735.3 Responsibilities and authorities.

(a) Employees shall:

(1) Comply with the statutes and the rules, standards of conduct, and other regulations set forth in this part.

(2) Consult the full text of applicable statutes as to whether an action in question may in any way violate the statutes.

(3) Be guided in all their actions by the Code of Ethics for Government Service, adopted by Concurrent Resolution of the Congress (Appendix A).

(4) Conduct themselves in such a manner as to create and maintain respect for ERDA and the U.S. Government and avoid situations which require or appear to require a balancing of private interests or obligations against official duties.

(5) Be mindful of the high standards of integrity expected of them in all their activities, personal and official.

(6) Not give or appear to give favored treatment or competitive advantage to any member of the public including former employees of ERDA, appearing before them on their own behalf or on behalf of any nongovernmental interest.

(7) Recognize that violation of any of the instructions or statutes referred to in this part may subject them to disciplinary action by ERDA in addition to the penalty prescribed by law for such violation.

(8) Discuss with their immediate supervisor, or counselor as appropriate, any problem arising out of this part.

(b) Supervisors:

(1) Inform themselves of any problems of their employees arising out of this part, consult with the cognizant ERDA counselor as appropriate, and take prompt action to see that the problems, if they cannot be resolved, are referred to higher authority.

(2) Relieve employees from assignments in accordance with § 735-22(a).

(c) The Deputy Administrator assumes responsibilities assigned in §§ 735-22(b), 735-28, 735-40(d), and 735-42(c)(10).

(d) The Heads of Headquarters Divisions and Offices and Heads of Field Organizations:

(1) Bring to the attention of appropriate contractors under their jurisdiction those provisions of this part (such as "Future Employment"; "Ex Parte Contracts"; "Assisting Former Employees"; "Gifts, Entertainment, and Favors"; "Cancellation of Contracts"; and others) which may affect the actions of a contractor and his employees in dealing with ERDA employees.

(2) Report to the Office of Internal Review all complaints concerning fraud, graft, corruption, diversion of ERDA assets, and misconduct of ERDA employees; take action as a result of investigations; and report on action taken, as provided in ERDA Manual Chapter 0702, "Notification and Investigation of Misconduct."

(3) Assume responsibilities assigned in §§ 735-21(b), 735-23(d), 735-27, 735-28, 735-40(b), and 735-49(a). In addition Heads of Field Organizations assume responsibilities assigned in § 735-22(b).

(e) The Heads of Headquarters Divisions and Offices and Heads of Field Organizations in addition:

(1) Provide a copy of this part to each employee and special Government employee, and to each such new employee at the time of his entrance on duty.

(2) Provide a copy of all revisions to each employee and special Government employee.

(3) Bring the provisions of this part to the attention of each employee and special Government employee annually, and at such other times as circumstances warrant.

(4) Assure the availability of counseling services under paragraph (h) of this section to each employee and special Government employee.

(5) Have available for review by employees and special Government employees, as appropriate, copies of laws, Executive Order 11222, ERDA regulations, and pertinent Civil Service Commission regulations and instructions relating to ethical and other conduct.

(6) Notify employees and special Government employees at time of entrance on duty and periodically thereafter of the availability of counseling services under paragraph (h) of this section and how and where these services are available.

(f) The Director, Division of Personnel, Headquarters, assumes the responsibilities assigned in § 735-49.

(g) The Director, Office of Internal Review, Headquarters, investigates all questions of employees' conduct, fraud, etc., in ERDA, in accordance with ERDA Manual Chapter 0702.

(h) The General Counsel:

(1) Is the counselor for ERDA.

(2) Serves as ERDA's designee to the Civil Service Commission on matters covered by this part.

(3) Designates deputy counselors for the Headquarters and for field organizations.

(4) Coordinates counseling services, and assures that counseling and interpretations on questions of conflicts of interest and other matters covered by the part are available to deputy counselors.

(5) Carries out the specific responsibilities assigned in §§ 735–21(b), 735–27, 735–28, and 735–49 (a) and (b).

§ 735.4 Definitions.

(a) "Administrator" means the head of ERDA, as provided by the Energy Reorganization Act of 1974, Section 102, Pub. L. 93–438, (42 U.S.C. 5812).

(b) "ERDA" means the agency established by the Energy Reorganization Act of 1974, Section 101, Pub. L. 93–438 (42 U.S.C. 5811), comprising all officers, employees, and representatives authorized to act in any case or matter, whether clothed with final authority or not.

(c) "Employee" means an ERDA officer or employee (including regular employee and, except where the contents indicate otherwise, a special government employee) or a member of the Uniformed Services or an employee of another Government agency assigned or detailed to ERDA.

(d) "Former employee" means a former Government employee (regular or special Government employee formerly employed by ERDA or by a component of an agency transferred to ERDA by the Energy Reorganization Act of 1974) and a former member of the Uniformed Services (other than enlisted personnel) assigned or detailed to ERDA.

(e) "Special Government employee" means an officer or employee of ERDA, who is retained, designated, appointed, or employed to perform, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days, temporary duties either on a full-time or intermittent basis. The term includes ERDA consultants, experts, and members of advisory boards, but does not include enlisted members of the Uniformed Services.

(f) "Official responsibility" means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government action.

(g) "Organization," as used in this part in connection with 18 U.S.C. 208, means universities, foundations, nonprofit research entities and similar nonprofit organizations, States, counties and municipalities and subdivisions thereof as well as business organizations.

(h) "Head of Divisions and Offices, Headquarters," means the Director of a Headquarters Division or Office. For employees in the immediate office of the Administrator, Deputy Administrator or an Assistant Administrator, the term refers to the particular official (Administrator, Deputy Administrator or the Assistant Administrator) to whom the employee reports.

(i) "Head of a Field Organization" means the Manager of an Operations Office, the Director of an Energy Center, or the Head of a Field Office reporting directly to an Assistant Administrator or Headquaters Division or Office Director.

(j) "Person" means an individual, a corporation, a company, an association, a firm, a partnership, a society, a joint stock company, or any other organization or institution.

(k) "Uniformed services" means the Army, Navy, Air Force, Marine Corps, Coast Guard, Environmental Science Services Administration, and Public Health Services. (37 U.S.C. 101(3).)

§ 735.5 Basic requirements.

(a) *Applicability.* The provisions of this part apply to all current and former employees including special Government employees. Members of the Uniformed Services and employees of other Government agencies assigned or detailed to ERDA are required by § 735–28 to furnish a statement of employment and financial interests if they are performing duties of a position specified in § 735–28(a). However, a member of the Uniformed Services or an employee of another Government agency assigned or detailed to ERDA is not relieved of his responsibilities under regulations or code of conduct prescribed by his parent military service or employing agency.

(b) *Cancellation of contracts.* ERDA reserves the right to declare void, in accordance with law, any contract negotiated or administered in violation of the provisions of ERDA regulations, or statute.

(c) *Scope of part.* This part incorporates the statutes, the instructions and specific procedures, pertaining to an employee's conduct.

(d) *Construction of criminal or civil statutes.* The paraphrased version of any criminal or civil statute in this part shall not constitute a binding interpretation thereof upon ERDA or the Federal Government.

(e) *Certifications.* Certifications called for by §§ 735–23(e) and 735–26 (c) and (d), shall be submitted for publication in the FEDERAL REGISTER.

(f) *Disciplinary and other remedial action.* (1) A violation of the regulations in this part by an employee or special Government employee may be cause for appropriate disciplinary action which may be in addition to any penalty prescribed by law.

(2) Remedial action, whether disciplinary or otherwise, shall be effected in accordance with any applicable laws, executive orders, and regulations.

(g) *Presidential appointees.* Presidential appointees covered by section 401(a) of Executive Order 11222 shall not receive compensation or anything of monetary value for any consultation, lecture, discussion, writing, or appearance the subject matter of which is devoted substantially to the responsibilities, programs, or operations of ERDA, or which draws substantially on official data or ideas which have not become part of the body of public information.

§ 735.6 National emergency application.

The provisions of this part continue in effect without modification in a national emergency.

Subpart B—Conflict of Interest Restrictions

§ 735.20 General.

(a) Part I, "Policy," of Executive Order 11222 states:

> Where government is based on the consent of the governed, every citizen is entitled to have complete confidence in the integrity of his government. Each individual officer, employee, or adviser of government must help to earn and must honor that trust by his own integrity and conduct in all official actions.

(b) The elimination of conflicts of interest in the Federal service is one of the most important objectives in establishing general standards of conduct. A conflict of interest situation may exist where a Federal employee's private interests, usually of an economic form, conflict, or rise a reasonable question of conflict with his public duties and responsibilities. The potential conflict is of concern whether it is real or only apparent.

(c) An employee shall not: (1) Have a direct or indirect financial interest that conflicts substantially, or appears to conflict substantially, with his Government duties and responsibilities; or (2) engage in, directly or indirectly, a financial transaction as a result of, or primarily relying on, information obtained through his Government employment.

(d) An employee is not precluded from having a financial interest or engaging in financial transactions to the same extent as a private citizen not employed by the Government so long as it is not prohibited by law, Executive Order 11222, Civil Service Commission regulations, or the regulations in this part.

(e) Certain provisions in 18 U.S.C. 201–209, dealing with conflicts of interest in Federal employment are referred to in §§ 735–21 through 735–27.

§ 735.21 Acts affecting a personal financial interest (based on 18 U.S.C. 208).

(a) General. Except as permitted by paragraphs (b), (c), and (d) of this section, no employee shall participate personally and substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation,

arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest.

(b) Granting of ad hoc exemptions.

(1) If an employee desires to request an exemption from the prohibition of paragraph (a) of this section, he shall fully inform the Head of the Headquarters Division or Office, or Head of the Field Organization, as appropriate, in writing of the nature and circumstances of the particular matter and of the financial interests involved and shall request a written determination in advance as to the propriety of his participation in such matter.

(2) The Head of the Headquarters Division or Office, or Head of the Field Organization, as appropriate, after examining the information submitted, may relieve the employee from participation in the particular matter and so advise him in writing; or, he may approve the employee's participation in such matter upon advising him in writing:

(i) That he has determined the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such officer or employee, and

(ii) That no provision of law and no regulation in this part would appear to be violated by the employee's participation in the particular matter.

(3) When the Head of the Headquarters Division or Office, or Head of the Field Organization, believes it is inappropriate for him to make a determination as provided in paragraph (b)(2) of this section, he shall forthwith submit the information with his recommendation through channels to the Deputy Administrator who shall make a determination as provided in paragraph (b)(2) of this section, forwarding the original of his determination to the submitting official and a copy to the employee involved.

(4) A copy of each request and response made under the provisions of paragraphs (b)(1) and (b)(2) of this section shall be forthwith forwarded through channels to the General Counsel as a matter of record. Copies of all documents referred to in paragraphs (b)(1), (2) and (3) of this section shall be filed by the holders thereof in their confidential files.

(5) Whenever it can be reasonably anticipated that there will be a need to invoke these procedures repeatedly, and where it also appears that a burden would be placed on ERDA thereby, consideration should be given by the Head of the Headquarters Division or Office, or Head of the Field Organization to dismissal or transfer of the employee to another position where the problems will not arise, or to the elimination of the outside interest creating the difficulty. It is expected that the employee concerned will take the initiative in resolving any problem in this area.

(c) Exemption of remote or inconsequential financial interest. (1) In accordance with the provisions of 18 U.S.C. 208(b)(2), ERDA has exempted the following financial interests from paragraph (a) of this section and from the requirements of paragraph (b) of this section, upon the ground that such interests are too remote or too inconsequential to affect the integrity of its employees' services: [1]

(i) Interests in the form of shares of common or preferred stocks, including warrants to purchase such shares, and of corporate bonds or other corporate securities, if the current aggregate market value of the stocks and other securities so owned in any single corporation does not exceed $5,000 and provided such stocks and securities do not exceed 1 percent of the dollar value of the outstanding shares, bonds or other securities of said class.

(ii) Interests in the form of bonds other than corporate bonds, regardless of the value of the interest.

(iii) Interests in the form of shares of a mutual fund or regulated investment company regardless of the value of such interest, provided the mutual fund or regulated investment company does not deal primarily in atomic energy or other energy stocks and bonds.

(2) Where a person covered by this exemption is a member of a group organized for the purpose of investing in equity or debt securities, the interest of such person in any enterprise in which the group holds securities shall be based upon said person's equity share of the holdings of the group in that enterprise.

(3) For purposes of paragraph (c)(1) of this section, computations of dollar value of financial interests in corporations shall be by means of:

(i) Market value in the case of stocks listed on national exchanges; or

(ii) Over-the-counter market quotations as reported by the National Daily Quotation Service in the case of unlisted stocks; or

(ii) By means of net book value (i.e. assets less liabilities) in the case of stocks not covered by the preceding two categories. With respect to debt securities, face value shall be used for valuation purposes.

(4) The dollar value and percentage of financial interests listed above in paragraph (c)(1) of this section shall be computed as of the date on which the employee first participated personally and substantially in any particular matter, within the meaning of 18 U.S.C. 208(a), relating to the enterprise concerned. The dollar value and percentage so computed shall govern during the entire period that the employee participates in the particular matter unless, after the aforesaid date of computation, he, or other person or organization referred to in paragraph (a) of this section, acquires an additional interest in the same enterprise. In the event of such subsequent acquisition, the dollar value and percentage shall be recomputed as of the date of such acquisition. If, in such case, the dollar value and percentage computed exceeds the limitations described in paragraph (c)(1) of this section, the general exemption provided therein shall no longer be applicable and an ad hoc exemption must be sought in accordance with paragraph (b) of this section.

(d) Special exemption for special Government employees. Federal Personnel Manual Chapter 735, Appendix C, provides that a special Government employee should in general be disqualified from participating as such in a matter of any type the outcome of which will have a direct and predictable effect upon the financial interests covered by 18 U.S.C. 208. However, that chapter states that the power of exemption may be exercised in this situation "if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization." It is the policy of ERDA, in conformity with the foregoing, to exercise the power of exemption pursuant to 18 U.S.C. 208(b) in such situations. The authority to grant such an exemption is delegated to the ERDA official responsible for appointment or designation of the particular consultant or advisor. This exemption is granted when the appointing official for the consultant or advisor concerned, signs the form ERDA-443 at item 18 which contains the statement that the employee "need not be precluded from rendering general advice in situations where no preference or advantage over others might be gained by any particular person or organization."

§ 735.22 Future employment (based on 18 U.S.C. 208).

(a) Solicitation, negotiation, or arrangements for private employment by an employee who is acting on behalf of ERDA in any particular matter in which the prospective employer has a financial interest are prohibited. With the authorization of his supervisor, an employee may be relieved of any assignment which, in the absence of such relief, might preclude such solicitation, negotiation, or arrangements.

(b) No employee shall undertake to act on behalf of ERDA in any capacity in a matter that to his knowledge affects even indirectly any party outside the Government with whom he is soliciting, negotiating, or has arrangements for future employment, except pursuant to the authorization of the Deputy Administrator after full disclosure, or in the case of a field employee, the Head of the Field Organization under whom he is employed. (See § 735-21.)

§ 735.23 Activities of officers and employees in claims against and other matters affecting the Government (based on 18 U.S.C. 205).

(a) No employee shall otherwise than in the proper discharge of his official duties:

[1] The interest of the employee includes the interest of the employee's spouse and minor child.

(1) Act as agent or attorney for prosecuting any claim against the United States, or receive any gratuity, or any share of or interest in any such claim in consideration of assistance in the prosecution of such claim, or

(2) Act as agent or attorney for anyone before any department, agency, court, court-martial, officer, or any civil, military, or naval commission in connection with any proceeeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest.

(b) A special Government employee shall be subjected to paragraph (a) of this section only in relation to a particular matter involving a specific party or parties (1) in which he has at any time participated personally and substantially as a Government employee or as a special Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise, or (2) which is pending in the department or agency of the Government in which he is serving: Provided, That paragraph (b) (2) of this section shall not apply in the case of a special Government employee who has served in such department or agency no more than 60 days during the immediately preceding period of 365 consecutive days.

(c) Nothing in paragraph (a) of this section prevents an employee, if not inconsistent with the faithful performance of his duties, from acting without compensation as agent or attorney for any person who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings.

(d) Nothing in paragraph (a) of this section prevents an employee from acting, with or without compensation, as agent or attorney for his parents, spouse, child, or any person for whom, or for any estate for which, he is serving as guardian, executor, administrator, trustee, or other personal fiduciary except in those matters in which he has participated personally and substantially as a Government employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, or which are the subject of his official responsibility, provided that the Head of the Division or Office, Headquarters, or Head of the Field Organization, as appropriate, approves.

(e) (1) Nothing in paragraph (a) of this section prevents a special Government employee from acting as agent or attorney for another person in the performance of work under a grant by, or a contract with or for the benefit of, the United States when represented by ERDA provided that the Administrator shall certify in writing that the national interest so requires. Such certification shall be submitted for publication in the FEDERAL REGISTER.

(2) The Special Government employee shall immediately notify ERDA when so designated to act as agent or attorney by his private employer.

(f) Nothing in paragraph (a) of this section prevents an employeee from giving testimony under oath or from making statements required to be made under penalty for perjury or contempt.

§ 735.24 Receiving salary from source other than the U.S. Government (based on 18 U.S.C. 209).

(a) No employee shall receive any salary, or any contribution to or supplementation of salary, as compensation for his services as an employee of ERDA from any source other than the Government of the United States, except as may be contributed out of the treasury of any State, county, or municipality.

(b) Nothing in paragraph (a) of this section prevents an employee of ERDA from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit sharing, stock bonus, or other employee welfare or benefit plan maintained by a former employer.

(c) Paragraph (a) of this section does not apply to a special Government employee or to an employee of the Government serving without compensation, whether or not he is a special Government employee.

(d) Paragraph (a) of this section does not prohibit acceptance of contributions, awards, or other expenses for training or to attend meetings under the terms of chapter 41 "Training" of title 5, United States Code. See ERDA Appendix 4150 "Employee Development and Training—Handbook".

§ 735.25 Compensation to employees in matters affecting the Government (based on 18 U.S.C. 203).

(a) No employee shall, otherwise than as provided by law for the proper discharge of official duties, directly or indirectly receive or agree to receive, or ask, demand, solicit, or seek, any compensation for any services rendered or to be rendered either by himself or another in relation to any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest, before any department, agency, court-martial, officer, or any civil, military, or naval commission.

(b) A special Government employee shall be subject to paragraph (a) of this section only in relation to a particular matter involving a specific party or parties (1) in which he has at any time participated personally and substantially as a Government employee or as a special Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, or (2) which is pending in the department or agency of the Government in which he is serving: Provided, That paragraph (b) (2) of this section shall not apply in the case of a special Government employee who has served in such department or agency no more than 60 days during the immediately preceding period of 365 consecutive days.

§ 735.26 Disqualification of former officers and employees in matters connected with former duties or official responsibilities (based on 18 U.S.C. 207).

(a) No employee, after his employment has ceased, shall knowingly act as agent or attorney for anyone other than the United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially as an employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, while so employed.

(b) No employee, within 1 year after his employment has ceased, may appear personally before any court or department or agency of the Government as agent, or attorney for, anyone other than the United States in connection with any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter involving a specific party or parties in which the United States is a party or directly and substantially interested, and which was under his official responsibility as an employee of the Government at any time within a period of 1 year prior to the termination of such responsibility.

(c) Nothing in paragraph (a) or (b) of this section prevents a former employee with outstanding scientific or technological qualifications from acting as attorney or agent or appearing personally in connection with a particular matter in a scientific or technological field if the Administrator shall make a certification in writing, submitted for publication in the FEDERAL REGISTER, that the national interest would be served by such action or appearance by the former employee.

(d) A former ERDA employee who desires to request for himself an exception to the legal restrictions set forth above on the basis of "scientific or technological" grounds may do so by submitting a written request to the Head of the ERDA office with which he would do business, who in turn will forward it to the Administrator with his recommendation. The Administrator, if he approves the exception, shall advise the former employee in writing through the ERDA office with which he applied and shall submit for publication in the FEDERAL REGISTER a statement to the effect that:

(1) The former employee has outstanding scientific or technological qualifications;

(2) The exception provided by 18 U.S.C. 207(b) is granted for a particular

matter in a scientific or technological field; and

(3) The national interest would be served by granting the exception.

§ 735.27 Appearances by former employees before ERDA.

When a former employee proposes to act as agent or attorney before ERDA on behalf of anyone other than the United States in connection with any of the matters cited in § 735-26, he is expected to make known to the appropriate official of ERDA the fact of his former assignment with ERDA (or with any of the components of other agencies transferred to ERDA under the Energy Reorganization Act of 1974). The Head of the Headquarters Division or Office or of the Field Organization or employee before whom the former employee appears, before transacting business with the former employee or authorizing employees under his jurisdiction to transact any business with the former employee, shall call the former employee's attention to the restrictions and penalties contained in 18 U.S.C. 207. No ERDA official or employee, except the General Counsel, shall offer to the former employee an interpretation of 18 U.S.C. 207 as applied to the situation at hand.

§ 735.28 Confidential statements of employment and financial interests.[2]

(a) Categories of employees required to submit statements. The following employees shall submit statements of employment and financial interests, prepared in accordance with paragraph (d) of this section:

(1) Employees paid at a level of the Executive Schedule in subchapter II of Chapter 53 of title 5, United States Code.

(2) Employees in positions or categories of positions regardless of their official titles, identified in Appendix B to this part.

(3) All consultants (including advisers and experts) (see ERDA Manual Chapter 4139 "Employment of Consultants and Advisers") and special Government employees. (A special Government employee who is not a consultant is not required to submit a statement of employment and financial interests when the operating (appointing) official finds that the duties of the position held by the special Government employee are of a nature and at such a level of responsibility that the submission of the statement by the incumbent is not necessary to protect the integrity of the Government. For this purpose, "consultant" and "expert" have the meaning given those terms by Chapter 304 of the Federal Personnel Manual ("Employment of Experts and Consultants") but do not include a physician, dentist, or allied medical specialist, whose services are procured to provide care and service to patients.)

(b) Appendix B. (1) Appendix B to this part shall be maintained and changes therein made by ERDA in accordance with the criteria set forth in Appendix C to this part.

(2) Heads of Headquarters Divisions and Offices and of Field Organizations shall, in conformity with the above referenced criteria, recommend changes in Appendix B to the Deputy Administrator for approval.

(c) (1) Heads of Divisions and Offices, Headquarters, and of Field Organizations shall as of September 30 of each year review the positions under their jurisdiction and determine, in accordance with Appendix B, the positions which require financial interest statements from their incumbents. The incumbent of each such position shall be notified of that fact and shall be furnished with three copies of the statement form. By copy of the notification (or a list of the names, grades and positions of employees required to file statements), the counselor or appropriate deputy counselor shall be informed by each Head of those employees required to submit statements. Each employee notified of the filing requirement as of September 30 shall submit his statement to his reviewing official by October 10.

(2) Whenever a new position is established, the Head of the Division or Office, Headquarters, or Field Organization Head establishing the position shall at that time determine whether the position calls for the submission of a statement in accordance with the criteria set out in Appendix B. If it is determined that a financial statement is a requirement of that position, any employee assigned to that position will be notified (with copy to the counselor or appropriate deputy counselor) of the requirement at the time of initial assignment and as of each September 30 thereafter. The employee shall submit the required statement to his reviewing official within 10 days of the notification or by October 10, as the case may be.

(3) Employees assigned to positions as Heads of Divisions or Offices, Headquarters, or of Field Organizations and persons employed under Professional Term Appointments shall submit a statement to their reviewing official prior to assuming the duties of the position and as of each September 30 thereafter. All other employees assigned to positions requiring the submission of a statement shall submit the required statement within 10 days of the initial assignment to that position and as of each September 30 thereafter.

(4) Statements of special Government employees who are not consultants (including experts and advisers) shall be submitted in accordance with the foregoing. Notice to such individuals shall also be in accordance with the foregoing. Statements of consultants (including experts and advisers) shall be submitted prior to appointment, and notice to same shall be in accordance with ERDA Manual Chapter 4139.

(d) Preparation of statement. Statements shall be prepared in accordance with the following:

(1) Form and content of statement. The forms prescribed by ERDA are:

Regular Government employees—Form ERDA-269.
Consultants (including experts and advisers)—Form ERDA-443.
Special Government employees (other than consultants)—Form ERDA-443 (excluding items 2-11).

(2) Interests of employee's relatives. The interest of a spouse, minor child, or other member of an employee's immediate household is considered to be an interest of the employee. For the purpose of this subparagraph, "member of an employee's immediate household" means those blood and in-law relations who are full-time residents of the employee's household.

(3) Information not known by employees. If any information required to be included on the statement or supplementary statement, including holdings placed in trust, is not known to the employee but is known to another person, the employee shall request that other person to submit information in his behalf, and shall report such request in Part IV of Form ERDA-269 or item 16b. of Form ERDA-443.

(4) Information not required to be submitted. This section does not require an employee to submit on a statement or supplementary statement the following:

(i) Any information relating to the employee's connection with, or interest in, a professional society or a charitable, religious, social, fraternal, recreational, public service, civic, or political organization or a similar organization not conducted as a business enterprise and which is not engaged in the ownership or conduct of a business enterprise. For the purpose of this section, educational and other institutions doing research and development or related work involving grants of money from or contracts with the Government are deemed "business enterprises" and are required to be included in an employee's statement.

(ii) Precise amounts of financial interests, indebtedness, or value of real property. The employee may, however, at a later time be required to reveal precise amounts if ERDA needs that information in order to carry out its responsibilities under applicable laws and regulations.

(iii) For special Government employees: In addition to (i) and (ii) above, those financial interests which are determined by the official responsible for such employee's appointment as not to be related either directly or indirectly to the duties and responsibilities of said employee.

(5) Supplementary statements—regular employees. Changes in, or additions to, the information contained in a regular Government employee's statement shall be reported by the employee as of September 30 each year, filed within 10 days thereof. The changes may be reported in a supplementary statement or

[2] Section 401 of Executive Order 11222 establishes separate reporting requirements for an agency head, a Presidential appointee in the Executive Office of the President who is not subordinate to the head of an agency in that Office, and a full-time member of a committee, board, or commission appointed by the President.

a wholly new statement as directed. The forms prescribed in paragraph (d)(1) of this section shall be used for this purpose. Where a supplementary statement is submitted, it shall be plainly marked "Supplementary." The changes and additions in such a supplementary statement shall be identified in terms of the specific part(s) of the statement being modified. All changes or additions occurring during the reporting period are to be reported, not merely employment and financial interests status as of the reporting date. If there are no changes in or additions to report, the supplementary statement shall so indicate. The employee shall submit his supplementary statement to the official who would be the recipient of an initial statement from the employee, as identified in paragraph (h) of this section. Notwithstanding the filing of the report(s) required by this section, each employee shall at all times avoid acquiring a financial interest that could result, or taking an action that would result, in a violation of the conflicts-of-interest provisions of section 208 of title 18, United States Code, or this Part 735.

(6) Supplementary statements—special Government employees. Changes in, or additions to, the information contained in a special Government employee's statement shall be reported in a supplementary statement within 10 days following the end of the calendar quarter in which the changes occur. Quarters end March 31, June 30, September 30, and December 31. The forms prescribed in paragraph (a)(1) shall be used for this purpose and plainly marked supplementary. The changes and additions shall be identified in terms of the specific part(s) of the statement being modified. All changes or additions occurring during the reporting period are to be reported, not merely employment and financial interests status as of the reporting date. If there are no changes or additions to report during a quarter, a negative report is not required. Each Head of Division or Office, Headquarters, and each Field Organization Head shall, 15 days prior to the end of each quarter, notify those special Government employees for whom the Head is responsible of the requirement for reporting changes in or additions to the special Government employee's statement. The special Government employee shall submit his supplementary statement to the official who would be the recipient of an initial statement from the employee, as identified in paragraph (h) of this section. Notwithstanding the filing of the report(s) required by this section, each special Government employee shall at all times avoid acquiring a financial interest that could result, or taking an action that would result, in a violation of the conflicts-of-interest provisions of section 208 of title 18, United States Code, or this Part 735.

(e) Reviewing statements and reporting conflicts of interest.

(1) The employee shall prepare the statement in triplicate, retain one copy, and submit two copies to the appropriate reviewer (see paragraph (h) of this section).

(2) The reviewer of the statement shall assess it for conflicts or the appearance of conflicts of interests in the context of the employee's assigned duties and responsibilities in ERDA.

(3) If the reviewer desires advice and guidance, he may discuss the statement with the counselor or appropriate deputy counselor.

(4) The reviewer shall discuss with the employee and point out any aspects of the statement which give rise, in the reviewer's opinion, to questions of conflict or of appearance of conflict. (The reviewer shall not take, or direct the employee to take, any action with respect to such conflict without first seeking the advice of the counselor or appropriate deputy counselor.)

(5) The reviewer shall in all cases record his opinion as to the absence of a conflict or the presence of an existing or potential conflict on both copies of the statement, and forward same to the ERDA counselor or deputy counselor, as appropriate.

(6) The ERDA counselor or deputy counselor shall review the statement, and discuss any questions with the reviewer and/or employee as necessary.

(7) If the ERDA counselor or deputy counselor believes that the statement evidences no question of conflict of interest, he shall record his opinion on both copies of the statement, and notify the reviewer.

(8) If the ERDA counselor or deputy counselor believes there is a question of conflict of interest, he shall record the question on the form. In addition he shall inform the reviewer of the conflicts question and of appropriate remedial action. (The counselor or deputy counselor shall make his services available to the reviewer and employee involved to assist in effecting a resolution of any conflict or appearance of conflict.) Action inconsistent with the advice of the counselor or deputy counselor shall not be taken without further consultation and approval. The reviewer shall report to the counselor or deputy counselor in writing the remedial action taken.

(9) When a statement submitted or information from other sources indicates a conflict between the interests of an employee and the performance of his services for ERDA and when the conflict or appearance of conflict is not resolved at a lower level in ERDA, the information concerning the conflict or appearance of conflict shall be reported to the Deputy Administrator, as appropriate, through the counselor. The employee concerned shall be provided an opportunity to explain the conflict or appearance of conflict.

(10) When, after consideration of the explanation of the employee provided for in paragraph (e)(9) of this section, the Deputy Administrator decides that remedial action is required, he shall take immediate action to end the conflict or appearance of conflict of interest. Remedial action may include, but is not limited to:

(i) Changes in assigned duties;

(ii) Divestment by the employee of his conflicting interest;

(iii) Disciplinary action; or

(iv) Disqualification for a particular assignment.

Remedial action, whether disciplinary or otherwise, shall be effected in accordance with any applicable laws, executive orders, and regulations. Disciplinary remedial action with respect to a member of the Uniformed Services or an employee of another Government agency assigned or detailed to ERDA shall be effected only by the parent military service or employing agency.

(11) Upon completion of processing, both ERDA copies of statements shall be filed in the office of the counselor or deputy counselor, in a special file maintained for that purpose. If an ERDA reviewer subsequently requires a copy of a statement for purposes of carrying out responsibilities under this part, he may request same from the counselor or deputy counselor.

(12) The required supplementary statements shall be processed in the same manner as an initial statement. When an ERDA reviewer or the counselor or a deputy counselor receives a supplementary statement from an employee for whom he does not have an initial statement, he shall request the file from the counselor or deputy counselor of the employee's previous office.

(f) Confidentiality of employees' statements. ERDA shall hold each statement of employment and financial interests, and each supplementary statement, in confidence. To insure this confidentiality only the ERDA counselor, deputy counselor(s), and those officials to whom reports are to be submitted under paragraph (h) of this section (including those employees specifically designated by them to assist in the review as may be necessary) are authorized to review the statements as provided in this section. The foregoing employees are responsible for maintaining the statements in confidence and shall not allow access to, or allow information to be disclosed from, a statement except to carry out the purpose of this part. ERDA shall not disclose information from a statement except in accordance with procedures set forth in paragraph (e) of this section, or as the Administrator or the Civil Service Commission shall determine for good cause shown.

(g) Effect of employee's statements on other requirements. The statements of employment and financial interests and supplementary statements required of employees are in addition to, and not in substitution for, or in derogation of, any similar requirement imposed by law, order, or regulation. The submission of a statement or supplementary statement by an employee or the absence of any requirement that an employee submit such a statement does not permit him or any other person to participate in a matter in which his or the other person's participation is prohibited by law, order, or regulation.

(h) To whom statements are to be submitted (reviewing officials). Submission of required statements shall be as indicated below. Each statement upon submission shall be reviewed by the reviewing official in accordance with paragraph (e) of this section.

(1) Submitted to the Administrator:

(i) Members of the Administrator's immediate staff.

(ii) The Deputy Administrator.

(iii) The Assistant Administrator for Fossil Energy.

(iv) The Assistant Administrator for Nuclear Energy.

(v) The Assistant Administrator for Environment and Safety.

(vi) The Assistant Administrator for Solar, Geothermal, and Advanced Energy Systems.

(vii) The Assistant Administrator for National Security.

(viii) The Assistant Administrator for Conservation.

(ix) The Chairman, Contract Appeals Board.

(x) The General Counsel.

(xi) The Director, Office of Internal Review.

(xii) Any other employee who holds a Presidentially appointed position.

(2) Submitted to the Deputy Administrator:

(i) Members of the Deputy Administrator's immediate staff.

(ii) All Assistant Administrators not enumerated in (1) above.

(iii) The Controller.

(iv) The Chairman, Patent Compensation Board.

(v) The Chairman, Military Liaison Committee.

(vi) The Heads of Headquarters Divisions and Offices reporting directly to the Administrator or Deputy Administrator not enumerated in (1) above.

(3) Submitted to the Assistant Administrator for Field Operations:

(i) Members of the immediate staff of the Assistant Administrator for Field Operations.

(ii) Heads of the Field Organizations responsible to the Assistant Administrator for Field Operations.

(4) Submitted to other Assistant Administrators:

(i) Members of the immediate staff of such Assistant Administrators.

(ii) Heads of Headquarters Divisions and Offices and of Field Organizations reporting directly to such Assistant Administrator.

(5) Submitted to Heads of Headquarters Divisions and Offices and of Field Organizations:

(i) Employees under their respective jurisdictions.

(6) Submitted to official responsible for their appointments:

(i) Special Government employees, including consultants, experts, and advisers.

(i) Availability of review. Any employee who believes that his position has been improperly included under this section as one requiring the submission of a statement of employment and financial interests may utilize the grievance procedures in ERDA Manual Chapter 4157 "Employee Grievances", for review of his complaint.

Subchapter C—Other Restrictions Imposed by Statute on Conduct of Employees

§ 735.30 Description of statutory provisions.

Each employee has a positive duty to acquaint himself with each statute that relates to his ethical and other conduct as an employee of ERDA and of the Government. Certain of these statutes are referred to in §§ 735-21—735-27. Attention of employees is also directed to the following statutory provisions:

(a) The prohibitions contained in the following sections of the Atomic Energy Act of 1954, as amended: Section 222, "Violation of Specific Sections"; Section 223, "Violation of Sections Generally"; Section 224, "Communication of Restricted Data"; Section 225, "Receipt of Restricted Data"; Section 226, "Tampering With Restricted Data"; and Section 227, "Disclosure of Restricted Data" (42 U.S.C. 2272 through 2277).

(b) The prohibitions against the disclosure of classified information (18 U.S.C. 798, 50 U.S.C. 783).

(c) The prohibitions against the disclosure of confidential information (18 U.S.C. 1905).

(d) The prohibition against lobbying with appropriated funds (18 U.S.C. 1913).

(e) The prohibition against proscribed political activities in subchapter III of chapter 73 of title 5, United States Code and 18 U.S.C. 602, 603, 607, and 608. (See ERDA Manual Chapter 4122, "Political Activity.")

(f) The prohibition against bribery of public officials and witnesses (18 U.S.C. 201).

(g) The prohibition against acceptance or solicitation to obtain appointive public office (18 U.S.C. 211).

(h) The prohibitions against disloyalty and striking (5 U.S.C. 7311, 18 U.S.C. 1918). (See also ERDA Manual Chapter 4121, "Oath of Office" and ERDA Manual Chapter 4166, "Labor Management Relations Program for Federal Employees".)

(i) The provisions relating to the habitual use of intoxicants to excess (5 U.S.C. 7352).

(j) The prohibition against the misuse of a Government vehicle (31 U.S.C. 638a (c)). (See also ERDA Property Management Instruction 109-38, "Motor Equipment Management.")

(k) The prohibition against the misuse of the franking privilege (18 U.S.C. 1719).

(l) The prohibition against the use of deceit in an examination or personnel action in connection with Government employment (18 U.S.C. 1917).

(m) The prohibition against fraud or false statements in a Government matter (18 U.S.C. 1001).

(n) The prohibition against mutilating or destroying a public record (18 U.S.C. 2071). (See also ERDA Appendix 0230, "Records Disposition.")

(o) The prohibition against counterfeiting and forging transportation requests (18 U.S.C. 508).

(p) The prohibition against embezzlement of Government money or property (18 U.S.C. 641). (See also ERDA Property Management Instruction 109-1.50, "Personal Property and Supply Management.")

(q) The prohibition against failing to account for public money (18 U.S.C. 643).

(r) The prohibition against an employee's private use of public money (18 U.S.C. 653).

(s) The prohibition against embezzlement of the money or property of another person in the possession of an employee by reason of his employment (18 U.S.C. 654).

(t) The prohibition against unauthorized use of documents relating to claims from or by the Government (18 U.S.C. 285).

(u) The prohibition against making false entries in official records with intent to defraud or making false reports concerning moneys and securities with such intent (18 U.S.C. 2073).

(v) The prohibition against an employee acting as the agent of a foreign principal registered under the Foreign Agents Registration Act (18 U.S.C. 219). The criminal penalties of this section do not apply in any case in which the Administrator sends to the Attorney General a certification that the employment of the agent as a special Government employee is in the national interest.

(w) The prohibition against discrimination because of politics, race, religion, or color (22 U.S.C. 807).

(x) The prohibition relating to the denial of the right to petition Congress (5 U.S.C. 7102).

(y) The prohibition against a public official appointing or promoting a relative, or advocating such an appointment or promotion (5 U.S.C. 3110).

(z) The prohibition against the employment of an individual convicted of felonious rioting or related offenses (5 U.S.C. 7313).

(aa) The prohibition against acceptance of any honorarium of more than $2,000 or honorariums totalling more than $25,000 in any calendar year (2 U.S.C. 441i, Public Law 94-283, May 11, 1976). See § 735-40(f).

(bb) The prohibition against arbitrary and capricious withholding of agency records requested under the Freedom of Information Act (5 U.S.C. 552).

(cc) The prohibition against knowing disclosure of information the disclosure of which is prohibited; the prohibition against willfully maintaining a system of records without appropriate notice provisions; and the prohibition against knowingly and willfully requesting or obtaining any record concerning an individual under false pretenses (5 U.S.C. 552a).

(dd) House Concurrent Resolution 175, 85th Congress, 2d session, 72 Stat. B12, the "Code of Ethics for Government Service." (See Appendix A)

Subpart D—Other Restrictions Imposed by ERDA on Conduct of Employees

§ 735.40 Outside employment and other outside activity.

(a) There is no general prohibition against employees engaging in outside employment or other outside activity. However, no employee shall engage in such employment or activity if it is not compatible with the full and proper discharge of the duties and responsibilities of his Government employment. Incompatible activities include but are not limited to:

(1) Acceptance of a fee, compensation, gift, payment of expense, or any other thing of monetary value in circumstances in which acceptance may result in, or create the appearance of, conflicts of interest; or

(2) Outside employment which tends to impair his mental or physical capacity to perform his Government duties and responsibilities in an acceptable manner.

(b) In any case in which there is a question as to the propriety of outside employment in which an employee proposes to engage, the employee shall inform his Division or Office Head, Headquarters, or Field Organization Head of the proposed activity and request a determination as to whether the proposed activity is compatible with the employee's full and proper discharge of his Government duties and responsibilities. The information submitted shall include: (1) Name, job title, and grade of the employee; (2) a brief summary of his official ERDA duties; (3) a brief description of the proposed employment, including the compensation to be received; and (4) the name and nature of the business of the employing individual or organization. The Division or Office Head, Headquarters, or Field Organization Head, in consultation with the counselor or an appropriate deputy counselor, shall rule on the request.

(c) An employee shall not receive any salary or anything of monetary value from a private source as compensation for his services to the Government (18 U.S.C. 209).

(d) Employees are encouraged to engage in teaching, lecturing, and writing that is not prohibited by law, Executive Order 11222 ("Prescribing Standards of Ethical Conduct for Government Officers and Employees"), regulations, or the regulations in this part. However, an employee shall not either for or without compensation, engage in teaching, lecturing, or writing, including teaching, lecturing, or writing for the purpose of the special preparation of a person or class of persons for an examination of the Civil Service Commission or Board of Examiners for the Foreign Service, that is dependent on information obtained as a result of his Government employment, except when that information has been made available to the general public or will be made available on request, or when the Deputy Administrator has given written authorization for the use of nonpublic information on the basis that the use is in the public interest.

(e) Except as allowed for training or to attend meetings under section 4111 ("Acceptance of Contributions, Awards and Other Payments") of title 5, United States Code (formerly, "Government Employees Training Act") and Executive Order 10800 ("Implementing the Government Employees Training Act"), no employee shall accept a fee from an outside source on account of a public appearance, a speech, or lecture, if the public appearance or the preparation or delivery of the speech or lecture was a part of the official duties of the employee; if the public appearance, speech, or lecture was made during official working hours; or if travel for the purpose of the public appearance, speech, or lecture was made at Government expense. In addition, no employee shall accept a fee for the preparation, publication, or review of an article, story, or book if it was prepared during official working hours and/or was a part of the official duties of the employee.

(f) An employee may accept a fee or other compensation for a private activity which is not prohibited by law or these regulations. However, in accordance with limitations imposed on the receipt of honorariums by Government employees by the Federal Election Campaign Act Amendments of 1976, no employee is permitted to receive more than $2,000 (excluding actual travel and subsistence expense) for any single appearance, speech or article or a total of more than $25,000 (excluding actual travel and subsistence expenses) for such activity in any calendar year.

(g) An employee is not precluded by this § 735–40 or § 735–42 from:

(1) Participation in the activities of political parties not proscribed by law. See ERDA Manual Chapter 4122 for further guidance on permissible and prohibited political activities.

(2) Participation in the affairs of or acceptance of an award for a meritorious public contribution or achievement given by a charitable, religious, professional, social, fraternal, nonprofit educational or recreational, public service, or civic organization.

§ 735.41 Misuse of information.

(a) For the purpose of furthering a private interest, an employee shall not, except as provided in § 735–40(d), directly or indirectly use, or allow the use of, official information obtained through or in connection with his Government employment which has not been made available to the general public.

(b) In addition to the prohibition specified in (a) above, employees are subject to the prohibition imposed by section 68a of the Atomic Energy Act of 1954, 42 U.S.C., section 2098(a), "Public and Acquired Lands," which has been incorporated into the Energy Reorganization Act of 1974:

> No individual, corporation, partnership, or association, which had any part, directly or indirectly, in the development of the atomic energy program, may benefit by any location, entry, or settlement upon the public domain made after such individual, corporation, partnership, or association took part in such project, if such individual, corporation, partnership, or association, by reason of having had such part in the development of the atomic energy program, acquired confidential official information as to the existence of deposits of uranium, thorium, or other materials in the specific lands upon which such location, entry, or settlement is made and subsequent to August 30, 1954, made such location, entry, or settlement, or caused the same to be made for his, or its, or their benefit.

§ 735.42 Gifts, entertainment, and favors.

(a) Except as provided in paragraphs (c), (e), and (f) of this section the direct or indirect solicitation or acceptance by an ERDA employee or his spouse or minor child of any gift, gratuity, entertainment (including food, refreshments, tickets or invitations to performances and other events), favors, loans, transportation, accommodations, or any other thing of monetary value from any person, is forbidden if the person:

(1) Has or is seeking to obtain contractual or other business or financial relationships with ERDA; or

(2) Has interests which may be substantially affected by such employee's performance or nonperformance of his official duty; or

(3) Is in any way attempting to affect the employee's official action.

(b) There are certain exceptions to the foregoing general rule which are set forth in paragraph (c) of this section. The exceptions are to be strictly construed. In determining whether one or more of the exceptions apply in any particular circumstance, each ERDA employee shall avoid any situation which would bring discredit to the Government or ERDA. Each ERDA employee will so govern his conduct in the light of this part as to have no difficulty in justifying his actions if required to do so. See also § 735–49a.

(c) The following are exceptions to the general rule set forth in paragraph (a) of this section:

(1) Acceptance of food and refreshments of nominal value on an infrequent basis when the conduct of official business will be facilitated and when no provision can be made for individual payment. An employee shall exercise care to avoid, wherever possible, all other situations, e.g., in private clubs, where no provision can be made for individual payment.

(2) Instances in which the interests of the Government are served by participation of an ERDA employee in widely attended luncheons, dinners, and similar gatherings sponsored by industrial, technical, or professional associations for the discussion of matters of mutual interest. Participation in such events is permitted only when the host is the association and not a private company and only when approved by the employee's supervisor as being a part of or related to his official duties. Acceptance of gratuities, food, or refreshments from a private company in connection with such association's activities shall be avoided.

(3) Acceptance of gifts, favors, or entertainment, where there is a family relationship between the employee, or be-

tween his spouse, children, or parents, and the donor, where the circumstances make it clear that it is that relationship rather than the business of the persons concerned which is the motivating factor for the gift, favor, or entertainment.

(4) Acceptance of modest food and refreshments, where there is an obvious personal relationship between the employee and the host, where it is clear that it is that relationship rather than the business of the persons concerned which is the motivating factor for the food and refreshments.

(5) Purchase of articles at advantageous rates where such rates are offered to Government employees as a class.

(6) Acceptance of loans from banks or other financial institutions on customary terms to finance proper and usual activities of employees, such as home mortgage loans.

(7) Acceptance of unsolicited advertising or promotional material, such as pens, pencils, note pads, calendars, or other items of trivial value, clearly less than $5.00.

(8) Acceptance of contractor-provided local transportation while on official business when alternative arrangements are clearly impracticable or where such acceptance will facilitate the conduct of official business.

(9) Acceptance of transportation, accommodations, subsistence, or services furnished under a reimbursable arrangement with ERDA from an industrial, technical, or professional association, when authorized in the employee's travel authorization as being in the interest of the Government. When transportation, accommodations, subsistence, or services are furnished in kind by such an association, appropriate deductions shall be made in the travel, per diem, and other allowances otherwise payable to the employee. When transportation, accommodations, subsistence, or services are provided under a cash reimbursable arrangement, the reimbursement must be paid directly to ERDA by check payable to ERDA; the employee will be reimbursed for necessary expenses by ERDA in accordance with applicable laws and regulations. In no case shall an ERDA employee accept benefits which are under prudent standards extravagant or excessive in nature.

(10) Special situations in which the Deputy Administrator, after consultation with the General Counsel, determines in advance in writing that the interest of the Government will be served by an employee's participation, in his official capacity and as a designated ERDA representative, in a public ceremony or other event at the expense of a private company.

(11) Acceptance of transportation or other services provided by a private company in special situations in which the Deputy Administrator determines in advance in writing that acceptance of such transportation or other services will facilitate the conduct of official business and be in the best interest of the Government.

(d) A gift or gratuity, the receipt of which is prohibited under paragraph (a) of this section, will be returned to the donor.

(e) An employee will not solicit a contribution from another employee for a gift to an official superior, make a donation as a gift to an official superior, or accept a gift presented as a contribution from an employee receiving less pay than himself (5 U.S.C. 7351). However, this paragraph does not prohibit a voluntary gift of nominal value or a donation in a nominal amount made on a special occasion such as marriage, illness or death, or retirement.

(f) An employee will not accept a gift, present, decoration, or other thing from a foreign government unless authorized by Congress as provided by the Constitution and in 5 U.S.C. 7342.

§ 735.43 Use of Government property.

An employee shall not directly or indirectly use, or allow the use of Government property of any kind, including property leased to the Government, for other than officially approved activities. An employee has a positive duty to protect and conserve Government property, including equipment, supplies, and other property entrusted or issued to him.

§ 735.44 Scandalous conduct.

No employee shall engage in criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or other conduct prejudicial to the Government.

§ 735.45 Employee indebtedness.

ERDA considers the credit affairs of its employees essentially their own concern. However, employees are expected to conduct their credit affairs in a manner which does not reflect adversely on the Government as their employer. An employee is expected to pay each just financial obligation in a proper and timely manner, especially one imposed by law such as Federal, State, or local taxes. Failure on the part of an employee without good reason to honor just financial obligations or to make or adhere to satisfactory arrangements for settlement may be cause for disciplinary action. For the purpose of this section, a "just financial obligation" means one acknowledged by the employee or reduced to judgment by a court, or one imposed by law such as Federal, State, or local taxes and "in a proper and timely manner" means in a manner which ERDA determines does not, under the circumstances, reflect adversely on the Government as his employer. In the event of a dispute between an employee and an alleged creditor, ERDA is not obliged to determine the validity or amount of the disputed debt.

§ 735.46 Gambling, betting, and lotteries.

An employee shall not participate, while on Government-owned or leased property or while on duty for the Government, in any gambling activity including the operation of a gambling device, in conducting a lottery or pool, in a game for money or property, or in selling or purchasing a numbers slip or ticket. However, this section does not preclude activities;

(a) Necessitated by an employee's law enforcement duties; or

(b) Under section 3 of Executive Order 10927 (on Conduct of Fund Raising Activities) and similar agency-approved activities.

§ 735.47 Handling of funds entrusted by fellow employees.

No employee shall receive, retain, or disburse funds entrusted to him by fellow employees, e.g., credit union deposits or donations to charitable organizations except with the utmost care in the safeguarding of such funds and the maintenance of full and complete records with regard to the receipt, custody, and disbursement of such funds. Such records shall be made available to appropriate authorities upon proper request.

§ 735.48 Ex parte contacts.

Ex parte contacts by an employee are prohibited in quasi-judicial proceedings.

§ 735.49 Employment under Professional Term Appointments of persons on extended leave of absence from a previous employer with reemployment rights or other benefits with the previous employer.

(a) ERDA may employ under Professional Term Appointments persons on extended leave of absence from private employers where it is the way most advantageous to ERDA to obtain qualified employees with needed skills and no violation of conflict of interest statutes would be involved. (See ERDA Manual Appendix 4108, Part V, paragraph 4, for the requirements governing Professional Term Appointments.) The necessity for continued employment of such persons shall be reviewed annually by the Director, Division of Personnel, Headquarters. In their ERDA assignments, such employees shall not be permitted to handle, directly or indirectly, or have access to, business confidential data of their former employers' competitors. Such persons shall not be permitted to participate in any matter involving their private employer in accordance with 18 U.S.C. 208. Exemptions from this restriction may be granted to Professional Term Employees by the appropriate Headquarters Division or Office Head or Field Organization Head, only after consultation with the General Counsel or an authorized deputy counselor.

(b) When it is proposed to employ such a person, a statement of the exact terms and conditions of the leave of absence from his employer (including retained benefits) will be obtained from the prospective employee and submitted to the General Counsel for a prior determination of possible violation of statute.

(c) The following quotation from 18 U.S.C. 209 is pertinent.

(b) Nothing herein prevents an officer or employee of the executive branch of the U.S. Government, or of any independent agency of the United States, or of the District of Columbia, from continuing to participate in a bona fide pension, retirement, group life,

health or accident insurance, profit-sharing, stock bonus, or other employee welfare or benefit plan maintained by a former employer.

§ 735.49a Other proscribed actions.

An employee shall avoid any action whether or not specifically prohibited by this Part 735, which might result in, or create the appearance of:

(a) Using a public office for private gain;

(b) Giving preferential treatment to any person;

(c) Impeding Government efficiency or economy;

(d) Losing complete independence or impartiality;

(e) Making a Government decision outside official channels; or

(f) Affecting adversely the confidence of the public in the integrity of the Government.

Subpart E—Ethical and Other Conduct Responsibilities of Special Government Employees

§ 735.50 Use of Government employment.

A special Government employee shall not use his Government employment for a purpose that is, or gives the appearance of being, motivated by the desire for private gain for himself or another person, particularly one with whom he has family, business, or financial ties.

§ 735.51 Use of inside information.

(a) A special Government employee shall not use inside information obtained as a result of his Government employment for private gain for himself or another person either by direct action on his part or by counsel, recommendation, or suggestion to another person, particularly one with whom he has family, business, or financial ties. For the purpose of this section, "inside information" means information obtained under Government authority which has not become part of the body of public information.

(b) Special Government employees may teach, lecture, or write in a manner not inconsistent with § 735–40(d), covering employees generally.

§ 735.52 Coercion.

A special Government employee shall not use his Government employment to coerce, or give the appearance of coercing, a person to provide financial benefit to himself or another person, particularly one with whom he has family, business, or financial ties.

§ 735.53 Gifts, entertainment, and favors.

(a) Except as provided in paragraph (b) of this section, a special Government employee, while so employed or in connection with his employment, shall not receive or solicit from a person having business with ERDA anything of value as a gift, gratuity, loan, entertainment, or favor for himself or another person, particularly one with whom he has family, business, or financial ties.

(b) Exceptions authorized for employees under § 735–42 shall have equal application with respect to special Government employees.

§ 735.54 Miscellaneous statutory provisions.

Each special Government employee shall acquaint himself with each statute that relates to his ethical and other conduct as a special Government employee of ERDA, and of the Government. The ERDA official responsible for his appointment shall call his attention specifically to §§ 735–21, 735–22, 735–23, 735–24(c), 735–25, 735–26, 735–27, and 735–30.

§ 735.55 Applicable standards of conduct.

Special Government employees shall adhere to the standards of conduct made applicable to such employees by Subpart B of this part and to the standards of conduct made applicable to regular employees by §§ 735–43, 735–44, 735–46, and 735–48.

APPENDIX A—CONCURRENT RESOLUTION

H. CON. RES. 175, JULY 11, 1958, 72 STAT. B12

Resolved by the House of Representatives (the Senate concurring), That it is the sense of the Congress that the following Code of Ethics should be adhered to by all Government employees, including officeholders:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.

3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.

4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.

6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

7. Engage in no business with the Government either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.

8. Never use any information coming to him confidentially in the performance of governmental duties as a means of making private profit.

9. Expose corruption wherever discovered.

10. Uphold these principles, ever conscious that public office is a public trust.

Approved by the House of Representatives August 28, 1957.

Approved by the Senate July 11, 1958.

APPENDIX B—POSITION CATEGORIES REQUIRING STATEMENTS OF EMPLOYMENT AND FINANCIAL INTERESTS BY INCUMBENTS

(1) The Deputy Administrator, Assistant Administrators, and Heads of Divisions and Offices, Headquarters, and of Field Organizations;

(2) Contracting officers (GG–13 and above);

(3) Contract administrators (GG–13 and above);

(4) Procurement officers (GG–13 and above);

(5) Auditors (GG–13 and above);

(6) Attorneys, including patent attorneys (GG–13 and above);

(7) Positions (in grades GG–13 and above) involving assigned duties and responsibilities which require the incumbent to exercise judgment in making or recommending a decision or in taking or recommending an action in regard to:

(a) Evaluation, appraisal, or selection of contractors or subcontractors, prospective contractors or prospective subcontractors, proposals of such contractors or subcontractors, the activities performed by such contractors or subcontractors, or determination of the extent of compliance of such contractors or subcontractors with contract provisions.

(b) Negotiation, modification, or approval of contracts or subcontracts.

(c) Evaluation, appraisal, or selection of prospective project sites, or locations of work or activities, including real property proposed for acquisition by purchase or otherwise.

(d) Inspection and quality assurance of material, products or components for acceptability.

(e) Review or approval of applications for access permits.

(f) Engineering planning and design which involves preparation of specifications and technical requirements.

(g) Negotiation of agreements for cooperation or implementing arrangements with foreign countries.

(h) Utilization or disposal of excess or surplus property.

(i) Procurement of materials, services, supplies, or equipment.

(j) Authorization or monitoring of grants to educational institutions or other non-Federal enterprises.

(k) Audit of financial transactions.

(l) Promulgation of safety standards, procedures and hazards evaluation systems.

(m) Nuclear materials management.

(n) Activities, other than those covered above, which have an economic impact on the interests of any non-Federal enterprise.

Positions in the above-enumerated categories (2–7) may be excluded when it is determined by the Administrator, Deputy Administrator, Assistant Administrator, Head of Headquarters Division or Office or Field Organization, as appropriate, that: (a) The duties of a position are such that the likelihood of the incumbent's involvement in a conflict-of-interest situation is remote; or (b) the duties of a position are at such a level of responsibility that the submission of a statement is not necessary because of the degree of supervision and review over the incumbent or the inconsequential effect on the integrity of the Government.

APPENDIX C—CRITERIA FOR DETERMINING POSITIONS OF CATEGORIES OF POSITIONS LISTED IN ANNEX B

Annex B shall be maintained and changes therein made by ERDA in accordance with the following criteria:

1. Positions shall be included, the basic duties and responsibilities of which require the incumbent to exercise judgment in making or recommending a Government decision or in taking or recommending Government action in regard to:

a. Contracting or procurement;

b. Administering or monitoring grants or subsidies;

c. Regulating or auditing private or other non-Federal enterprise; or

d. Other activities where the decision or action has an economic impact on the interests of any non-Federal enterprise.

Generally, such duties and responsibilities will have been spelled out in local statements of delegation of authority and responsibility and the degree of responsibility for decisions will be reflected in the Position Evaluation records under the factor "Decisions". Inclusion of positions classified below GG-13 which meet the criteria of this paragraph 1 or paragraph 3 below must be specifically justified by ERDA in writing to the Civil Service Commission as an exception that is essential to protect the integrity of the Government and avoid employee involvement in a possible conflict-of-interest situation.

2. Positions in 1., above, may be excluded when:

a. The duties of a position are such that the likelihood of the incumbent's involvement in a conflict-of-interest situation is remote; and

b. The duties are at such a level of responsibility that the submission of a statement is not necessary because of the degree of supervision and review over the incumbent and the remote and inconsequential effect on the integrity of the Government.

3. In addition to 1., above, those positions classified GG-13 or above shall be included which are determined by ERDA as requiring the incumbents to report employment and financial interests in order to avoid involvement in a possible conflict-of-interest situation and to carry out the purpose of law, Executive Order 11222, and Civil Service Commission and ERDA regulations.

[FR Doc.76-23920 Filed 8-16-76;8:45 am]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket 9026]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

New England Tractor Trailer Training of Massachusetts, Inc., et al.

Correction

In FR Doc. 76-23453 appearing in the Thursday, August 12, 1976 issue of the FEDERAL REGISTER on page 34021, the second line, paragraph (h) should be corrected to read, "* * * containing all inquiries or complaints * * *".

Title 21—Foods and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

[Docket No. 76F-0350]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

DIMETHYLAMINE-EPICHLOROHYDRIN COPOLYMER

The Food and Drug Administration is amending the food additive regulations to provide for the use of a retention aid in the manufacture of paper and paperboard; effective August 17, 1976; objections by September 16, 1976.

Notice was given in the FEDERAL REGISTER of December 12, 1975 (40 FR 57829) that a petition (FAP 6B3120) had been filed by the American Cyanamid Co., Wayne, NJ 07470, proposing that §121.-2526 Components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 121.2526) be amended to provide for the safe use of dimethylamine-epichlorohydrin copolymer, in which up to 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine, as a component of paper and paperboard for food-contact use.

The Commissioner of Food and Drugs, having evaluated data in the petition and other relevant material, concludes that § 121.2526 should be amended as set forth below.

Therefore, under the Federal Food, Drug and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), § 121.-2526(a)(5) is amended by adding alphabetically a new item to the list of substances as follows:

§ 121.2526 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	*Limitations*
* * *	* *
Dimethylamine - epichlorohydrin copolymer in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine and in which the ratio of total amine to epichlorohydrin does not exceed 1:1. The nitrogen content of the copolymer shall be 9.4 to 10.8 weight percent on a dry basis and a 10 percent by weight aqueous solution of the final product has a minimum viscosity of 5.0 centipoises at 25° C, as determined by LVT-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a retention aid employed before the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished paper and paperboard.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before September 16, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date: This regulation shall become effective August 17, 1976.

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

Dated: August 10, 1976.

JOSEPH P. HILE,
Acting Associate Commissioner for Compliance.

[FR Doc.76-23924 Filed 8-16-76;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 76N-0222]

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

Petri Dish Covers

The Food and Drug Administration (FDA) is amending requirements for Petri dish covers used in microbiological assay of certain antibiotic drugs, effective August 17, 1976.

Section 436.100 (21 CFR 436.100), which describes the equipment used in microbiological assays, specifies that covers of Petri dishes should be made of porcelain. The Food and Drug Administration has conducted a study comparing porcelain and plastic covers, and concludes that covers fabricated from plastic, glass, or other suitable material are satisfactory for use in conducting microbiological assays required by the regulations. However, when nonporous covers are used, they must be left ajar until the agar hardens to prevent condensation from the hot agar base layers.

Therefore, the Commissioner of Food and Drugs concludes that the regulations should be amended to permit the use of Petri dish covers of suitable material and to establish procedures to prevent moisture condensation when nonporous covers are used. Because the porcelain-only restriction for Petri dish covers is being relaxed, references to specific cover materials in two other sections of the regulations should be deleted.

Pursuant to the Administrative Procedure Act (5 U.S.C. 553 (b) and (d)), the Commissioner concludes that notice, public procedure, and delayed effective date are unnecessary for the promulgation of this regulation because it is of a minor nature and relieves restrictions under regulations currently in effect.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) and under authority delegated to him (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976

(41 FR 24262)), the Commissioner is amending Part 436 of Chapter I of Title 21 of the Code of Federal Regulations as follows:

1. In § 436.100 by revising paragraph (a)(2) to read as follows:

§ 436.100 **Laboratory equipment.**

* * * * *

(a) * * *

(2) *Plates.* Plastic or glass Petri dishes may be used, having dimensions of 20 by 100 millimeters. Covers should be of suitable material.

* * * * *

2. In § 436.104, by deleting the next to the last sentence in paragraph (a), which reads: "Disposable plastic covers may be used in lieu of porcelain covers." Paragraph (a) is revised to read as follows:

§ 436.104 **Penicillin activity.**

* * * * *

(a) *Preparation of inoculated plates.* Proceed as directed in § 436.105(a), using 10 milliliters of medium 1 for the base layer. For the seed layer, use 4 milliliters of medium 4, inoculated with the amount of test organism C which gave the clearest, sharpest zones of inhibition measuring 17 to 21 millimeters in diameter when standardized as described in § 436.103(b)(1)(ii). Use the plates the same day they are prepared.

* * * * *

3. In § 436.105(a), by revising the second and fifth sentences and adding a new sentence after the second sentence. Paragraph (a) is revised to read as follows:

§ 436.105 **Microbiological agar diffusion assay.**

* * * * *

(a) *Preparation of inoculated plates.* For each antibiotic listed in the table in this paragraph, select the media (as listed by medium number in § 436.102(b)), the amount of media to be used in the base and seed layers, the test organism (as listed in § 436.103(a)), and the suggested inoculum and prepare the inoculated plates as follows: Prepare the base layer by adding the appropriate amount of melted agar to each Petri dish (nominal dimensions 20 by 100 millimeters). Distribute the agar evenly in each dish on a flat, level surface, placing a cover on each plate in turn; if a nonporous cover is used, leave it slightly ajar to prevent accumulation of condensed moisture from the hot agar base layer. After the agar hardens, seat the nonporous cover on each plate. To prepare the seed layer, add the suggested inoculum of the test organism suspension to a sufficient amount of agar, which has been melted and cooled to 48° C–50° C. Swirl the flask to obtain a homogeneous suspension, and add the appropriate amount of the inoculated media to each of the plates containing the uninoculated base agar. Spread evenly over the agar surface, cover, and allow to harden on a flat, level surface. After the agar has hardened, place 6 cylinders described in § 436.100(a)(1) on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

* * * * *

Effective date: This regulation shall become effective on August 17, 1976.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357).)

Dated: August 11, 1976.

MARY A. MCENIRY,
Assistant to the Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc.76-23922 Filed 8-16-76;8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

Subpart G—Sponsors of Approved Applications

NUMERICAL LISTING OF SPONSORS

The Food and Drug Administration is correcting a listing for Burns-Biotec Laboratories, effective August 17, 1976.

An amendment published in the FEDERAL REGISTER of October 24, 1974 revised the listing for Burns-Biotec in § 135.501(c). Subsequently, the section was redesignated as § 510.600 (21 CFR 510.600) (recodification published in the FEDERAL REGISTER of March 27, 1975 (40 FR 13802)). Two listings for Burns-Biotec were included in § 510.600, in paragraphs (c)(1) and (2) of the section. The revised listing for Burns-Biotec was made in paragraph (c)(1); it was not made in paragraph (c)(2). The correction below makes the revision in paragraph (c)(2).

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), § 510.600 is corrected in paragraph (c)(2) by revising the listing for numerical entry "000845" to read as follows:

§ 510.600 **Names, addresses, and code numbers of sponsors of approved applications.**

* * * * *

(c) * * *

(2) * * *

Drug listing No.:	*Firm name and address*
* *	* * *
000845	Burns-Biotec Laboratories Division, Chromalloy Pharmaceuticals, Inc., 7711 Oakport St., Oakland, CA 94621.

* * * * *

Effective date: This correction shall be effective August 17, 1976.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: August 9, 1976.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc.76-23923 Filed 8-16-76;8:45 am]

Title 22—Foreign Relations

CHAPTER I—DEPARTMENT OF STATE

SUBCHAPTER K—ECONOMIC, COMMERCIAL AND CIVIL AVIATION FUNCTIONS

[Departmental Regulation 108.726]

PART 102—CIVIL AVIATION

Recommendations to the President Under Section 801 of the Federal Aviation Act of 1958

Correction

In FR Doc. 76-22153 appearing on page 31548 of the issue for Thursday, July 29, 1976, the Departmental Regulation number was incorrectly printed as 108.76. It should be 108.726, as shown in the headings above.

Title 25—Indians

CHAPTER I—BUREAU OF INDIAN AFFAIRS, DEPARTMENT OF THE INTERIOR

SUBCHAPTER T—OPERATION AND MAINTENANCE

PART 221—OPERATION AND MAINTENANCE CHARGES

Revocation of Assessment Regulations for Fort Apache Indian Irrigation Project

This notice is published in the exercise of rulemaking authority delegated by the Secretary of the Interior to the Commissioner of Indian Affairs by 230 DM 2.

The authority to issue regulations is vested in the Secretary of the Interior by 5 U.S.C. 301 and sections 463 and 465 of the Revised Statutes (25 U.S.C. 2 and 9).

Beginning on page 34605 of the August 18, 1975, FEDERAL REGISTER (40 FR 34605) there was published a notice of proposed rulemaking to revise part 221 of Subchapter T, Chapter I, Title 25 of the Code of Federal Regulations. The purpose of this revocation is to eliminate all assessments for operation and maintenance for the Fort Apache Indian Irrigation Project, Arizona and to reinstate the non-reimbursable status which existed prior to promulgation of these regulations in 1963 and promulgation of the predecessor to these regulations in 1959.

This revision was proposed pursuant to the authority contained in the Act of August 1, 1914 (39 Stat. 583, 25 U.S.C. 385).

The public was given until September 17, 1975 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.

Sections (§§) 221.180 through 221.184 of Part 221, Subchapter T, Chapter I of

Title 25 of the Code of Federal Regulations are hereby revoked.

Effective date. These revised regulations shall become effective September 16, 1976.

(Catalog of Federal Domestic Assistance Program No. 15.106, Indian Lands—Irrigation, Construction, Maintenance, Operation, and Related Power Systems).

JOSE A. ZUNI,
Acting Deputy Commissioner of Indian Affairs.

[FR Doc.76-23931 Filed 8-16-76;8:45 am]

Title 29—Labor

CHAPTER V—WAGE AND HOUR DIVISION, DEPARTMENT OF LABOR

PART 699—TEXTILE MILL PRODUCTS

Wage Order

Pursuant to sections 5, 6, and 8 of the Fair Labor Standards Act of 1938 (52 Stat. 1062, 1064, as amended (29 U.S.C. 205, 206, 208)), including the Fair Labor Standards Amendments of 1974 (Pub. L 93-259); 84 Stat. 35 and Reorganization Plan No. 6 of 1950 (3 CFR 1949-53 Comp., p. 1004), and by means of Administrative Order No. 643 (41 FR 11038), the Secretary of Labor appointed and convened Industry Committee No. 132 for Textile Mill Products, referred to the Committee the question of the minimum rate or rates of wages to be paid under section 6 of the Act to such employees, and gave notice of a hearing to be held by the Committee.

Subsequent to an investigation and a hearing conducted pursuant to the notice, the Committee has filed with the Administrator of the Wage and Hour Division of the Department of Labor a report containing its findings of fact and recommendations with respect to the matters referred to it.

Accordingly, as authorized and required by section 8 of the Fair Labor Standards Act of 1938, Reorganization Plan No. 6 of 1950, and 29 CFR 511.18, the recommendations of Industry Committee 132 are hereby published, revising the title and §§ 699.1, 699.2, and 699.3 of Part 699, Title 29, Code of Federal Regulations.

Sec.
699.1 Definition.
699.2 Wage Rates.
699.3 Notices.

AUTHORITY: Sec. 8, Fair Labor Standards Act of 1938, Reorganization Plan No. 6 of 1950, and 29 CFR 511.18.

§ 699.1 Definition.

The textile mill products industry in Puerto Rico is defined as follows: The preparation of textile fibers, including the ginning and compressing of cotton; the manufacture of batting, wadding, and filling: The manufacture, including dyeing and finishing, of yarn, thread, cordage, twine, felt, woven and knitted fabrics, and lace-machine products from cotton, jute, sisal, coir, maguey, silk, rayon, nylon, wool or other vegetable, animal, or synthetic fiber, or from mixtures of these fibers; and the manufacture of blankets, textile bags, quilts, pillows, swabs, bandages, hairnets, oilcloth and artificial leather containing a textile or paper base, woven carpets and rugs, and hooked or punched rugs and carpeting: *Provided, however,* That the industry shall not include any product or activity included in the chemical, petroleum, and related products industry; the furniture and fixtures and lumber and wood products industry; or in any apparel or needlework industry in Puerto Rico for which a separate wage order has been issued.

§ 699.2 Wage rates.

Wages at rates not less than those prescribed in this section shall be paid under subsection 6(c) of the Fair Labor Standards Act of 1938 by every employer to each of his employees in each of the classifications in the textile mill products industry in Puerto Rico who in any workweek is engaged in commerce or in the production of goods for commerce or is employed in an enterprise engaged in commerce or in the production of goods for commerce as those terms are defined in section 3 of the Act.

(a) *Pre-1961 coverage classifications.* The classifications in this paragraph (a) apply to all activities of employees in the textile mill products industry in Puerto Rico to which section 6 of this Act applies without reference to the Fair Labor Standards Amendments of 1961.

(1) *Multiple-needle power-driven machine operations on hooked rugs classification.*—(i) The minimum wage for this classification is $2.00 an hour through December 31, 1976; $2.15 an hour, effective January 1, 1977; and $2.30 an hour, effective May 1, 1977, by reason of section 6(c)(2).

(ii) This classification is defined as the punching or tufting in the manufacture of hooked or punched rugs and carpeting with multiple-needle machines containing five or more needles, including the operations of the machine, the work of the assistant or helper thereon, and the work of the maintenance employees who set up or repair these machines.

(2) *Other operations on hooked rugs classification.*—(i) The minimum wage for this classification is $1.72 an hour through December 31, 1976; and $1.85 an hour effective January 1, 1977 through April 30, 1977. Under section 6(c) the rate will be increased by $0.15 an hour on May 1, 1977, and on May 1 of each subsequent year until the mainland rate is reached (section 6(c)(2)).

(ii) This classification is defined as all operations and processes in the manufacture of hooked or punched rugs and carpeting except those included in the multiple-needle power-driven machine operations on hooked rugs classification as defined in paragraphs (a)(1).

(3) *Pillow classification.*—(i) The minimum wage for this classification is $2.05 an hour through December 31, 1976; $2.15 an hour, effective January 1, 1977; and $2.30 an hour, effective May 1, 1977, by reason of section 6(c)(2).

(ii) This classification is defined as the manufacture of pillows.

(4) *Cotton swab and bandage classification.*—(i) The minimum wage for this classification is $2.15 an hour, effective September 1, 1976, and $2.30 an hour, effective May 1, 1977, by reason of section 6(c)(2).

(ii) This classification is defined as the manufacture of cotton swabs and elastic and cotton bandages.

(5) *Other products and activities.*—(i) The minimum wage for this classification is $1.90 an hour through December 31, 1976; and $1.95 an hour, effective January 1, 1977 through April 30, 1977. Under section 6(c) the rate will be $2.10 an hour on May 1, 1977; $2.15 an hour, effective January 1, 1978; and $2.30 an hour, effective May 1, 1978, by reason of section 6(c)(2).

(ii) This classification is defined as the manufacture of all products and all activities that are not specifically included in any other pre-1961 coverage classification of the industry.

(b) *1961 coverage classification.* (1) The minimum wage for this classification is $2.05 an hour through December 31, 1976; $2.15 an hour, effective January 1, 1977; and $2.30 an hour effective May 1, 1977, by reason of section 6(c)(2).

(2) This classification is defined as all activities of employees in the textile mill products industry to which section 6 of the Act applies only by reason of the Fair Labor Standards Amendments of 1961.

(c) *1966 coverage classification.* (1) The minimum wage for this classification is $2.05 an hour through December 31, 1976; $2.15 an hour, effective January 1, 1977; and $2.30 an hour, effective May 1, 1977, by reason of section 6(c)(2).

(2) This classification is defined as all activities of employees in the textile mill products industry to which section 6 of the Act applies solely by reason of the Fair Labor Standards Amendments of 1966.

§ 699.3 Notices.

Every employer subject to the provisions of § 699.2 shall post in a conspicuous place in each department of his establishment where employees subject to the provisions of § 699.2 are working such notices of this part as shall be prescribed from time to time by the Administrator of the Wage and Hour Division of the United States Department of Labor and shall give such other notice as the Administrator may prescribe. (Secs. 5, 6, 52 Stat. 1062 and 1064, as amended; 29 U.S.C. 205, 206, 208)

Signed in Washington, D.C. this 10th day of August 1976.

RONALD J. JAMES,
Administrator, Wage and Hour Division, U.S. Department of Labor.

[FR Doc.76-24081 Filed 8-16-76;8:45 am]

CHAPTER XIV—EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

PART 1601—PROCEDURAL REGULATIONS

Definitions

Section 705 of Title VII of the Civil Rights Act of 1964, as amended, provides for the establishment of such regional or district offices of the Equal Employment Opportunity Commission as necessary to carry out the purposes of Title VII, and for the appointment of officers and employees needed in the performance of the Commission's functions. To further implement the provisions of Section 705 of Title VII, the Equal Employment Opportunity Commission has approved certain amendments to § 1601.4 of the Commission's Procedural Regulations. The amendments to § 1601.4 delete the term "subregion" and revise the language to reflect the Commission's present field organizational structure of regional and district offices. The revisions provide the Commission's definitions of the terms region and district, and designate the chief officer of the Commission in each region or district.

The amendments also add a delegation of authority to Regional Directors which previously was not expressly set forth. Finally, the amendments make clear that the Regional Offices of General Counsel are under the direct control of the Commission's General Counsel.

Because this amendment is procedural in nature, the public rulemaking process is not required. This amendment will become effective immediately.

By virtue of the authority vested in it by Section 713(a) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–12(a), 78 Stat. 265, the Equal Employment Opportunity Commission (hereinafter referred to as the Commission) hereby amends Title 29, Chapter XIV, § 1601.4 as follows:

Section 1601.4 is revised to read as follows:

§ 1601.4 Region; district.

The term "region" as used herein shall mean that part of the United States or any territory thereof fixed by the Commission as a particular region. The term "Regional Director" shall refer to that person designated as the Commission's chief officer in each region. The term "district" shall mean that area within a region fixed by the Commission as a particular sub-unit of a region. The term "District Director" shall refer to that person designated as the Commission's chief officer in each district. The Regional Director is hereby delegated all of the authority granted in this part to District Directors to be exercised within the scope of his or her supervisory authority over each District Director in his or her region. The Regional Offices of the General Counsel are under direct control of the Commission's General Counsel.

It is hereby certified that the revised regulation has been assessed for the need of an Inflationary Impact Statement. Because of the nature of the changes, this revision does not require an Inflationary Impact Statement.

Signed at Washington, D.C. on this 11th day of August, 1976.

ETHEL BENT WALSH,
Vice Chairman, Equal Employment Opportunity Commission.

[FR Doc.76-23826 Filed 8-16-76;8:45 am]

PART 1601—PROCEDURAL REGULATIONS

Procedure for the Prevention of Unlawful Employment Practices

The amendment to § 1601.13 sets forth changes necessary to implement Section 706 of Title VII of the Civil Rights Act of 1964, as amended, which requires that a respondent be served with notice of a charge of discrimination within ten days after the filing of such charge. Prior to this revision, § 1601.13 provided that the Commission furnish a respondent charged with an unlawful employment practice with notice of the charge (including the date, place and circumstances of the alleged unlawful employment practice) within 10 days after the filing thereof. This revision provides for service of a copy of the charge itself (including the identity of the person filing the charge or, in the case of a charge filed on behalf of any individual or individuals, the identity of the person or organization so filing) by mail or in person within 10 days after filing of the charge where such service would not impede the law enforcement functions of the Commission. Where the Commission determines that service of the charge itself within the 10 day notice period provided in 706(b) of Title VII would impede its law enforcement function, it will serve the notice of the charge, as is its current practice, rather than a copy of the charge.

This amendment is procedural in nature, and the public rulemaking process is not required. This amendment is effective immediately.

By virtue of the authority vested in it by Section 713(a) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–12(a), 78 Stat. 265, the Equal Employment Opportunity Commission (hereinafter referred to as the Commission) hereby amends Title 29, Chapter XIV, § 1601.13 as follows:

Section 1601.13 is revised to read as follows:

§ 1601.13 Service of Notice of Charge.

(a) Within ten days after the filing of a charge in the appropriate Commission office, the Commission shall serve respondent a copy of the charge, by mail or in person except when it is determined that providing a copy of the charge would impede the law enforcement functions of the Commission. Where a copy of the charge is not provided, the respondent will be served with the notice of the charge within ten days after the filing of the charge (including the date, place, circumstances and identity of the person filing the charge or, in the case of a charge filed on behalf of any individual or individuals, the identity of the person or organization so filing).

(b) The District Directors, the Commission's Director of the Office of Compliance Programs, and the designated representative of each are hereby delegated the authority to issue the notice described in paragraph (a) of this section.

It is hereby certified that the revised regulation has been assessed for the need of an Inflationary Impact Statement. Because of the nature of the changes this revision does not require an Inflationary Impact Statement.

Signed at Washington, D.C., on this 11th day of August, 1976.

ETHEL BENT WALSH,
Vice Chairman, Equal Employment Opportunity Commission.

[FR Doc.76-23827 Filed 8-16-76;8:45 am]

Title 32—National Defense

CHAPTER VI—DEPARTMENT OF THE NAVY

PART 722—REPORTING PROCEDURES ON DEFENSE RELATED EMPLOYMENT

Revision

Pursuant to the authority conferred under 5 U.S.C. 301 and 10 U.S.C. 166 and 5031, the Secretary of the Navy revises 32 CFR Part 722. This reflects a revision to a Secretary of the Navy Instruction (SECNAVINST 5314.5A) entitled "Reporting procedures on defense related employment" adopted on July 7, 1976. This revision implements 50 U.S.C. 1436 and Department of Defense Directive 7700.15 of October 30, 1970, codified at 32 CFR Part 166, which establish requirements and procedures for annual filing and review of reports of Department of Defense and defense related employment to be submitted by certain categories of personnel and former personnel. The objective of this revision is to improve existing Department of the Navy implementation of the underlying statute and DoD directive by: (1) Promoting individual awareness of and compliance with these instructions; (2) providing more explicit instructions concerning the scope and substance of the prescribed review of filed reports; (3) establishing alerting and monitoring systems in this area; and (4) delineating the responsibilities of commanding officers, heads of naval commands and activities, and the Judge Advocate General with respect to acting on reports of violations of this Part. To the limited extent that this revision could be deemed to originate any requirements within the Department of the Navy, it has been determined that such requirements relate to internal naval management and personnel practices that can be administered more effectively without public participation in the rulemaking process. It has therefore been determined that invitation of public comment on this revision would be impracticable and is not

required under the provisions of Parts 296 and 701 of 32 CFR. Accordingly, 32 CFR Part 722 is revised to provide as follows:

Sec.
722.1 Purpose.
722.2 Scope and effect.
722.3 Persons required to file form DD 1787.
722.4 Filing and review procedures.
722.5 Responsibilities for informing personnel.
722.6 Responsibilities for monitoring and enforcing compliance.
722.7 Availability of forms.

AUTHORITY: 5 U.S.C. 301; 10 U.S.C. 166 and 5031; 50 U.S.C. 1436.

§ 722.1 Purpose.

This Part 722 implements 50 U.S.C. 1436 and Part 166 of this title, which establish requirements and procedures for annual filing and review of reports of Department of Defense (DoD) and defense related employment (form DD 1787) submitted by:

(a) Certain categories of civilian officers and employees of the Department of Defense who were formerly employed by defense prime contractors, and

(b) Certain categories of former military officers and former DoD civilian officers and employees who were subsequently employed by defense prime contractors.

§ 722.2 Scope and effect.

The provisions of this part apply to all Navy and Marine Corps activities, and to the Department of the Navy personnel and former or retired personnel indicated in § 722.3, including personnel of Navy or Marine Corps nonappropriated fund activities. An individual who is required to file a report of DoD and defense related employment (form DD 1787) and fails to do so for any reason is subject under 50 U.S.C. 1436 to a penalty of six months imprisonment, a fine of $1,000, or both.

§ 722.3 Persons required to file form DD 1787.

(a) *Criteria.* The Department of the Navy personnel and former or retired personnel indicated below shall file form DD 1787 with the Secretary of the Navy, in the manner prescribed in § 722.4, not later than January 15 following the close of any fiscal year in which all the specified conditions occur.

(1) *Civilian personnel formerly employed by defense prime contractors.* A civilian officer or employee of the Department of the Navy, including a consultant or part-time employee, shall file form DD 1787, if:

(i) He was employed during any part of the fiscal year by the Department of the Navy or another DoD component at a salary rate at least equal to the minimum rate for grade GS–13;

(ii) At any time during the three-year period preceding the beginning of the fiscal year, he was employed by or performed services for a defense prime contractor, as defined in paragraph (b)(2) of this § 722.3, at a salary rate of at least $15,000 per year; and

(iii) Such defense prime contractor received $10 million or more of negotiated defense contracts during the fiscal year.

(2) *Former civilian personnel subsequently employed by defense prime contractors.* A former civilian officer or employee of the Department of the Navy, including a consultant or part-time employee, shall file form DD 1787, if:

(i) During any part of the fiscal year, he was employed by or performed services for a defense prime contractor, as defined in paragraph (b)(2) of this § 722.3, at a salary rate of at least $15,000 per year;

(ii) Such defense prime contractor received at least $10 million of negotiated defense contracts during the fiscal year;

(iii) The employee's last employment with the Department of the Navy was terminated not more than three years prior to the beginning of the fiscal year; and

(iv) At any time during the three-year period preceding the termination of his last employment by the Department of the Navy, he was paid at a rate at least equal to the minimum rate provided at the time for grade GS–13.

(3) *Former military officers subsequently employed by defense prime contractors.* A former officer, including a retired officer, of the Navy, Marine Corps, Naval Reserve, or Marine Corps Reserve, who served on extended active duty for at least 10 years and was serving in the grade of lieutenant commander, major, or above, at the time of retirement or release from or termination of extended active duty, shall file a form DD 1787, if:

(i) During any part of the fiscal year, he was employed by or performed services for a defense prime contractor, as defined in paragraph (b)(2) of this § 722.3, at a salary rate of at least $15,000 per year;

(ii) Such defense prime contractor received at least $10 million of negotiated defense contracts during the fiscal year; and

(iii) The former or retired officer's extended active duty terminated not more than three years prior to the beginning of the fiscal year. (A retired military officer is subject to the reporting requirement, if otherwise applicable, even if his military retirement pay is waived. A Reserve officer, not on active duty who is not a "retired officer" is a "former officer" for the purpose of form DD 1787 even though he currently holds a commission in a Reserve component.

(b) *Definitions*—(1) *Employed or employment* is used in a broad sense in this part to include services performed, as a consultant or otherwise, either for a defense prime contractor or for a component of the Department of the Navy or DoD. This definition includes, among other services which might have been performed for a defense prime contractor, representing a contractor at a hearing, trial, appeal, or other action in which the United States was a party and which involved services and materials provided or to be provided to DoD by such contractor, and representing a contractor in any transaction with DoD involving services or materials provided or to be provided by such contractor to DoD.

(2) *Defense prime contractor* is used in this part to mean any individual, firm, corporation, partnership, association, or other legal entity that enters into a contract directly with DoD, or any component thereof, to furnish services or materials, including construction, to DoD or a component, and which is awarded $10 million or more of negotiated defense contracts (as distinguished from contracts awarded by formal advertising) during a given fiscal year. The definition thus excludes subcontractors, and excludes prime contractors that receive less than $10 million of negotiated defense contract awards in a fiscal year. Also, a subsidiary of a large corporation may be a separate entity and contract directly with DoD in its own name, in which case the "defense prime contractor" would be the subsidiary corporation, not the parent corporation. Therefore, only the dollar amount of negotiated contracts awarded by DoD components to a subsidiary contracting in its own name during a fiscal year would be considered in determining whether the subsidiary's employees or former employees may be required to file form DD 1787. A list of the "defense prime contractors" meeting the criteria of this definition for the preceding fiscal year is published each December (each September for fiscal years prior to FY 1976) in the FEDERAL REGISTER, appearing as an amendment of 32 Code of Federal Regulations § 166.11. As provided in paragraph (e) of § 722.5, such a list will also be disseminated annually to all naval activities by a JAG Notice.

(3) *Fiscal year* means the period beginning on July 1, 1975 and ending on September 30, 1976, and, after the latter date, means a year beginning on October 1 and ending on September 30 of the following year. It is designated by the calendar year in which it ends—for example, FY 1977 begins on October 1, 1976 and ends on September 30, 1977.

§ 722.4 Filing and review procedures.

(a) Individuals required under § 722.3 to file reports of DoD and defense related employment (form DD 1787) shall submit such reports, in triplicate, in the format prescribed in form DD 1787 and the completion instruction which accompany the form, not later than January 15 following the close of the fiscal year to which the report pertains. The reports shall be submitted to the following officials:

(1) Active civilian personnel formerly employed by defense prime contractors: the Director of Civilian Manpower Management (Administrative Office (01B)), Department of the Navy, Washington, D.C. 20390, via the commanding officers or heads of the activities at which they are employed;

(2) Former civilian personnel subsequently employed by defense prime contractors: The Director of Civilian Man-

power Management (Administrative Office (01B)), Department of the Navy, Washington, D.C. 20390;

(3) Former or retired Navy or Naval Reserve officers subsequently employed by defense prime contractors: the Chief of Naval Personnel (Pers–14), Department of the Navy, Washington, D.C. 20370;

(4) Former or retired Marine Corps or Marine Corps Reserve officers subsequently employed by defense prime contractors: The Commandant of the Marine Corps (Code MSPA–3), Department of the Navy, Washington, D.C. 20380.

(b) The Director of Civilian Manpower Management, Chief of Naval Personnel, and Commandant of the Marine Corps shall receive for the Secretary of the Navy, as provided in paragraph (a) of this § 722.4, all reports of DoD and defense related employment (form DD 1787) submitted by personnel and former personnel of the Department of the Navy, and shall review each report in the manner prescribed in paragraph (d) of this § 722.4. Not later than February 15 each year, they shall forward to the Assistant Secretary of the Navy (Manpower and Reserve Affairs) three copies of each form received by them, together with a listing of the names of individuals submitting the forms, segregated by the names of the defense prime contractors for which the individuals were employed or performed services. (RCS DD–M&RA (A) 1051 (5370).)

(c) Not later than February 28 each year, the Assistant Secretary of the Navy (Manpower and Reserve Affairs) shall forward to the Assistant Secretary of Defense (Manpower and Reserve Affairs) three copies of each form received pursuant to paragraph (b) of this § 722.4, together with a composite listing, in triplicate, of the names of individuals submitting the forms, segregated by the names of the defense prime contractors concerned. (RCS DD–M&RA(A) 1051 (5370).) (Copies of the completed forms and listings are later provided by the Assistant Secretary of Defense (Manpower and Reserve Affairs) to the Congress and are filed for public inspection in the Office of the Secretary of Defense.)

(d) In conducting the review prescribed in paragraph (b) of this § 722.4, the Director of Civilian Manpower Management, Chief of Naval Personnel and Commandant of the Marine Corps, as appropriate, shall determine whether:

(1) Each form submitted is required under this part and 50 U.S.C. 1436;

(2) All required information has been furnished; and

(3) The information submitted indicates an apparent violation of a conflict-of-interests law or regulation cited or provided in Part 721 of this chapter. (For example, the fact that a former officer became employed by a defense prime contractor after terminating Government duties involving that contractor might indicate a possible violation of 18 U.S.C. 207 or 208(a), or the fact that a retired Regular officer represents a contractor in transactions or negotiations with DoD components might indicate a possible violation of 18 U.S.C. 281 or temporarily disentitle him from receiving military retirement pay under 31 U.S.C. 801(c).)

(e) If, upon review of a form, it is determined that the form was not required to be submitted or that all required information has not been furnished, appropriate corrective action shall be taken. If it is determined that a conflict-of-interests violation may have been committed, the form will be processed as provided in paragraph (b) of this § 722.4, but a copy of the form shall be forwarded, for such additional review, inquiry, advice, or further action as may be warranted, to the Chief of Naval Material if involving a possible violation in connection with the procurement, acquisition, or disposal of property within the purview of SECNAVINST 4385.1B; or to the Judge Advocate General in any other case.

§ 722.5 Responsibilities for informing personnel.

Although this part and Part 166 of this title are published in the FEDERAL REGISTER and codified in the "Code of Federal Regulations" in order to provide constructive notice to all individuals affected for purposes of perfecting the legal basis for invoking the penal provisions of 50 U.S.C. 1436 for failure to file form DD 1787, where required, it is imperative that the Department of the Navy take diligent action to ensure that the personnel and former personnel affected receive actual and timely notice of the filing requirement, and to ensure compliance on the part of personnel who are under departmental control. Such action shall include, at the minimum, the following:

(a) Each commanding officer or head of a command, bureau, office, or activity shall:

(1) Direct attention to this part within the organization on a continuing basis in a manner that will ensure that all civilian personnel who may be required to file form DD 1787 are informed of the requirement—this will include providing information in entrance-orientation and exit-interview or separation-counselling procedures, and providing information to civilian personnel who may become subject to the filing requirement by virtue of a promotion or step increase after initial employment; and

(2) Establish controlled procedures to ascertain the identity of each civilian employee within the organization who is required to file form DD 1787 for a given fiscal year, to provide each such employee with a copy of this part and copies of form DD 1787 and the completion instructions which accompany the form, and to ensure that each such employee does file the form in the prescribed manner not later than January 15 following the end of the fiscal year for which it is required.

(3) In providing the foregoing information and notifications, it should be pointed out that the requirement for filing form DD 1787 is distinct from the possible additional requirement for personnel to file confidential statements of employment and financial interests (forms DD 1555 or DD 1555–1) pursuant to Part 721 of this chapter.

(b) The Chief of Naval Personnel or the Commandant of the Marine Corps, as appropriate, shall provide instructions to each Regular or Reserve officer in pay grade O–4 or above who has served on extended active duty for ten years or more, as part of the separation check-out procedures upon retirement, or upon release from or termination of extended active duty, with instructions concerning the possible future requirement for filing form DD 1787. These instructions should be combined, where applicable, with the instructions prescribed in Part 721 of this title concerning additional requirements for retired Regular officers to file statements of employment (form DD 1357). Further, the Chief of Naval Personnel and the Commandant of the Marine Corps shall provide reminders in appropriate publications directed at former or retired officers who may be subject to the requirement for filing form DD 1787.

(c) The Comptroller of the Navy and the Commandant of the Marine Corps shall ensure that periodic reminders are disseminated to those retired Navy, Naval Reserve, Marine Corps, and Marine Corps Reserve officers who may be subject to the requirement for filing form DD 1787. These reminders should be combined, where appropriate, with reminder concerning additional requirements for retired Regular officers to file statements of employment (form DD 1357) pursuant to Part 721 of the chapter.

(d) The Chief of Naval Material, in coordination with the Office of the Secretary of Defense and the other military departments, if deemed appropriate, shall ensure that the contents of this part are periodically brought to the attention of the principal officer of each defense prime contractor identified by the Assistant Secretary of Defense (Comptroller) as receiving $10 million or more of negotiated defense contracts during the preceding fiscal year. Such contractors' principal officers shall be requested to inform all former or retired Department of the Navy personnel in their employ of the requirements of 50 U.S.C. 1436 and this part.

(e) The Judge Advocate General of the Navy shall, at the earliest practicable time following the end of each fiscal year, disseminate a notice to all naval activities containing the list prepared by the Assistant Secretary of Defense (Comptroller) of the business entities which met the criteria as "defense prime contractors" for the purposes of this part during the preceding fiscal year.

(f) The Judge Advocate General of the Navy and the General Counsel of the Navy shall provide, within their respective areas of cognizance, legal advice regarding questions which may arise under this part. Additionally, the deputy ethics counselors designated in Part 721 of this title shall provide advice in local areas.

§ 722.6 Responsibilities for monitoring and enforcing compliance.

(a) Each commanding officer or head of command, bureau, office, or activity shall establish the procedures prescribed in paragraph (a)(2) of § 722.5 and take corrective action in the case of any civilian employee of his organization who has not correctly compiled with this part. Where appropriate, corrective action might include reporting the matter to the Judge Advocate General, via the chain of command and the Director of Civilian Manpower Management, for action in accordance with paragraph (b) of this § 722.6. Further, each such officer receiving a report of an apparent violation of this part by a former or retired civilian or military employee or officer shall forward the report, via the chain of command, to the Judge Advocate General for action in accordance with paragraph (b) of this § 722.6.

(b) The Judge Advocate General and the Chief of Naval Material shall receive reports of apparent violations of this part, as provided above, and, where warranted, refer the same to appropriate investigative authorities. When prosecution is indicated, the matter may be referred by Chief of Naval Material (in coordination with the General Counsel of the Navy) or by the Judge Advocate General to the Department of Justice, in coordination with the General Counsel of the Department of Defense.

(c) The Naval Inspector General and the Inspector General of the Marine Corps shall ensure that periodic administrative inspections of organizations under their cognizance routinely include inquiry into the effectiveness of the organizations' compliance with the provisions of this part.

(d) The Auditor General of the Navy shall ensure that the Naval Audit Service audit program routinely includes inquiry into the effectiveness of organizations' compliance with the provisions of this part.

§ 722.7 Availability of forms.

Supplies of form DD 1787 are available in the Forms and Publications Segment of the Navy Supply System under Stock Number 0102-LF-025-5090.

Dated: August 9, 1976.

JOHN S. JENKINS,
Captain, JAGC, U.S. Navy, Assistant Judge Advocate General (Civil Law).

[FR Doc.76-23904 Filed 8-16-76;8:45 am]

Title 36—Parks, Forests and Public Property

CHAPTER I—NATIONAL PARK SERVICE, DEPARTMENT OF THE INTERIOR

PART 50—NATIONAL CAPITAL PARKS REGULATIONS

Soliciting, Advertising, Sales

On April 6, 1976, there was published in the FEDERAL REGISTER 41 FR 14525 (1976), a notice of proposed rulemaking concerning the regulations governing the sale or distribution of newspapers, leaflets, and pamphlets in park areas.

Interested persons were given an opportunity to participate in the rulemaking proceedings by submission of written comments to the Director, National Capital Parks, National Park Service. Written comments were received from two parties. All comments with respect to the proposed revision were given due consideration.

A. As a result of comments received, the following change in the proposed regulations was made in addition to language changes for clarification:

1. In order to have the definitions contained in this regulation consistent with those covering Demonstrations/Special Events, 36 CFR 50.19, 41 FR 12879 (1976), the definition of the "Lincoln Memorial" was changed to that used at 36 CFR 50.19(a)(9). It is felt that this change was necessary in order to alleviate the confusion that two definitions caused. This confusion was pointed out in a comment received from the American Civil Liberties Union.

B. Certain other recommendations have been carefully considered but have not been adopted. The following suggestions are not adopted for the reasons outlined below:

1. A comment was received concerning the scope of the proposed regulation in that it only applies to the sale or distribution of newspapers, leaflets, and pamphlets conducted without the aid of stands or structures. The proposed amendment regulates only the sale or distribution of the enumerated literature by itinerant vendors and allows such activities without permit in all park areas except those specifically listed. The sale or distribution from stands or structures is governed by the provisions of 36 CFR 50.24(c)(1) which requires a permit for all other sales activities.

2. Comments were received criticizing the proposed regulation as an unconstitutional limitation upon the First Amendment guarantee of freedom of the press. The National Park Service disagrees. The proposed regulation only limits the method of sale or distribution in a few limited areas. The proposed amendment allows for the unfettered distribution in all other park areas and provides reasonable access to the persons using the enumerated areas while preserving the visitor's park experience.

3. Comments were received criticizing the lack of justification or need for the proposed regulations. The National Park Service respectfully disagrees. The voluntary cooperation of the vendors sought by National Capital Parks was not forthcoming.

The views of park visitors made evident to National Capital Parks that the presence of these vendors substantially detracted from visitors' park experience. It was these views that prompted the National Park Service to act in order to protect the visitor experience at each of the enumerated sites.

4. The proposed regulation was criticized as being overbroad in its application to the Kennedy Center, Ford's Theatre, Constitution Gardens, and "all park buildings." The National Park Service must respectfully disagree. The presence of itinerant vendors inside those park buildings dedicated to the performing arts has proven to be a source of constant irritation to park visitors there to honor the memory of a past president or to attend a performing arts function. The limitation against itinerant distributors of literature was extended to include Constitutional Gardens because it is intended that this park will be an area of tranquility where a park visitor may relax without fear of any activity intrusions. The limitation was also extended to "all park buildings" since it was felt that itinerant sales activities there would unreasonably interfere with park administration.

5. A comment was received indicating that the commentator interpreted the proposed regulation as prohibiting the distribution of written material in the White House area and charging the Department with "carelessness or deception." The National Park Service regrets this characterization. The definition of the "White House area" § 50.24(c)(vi), specifically excludes from the limitation "* * * Lafayette Park, the White House sidewalk (the south Pennsylvania Avenue, NW. sidewalk between East and West Executive Avenues) and the Ellipse." Thus the proposed regulation provides for the unfettered distribution or sale of literature in the same areas within which 36 CFR 50.19 permits demonstrations.

6. A comment was received objecting to the form of the notice and suggesting that in order to be proper the National Park Service must re-publish the notice with diagrams denoting exactly the proscribed areas. The National Park Service respectfully disagrees.

It is the opinion of the National Park Service that the description of the proscribed areas are simple and readily understandable.

7. A comment was received criticizing the proposed amendment's application to the Washington Monument since it "does not have an atmosphere of 'calm, tranquility and reverence'". National Capital Parks has taken steps to alleviate the situation which the commentator relies upon. Moreover, it is the position of the National Park Service that heavy visitation to a memorial does not deprive the Park Service of the ability to take reasonable steps to maintain an atmosphere of calm, tranquility and reverence.

Effective date: This regulation shall become effective August 17, 1976.

Adopted by the National Park Service at its office in Washington, D.C. on the 6th day of August 1976.

GARY EVERHARDT,
Director, National Park Service.

Accordingly, 36 CFR 50.24(c) is revised to read as follows:

§ 50.24 Soliciting, advertising, sales.

* * * * *

(c) *Sales* (1) No sales shall be made nor admission fee charged and no article shall be exposed for sale in a park area without an official permit.

(2) The sale or distribution of newspapers, leaflets, and pamphlets, conducted without the aid of stands or structures, is permitted in all park areas, open to the general public, without permit except the following areas where such sale or distribution is prohibited:

(i) Lincoln Memorial area which is on the same level or above the base of the large marble columns surrounding the structure, and the single series of marble stairs immediately adjacent to and below that level.

(ii) Jefferson Memorial area enclosed by the outermost series of columns, and all portions on the same levels or above the base of these columns.

(iii) Washington Monument area enclosed within a circle extending ten feet from the paved area surrounding the base of the Washington Monument.

(iv) Constitution Gardens area bounded on the north by Constitution Avenue NW.; on the south by the north reflecting pool walk extending from 17th Street NW.; to Bacon Drive NW.; on the east by 17th Street NW.; and on the west by Bacon Drive NW.

(v) The interior of all park buildings, including, but not limited to, those portions of the Kennedy Center and Ford's Theatre administered by the National Park Service.

(vi) The White House Park area bounded on the north by H Street NW.; on the south by Constitution Avenue NW.; on the west by 17th Street NW.; and on the east by 15th Street NW.; except for Lafayette Park, the White House sidewalk (the south Pennsylvania Avenue NW. sidewalk between East and West Executive Avenues) and the Ellipse.

[FR Doc.76-24024 Filed 8-16-76;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 599-2]

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

New Mexico, Revocation of Approval of Regulation for Control of Sulfur Oxides Emissions From Coal Burning Equipment

The purpose of this rulemaking is to revoke the approval of the New Mexico Regulation for control of sulfur oxides emissions from existing coal burning equipment and to disapprove that portion of the State Implementation Plan relating to the attainment of sulfur oxides National Ambient Air Quality Standards (NAAQS), in the Four Corners Air Quality Control Region (AQCR).

On October 3, 1975, the Governor of New Mexico submitted a revision to the State Implementation Plan regarding Regulation 602B, Coal Burning Equipment-Sulfur Dioxide, which controlled emissions from existing facilities. The Environmental Protection Agency had previously disapproved the State plan on July 27, 1972 (37 FR 15086) and corrective regulations were promulgated by EPA on March 23, 1973, (38 FR 7556) with amendments published on March 21, 1974 (39 FR 10582). The New Mexico submittal showed a degree of control greater than the Federal promulgation and was considered corrective action to the State Implementation Plan. Therefore, on February 24, 1976 (41 FR 8057) the Administrator issued approval of the New Mexico plan and revoked the federally promulgated regulation.

In the preamble to the February 24, 1976 action, pending litigation was noted. The State Regulation 602B had been appealed to the New Mexico Court of Appeals. On April 6, 1976, the New Mexico Court of Appeals invalidated a portion of that regulation, namely Sections 602(B) (2) and (3), and the New Mexico Supreme Court subsequently denied a petition for certiorari. With these decisions, the invalidation is now fully operative. Therefore, EPA hereby revokes its previous approval of Regulation 602(B) (2) and (3). In addition, the New Mexico plan is once again deficient in meeting the requirements of § 51.13 of this chapter, since the plan does not provide for attainment and maintenance of national standards for sulfur oxides in New Mexico's portion of the Four Corners Interstate Region. Negotiations with the State are progressing to develop replacement regulations.

Publications occurring on October 20, 1975 (40 FR 48941), February 24, 1976 (41 FR 8057), and April 30, 1976 (41 FR 18077), discussed the actions in New Mexico and the State conducted public hearings on August 27 through August 29, 1974, in accordance with § 51.4 of the chapter. For this reason and since the court decision is fully operative, the Administrator finds good cause to complete the invalidation of New Mexico Regulation 602(B) (2) and (3) and make the actions herein effective immediately. This rulemaking is issued under the authority of section 110 of the Clean Air Act as amended 42 U.S.C. 1857c-5.

Dated: August 11, 1976.

JOHN QUARLES,
Acting Administrator,
Environmental Protection Agency.

Part 52 of Chapter I Title 40 of the Code of Federal Regulations is amended as follows:

Subpart GG—New Mexico

1. In § 52.1620, paragraph (c)(8) is amended.

§ 52.1620 Identification of plan.

* * * * *

(c) * * *

(8) Revisions to Air Quality Control Regulation 602, Coal Burning Equipment—Sulfur Dioxide, adopted by the New Mexico Environmental Improvement Board on December 13, 1974, and submitted by the Governor on October 3, 1975, except sections 602B (2) and (3).

2. § 52.1624 is amended by adding paragraphs (a)(1) and (b)(1) as follows:

§ 52.1624 Control strategy and regulations: Sulfur oxides.

* * * * *

(a) * * *

(1) The plan does not provide for attainment and maintenance of the national standards for sulfur oxides in New Mexico's portion of the Four Corners Interstate Region.

* * * * *

(b) * * *

(1) Regulation 602B, except section 602(B)(1) (emission limitation for sulfur dioxide from existing coal-burning equipment) is disapproved since it does not provide for the degree of control necessary to attain and maintain the national standards for sulfur oxides in New Mexico's portion of the Four Corners Interstate Region.

[FR Doc.76-24086 Filed 8-16-76;8:45 am]

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 122—HEALTH SYSTEMS AGENCIES

Subpart B—Designation of Health Systems Agencies

Correction

In FR Doc. 76-21707 appearing on page 31208 in the issue for Tuesday, July 27, 1976, the effective date of "August 27, 1976" given twice at the end of the preamble in the third column of page 31208 is incorrect and should have read "July 27, 1976".

Title 43—Public Lands: Interior

CHAPTER II—BUREAU OF LAND MANAGEMENT, DEPARTMENT OF THE INTERIOR

APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 5599; Utah 30209]

UTAH

Powersite Restoration No. 740, Revocation of Powersite Reserve No. 122, San Juan River, Southeastern Utah

By virtue of the authority vested in the President by section 1 of the Act of June 25, 1910, 36 Stat. 847; 43 U.S.C. 141 (1970), and pursuant to Executive Order No. 10355 of May 26, 1952 (17 FR 4831), and pursuant to the determination of the Federal Power Commission in DA-200-Utah, it is ordered as follows:

1. The withdrawal order of July 2, 1910, creating Powersite Reserve No. 122, is hereby revoked to the extent that it affects the following described lands:

SALT LAKE MERIDIAN

T. 40 S., R 22 E.,
Sec. 20, S½SW¼, SW¼SE¼, W½SE¼SE¼;
Sec. 21, E½SW¼SW¼;
Sec. 22, SE¼SE¼;
Sec. 23, S½S½.

The total area aggregates 360 acres in San Juan County.

2. This revocation is made pursuant to a petition for revocation filed by the

State of Utah to allow a State exchange under section 8 of the Act of June 28, 1934, as amended, 43 U.S.C. 315g (1970).

Inquiries concerning the lands should be addressed to the Utah State Director, Bureau of Land Management, Post Office Box 11505, Salt Lake City, Utah 84111.

JACK O. HORTON,
Assistant Secretary of the Interior.

AUGUST 9, 1976.

[FR Doc.76-23908 Filed 8-16-76;8:45 am]

Title 50—Wildlife

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 32—HUNTING

Seney National Wildlife Refuge, Mich.

The following special regulation is issued and is effective on August 17, 1976.

§ 32.32 Special regulations; upland game; for individual wildlife refuge areas.

MICHIGAN

SENEY NATIONAL WILDLIFE REFUGE

The public hunting of Ruffed Grouse and Snowshoe Hare on the Seney National Wildlife Refuge is permitted only on the area designated as open to hunting. This open area, comprising 33,525 acres, is delineated on maps available at refuge headquarters, Seney, Michigan and from the Regional Director, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111.

Hunting shall be in accordance with all applicable State regulations governing the hunting of these species subject to the following special conditions:

(1) That portion of the refuge designated as Area A is closed to all hunting until November 15.

(2) All motorized conveyances are prohibited from traveling on dikes or off established roads and trails. Motorized bikes, All-Terrain Vehicles and Snowmobiles are not permitted on the refuge.

The provisions of this special regulation supplements the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through February 28, 1977.

JOHN R. FRYE,
Refuge Manager, Seney National Wildlife Refuge, Seney, Mich.

AUGUST 9, 1976.

[FR Doc.76-23910 Filed 8-16-76;8:45 am]

PART 32—HUNTING

Seney National Wildlife Refuge, Mich.

The following special regulation is issued and is effective on August 17, 1976.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

MICHIGAN

SENEY NATIONAL WILDLIFE REFUGE

Public hunting of deer and bear on the Seney National Wildlife Refuge is permitted only on the area designated as open to hunting. The open area, comprising 85,200 acres, is delineated on a map available at the refuge headquarters, Seney, Michigan and from the Regional Director, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111.

Hunting shall be in accordance with all applicable State and Federal regulations covering the hunting of deer and bear subject to the following special conditions:

(1) Bow and arrow hunting is permitted only on 33,525 acres of the refuge designated as Area B, from October 1 through November 14; and on the 85,200 acres of the refuge designated as Area A and Area B, from December 1 through December 31.

(2) Bear may be taken by archers only from October 1 through November 14 and by gun hunters only from November 15 through November 30. Bear may not be taken with the aid of dogs.

(3) Camping is permitted only west of the Driggs River except in designated Wilderness Area during the gun season. A Camp Registration Permit, obtainable at refuge headquarters, is required.

(4) All motorized conveyances are prohibited from traveling on dikes or off established roads and trails. Motorized bikes, All-Terrain Vehicles and Snowmobiles are not permitted on the refuge.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32 and are effective through December 31, 1976.

AUGUST 9, 1976.

JOHN R. FRYE,
Refuge Manager, Seney National Wildlife Refuge, Seney, Mich.

[FR Doc.76-23911 Filed 8-16-76;8:45 am]

PART 32—HUNTING

Mark Twain National Wildlife Refuge—Illinois

The following special regulation is issued and is effective August 17, 1976.

§ 32.22 Special regulations; upland game; for individual wildlife refuge areas.

ILLINOIS

MARK TWAIN NATIONAL WILDLIFE REFUGE

Public hunting of black, gray, and fox squirrels on the Mark Twain National Wildlife Refuge, Illinois, is permitted only on the areas designated by signs as open to hunting. These open areas, comprising 1,400 acres, are delineated on maps available at refuge headquarters and from the office of the Regional Director, United States Fish and Wildlife Service, Federal Building Fort Snelling, Twin Cities, Minnesota 55111. Hunting shall be in accordance with all applicable State regulations concerning the hunting of squirrels subject to the following special conditions:

(1) The open season for hunting squirrels on the Keithsburg Division of the Mark Twain National Wildlife Refuge extends from September 1, 1976, through October 15, 1976, inclusive.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuges generally, which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through October 15, 1976.

HOWARD A. LIPKE,
Refuge Manager, Mark Twain National Wildlife Refuge, Quincy, Illinois 62301.

JULY 23, 1976.

[FR Doc.76-23984 Filed 8-16-76;8:45 am]

PART 32—HUNTING

Mark Twain National Wildlife Refuge—Illinois

The following special regulation is issued and is effective August 17, 1976.

§ 32.32 Special regulations; big game, for individual wildlife refuge areas.

ILLINOIS

MARK TWAIN NATIONAL WILDLIFE REFUGE

Public hunting of white-tailed deer with shotgun on the Mark Twain National Wildlife Refuge, Illinois, is permitted from November 19, 1976 through November 21, 1976, only on the area of the Gardner Division designated by signs as open to hunting. The open area, comprising 4,831 acres, is delineated on a map available at the refuge headquarters and from the Regional Director, United States Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111. Hunting shall be in accordance with all applicable State regulations concerning the hunting of white-tailed deer with shotgun subject to the following conditions:

(1) A valid State-issued shotgun deer permit with Mark Twain National Wildlife Refuge designation will serve as authorization to enter the public hunting area. One hundred and fifty (150) permits will be issued following a May 17, 1976 drawing.

(2) Successful hunters will be required to check their deer through the Adams County Check Station near the Division.

(3) Hunting will be from 6:30 a.m. to 3:00 p.m. (CST).

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through November 21, 1976.

HOWARD A. LIPKE,
Refuge Manager, Mark Twain National Wildlife Refuge.

AUGUST 9, 1976.

[FR Doc.76-23985 Filed 8-16-76;8:45 am]

PART 32—HUNTING

Mark Twain National Wildlife Refuge—Iowa

The following special regulation is issued and is effective August 17, 1976.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

IOWA

MARK TWAIN NATIONAL WILDLIFE REFUGE

Public hunting of big game on the Mark Twain National Wildlife Refuge, Iowa, is permitted only on the areas known as the Big Timber Division and the Turkey Island area designated by signs as open to hunting. These open areas, comprising 1,760 acres, are delineated on a map available at the refuge headquarters and from the Regional Director, United States Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111. Hunting shall be in accordance with all applicable State regulations.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through December 31, 1976.

HOWARD A. LIPKE,
Refuge Manager, Mark Twain National Wildlife Refuge Quincy, Ill.

JULY 23, 1976.

[FR Doc.76-23987 Filed 8-16-76;8:45 am]

PART 32—HUNTING

Mark Twain National Wildlife Refuge—Iowa

The following special regulation is issued and is effective August 17, 1976.

§ 32.22 Special regulations; upland game; for individual wildlife refuge areas.

IOWA

MARK TWAIN NATIONAL WILDLIFE REFUGE

Public hunting of upland game on the Mark Twain National Wildlife Refuge, Iowa, is permitted only on the areas known as Big Timber Division and Turkey Island area designated by signs as open to hunting. These open areas, comprising 1,760 acres, are delineated on a map available at the refuge headquarters and from the Regional Director, United States Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111. Hunting shall be in accordance with all applicable State regulations concerning the hunting of upland game.

The provisions of this special regulation supplements the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through February 28, 1977.

HOWARD A. LIPKE,
Refuge Manager, Mark Twain National Wildlife Refuge, Quincy, Illinois.

JULY 23, 1976.

[FR Doc.76-23986 Filed 8-16-76;8:45 am]

Title 7—Agriculture

CHAPTER I—AGRICULTURAL MARKETING SERVICE (STANDARDS, INSPECTION, MARKETING PRACTICES), DEPARTMENT OF AGRICULTURE

PART 52—PROCESSED FRUITS AND VEGETABLES, PROCESSED PRODUCTS THEREOF, AND CERTAIN OTHER PROCESSED FOOD PRODUCTS

Subpart—United States Standards for Grades of Processed Raisins

On pages 26021 through 26026 of the FEDERAL REGISTER of June 24, 1976 (41 FR 26021), there was published a notice of proposed rulemaking to revise the United States Standards for Grades of Processed Raisins.

STATEMENT OF CONSIDERATIONS

The proposed revision incorporated the United States Standards for Grades of Dried Currants into the United States Standards for Grades of Processed Raisins as a separate type of raisin in an effort to reduce the misunderstanding and confusion about the product customarily called, and marketed in the United States as, dried currants. Domestic dried currants are raisins processed from either the White Corinth or the Black Corinth grape—both of which are vinifera variety grapes. Their method of drying and preparation is the same as for other, more popular vinifera varieties such as the Thompson Seedless, Muscat of Alexandria, Muscatel Gordo Blanco, and Sultana. Editorial changes such as eliminating text in favor of using graphic tables to reduce misunderstanding; simplifying grade nomenclature by eliminating the alternative quality terms "U.S. Fancy," "U.S. Choice," and "U.S. Standard"; and relocating text to bring sections of like information together were also proposed.

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

The proposal also considered changing the method of determining some defect categories from a "by count" to a "by weight" basis; and combining two similar development characteristics into a single scoring category.

Interested persons were given until July 26, 1976, to submit data, views, or arguments regarding the proposed revision.

One objection was received taking exception to the allowance for mold in all types of raisins.

The allowance provided in the Standards is a reasonable and workable allowance. It is the level (for this type of defect) that has been allowed in the standards for several years.

The response from the (California) Raisin Administrative Committee reflecting the views of some 4,000 raisin growers, handlers, and producers support the proposed revision and request its adoption.

The proposed revision to the United States Standards for Grades of Processed Raisins is adopted with minor editorial changes as set forth below.

Effective date. The revised United States Standards for Grades of Processed Raisins shall become effective on September 1, 1976.

§§ 52.981–52.985 [Reserved]

1. In 7 CFR Part 52—§ 52.981 through 52.985 are revoked and reserved effective September 1, 1976.

2. Sections 52.1841 through 52.1858 are revised to read as follows:

52.1841 Product description.
52.1842 Product description for Layer (or Cluster) Raisins with Seeds.
52.1843 Summary of types (varieties) of processed raisins.
52.1844 Definition of terms.

TYPE I—SEEDLESS RAISINS

52.1845 Sizes of seedless raisins.
52.1846 Grades of seedless raisins.

TYPE II—GOLDEN SEEDLESS RAISINS

52.1847 Colors of golden seedless raisins.
52.1848 Sizes of golden seedless raisins.
52.1849 Grades of golden seedless raisins.

TYPE III—RAISINS WITH SEEDS

52.1850 Sizes of raisins with seeds—except layer or cluster.
52.1851 Sizes of raisins with seeds—layer or cluster.
52.1852 Grades of raisins with seeds—except layer or cluster.
52.1853 Grades of raisins with seeds—layer or cluster.

TYPE IV—SULTANA RAISINS

52.1854 Sizes of sultana raisins.
52.1855 Grades of sultana raisins.

TYPE V—ZANTE CURRANT RAISINS

52.1856 Sizes of zanta currant raisins.
52.1857 Grades of zante currant raisins.

TYPE VI—MIXED TYPE OF RAISINS

52.1858 Grades of mixed types or varieties of raisins.

AUTHORITY: Agricultural Marketing Act of 1946, secs. 203, 205, 60 Stat. 1087, as amended 1090, as amended; (7 U.S.C. 1622, 1624).

§ 52.1841 Product description.

Processed Raisins are dried grapes of the Vinifera varieties, such as Thompson Seedless (Sultanina), Muscat of Alexandria, Muscatel Gordo Blanco, Sultana, Black Corinth or White Corinth. The processed raisins are prepared from clean, sound, dried grapes; are properly stemmed and capstemmed except for cluster or uncapstemmed raisins; are properly seeded in seeded styles; are sorted or cleaned, or both; and except

for cluster or uncapstemmed raisins, are washed in water to assure a wholesome product.

§ 52.1842 Product description of layer or cluster raisins with seeds.

Raisins with Seeds that are referred to as "Layer or Cluster raisins" means that the raisins have not been detached from the main bunch.

§ 52.1843 Summary of types (varieties) of processed raisins.

(a) Type I—Seedless Raisins
(1) Natural.
(2) Dipped, Vine-dried, or similarly processed raisins.
(b) Type II—Golden Seedless Raisins
(c) Type III—Raisins with Seeds
(1) Natural.
(i) Seeded (seeds removed).
(ii) Unseeded-capstemmed (loose).
(iii) Unseeded-uncapstemmed (loose).
(iv) Layer (or Cluster).
(2) Dipped, Vine-dried, or other similarly processed raisins.
(i) Seeded (seeds removed).
(ii) Unseeded-capstemmed (loose).
(iii) Unseeded-uncapstemmed (loose).
(d) Type IV—Sultana Raisins.
(e) Type V—Zante Currant Raisins.
(i) Unseeded.
(ii) Seeded.
(f) Type VI—Mixed Types or Varieties of Raisins. A mixture of two or more different types (varieties) of raisins including sub-types outlined in this section but other than: (1) mixtures containing Layer or Cluster Raisins with seeds;
(2) mixtures containing Unseeded-capstemmed and Unseeded-uncapstemmed Raisins with Seeds; and (3) mixture of Seeded and Unseeded Raisins with Seeds.

§ 52.1844 Definition of terms.

(a) "Capstems" means small woody stems exceeding ⅛-inch in length which attach the raisins to the branches of the bunch.
(b) A "piece of stem" means a portion of the branch or main stem.
(c) "Seeds" refers to whole, fully developed seeds which have not been removed during the processing of seeded Raisins with seeds.
(d) "Damaged raisins" means raisins affected by sunburn, scars, insect injury, mechanical injury, or other similar means which seriously affect the appearance, edibility, keeping quality, or shipping quality of the raisins. In seeded Raisins with Seeds, mechanical injury resulting from normal seeding operations is not considered damage.
(e) "Sugared" means either external or internal sugar crystals are present and the accumulation of such crystallized fruit sugars in the flesh or on the surface of the raisins is readily apparent.
(f) "Grit, sand, or silt" means any particle or earthy material.
(g) "Moisture" means the percentage by weight of the processed raisins, exclusive of branch and heavy stem material, that is moisture when determined by the "Dried Fruit Moisture Tester Method" or in accordance with other methods that give equivalent results.
(h) "Slightly discolored" means a raisin affected by a brown to dark brown discolored area around the capstem end of the raisin that is less than the area of a circle ⅛-inch in diameter.
(i) "Discolored" means a raisin affected by a brown to dark brown discolored area around the capstem end of the raisin that equals or exceeds the area of a circle ⅛-inch in diameter; Provided, That the overall appearance, keeping quality, and edibility of the product are not seriously affected.
(j) "Well-matured" means raisins that are full-fleshed, may have fine wrinkles and are rounded in appearance.
(k) "Reasonably well-matured" means raisins that are reasonably full-fleshed and may have shallow wrinkles with thick edged ridges.
(l) "Fairly well-matured" means raisins that are thin-fleshed and angular in appearance.
(m) "Substandard development" means raisins that are practically lacking in flesh.
(n) "Undeveloped" refers to extremely light berries that are lacking in sugary tissue indicating incomplete development; are reddish in color; are completely shriveled; have fine wrinkles on smaller units and moderately deep wrinkles on slightly larger units; and are commonly referred to as "worthless."

TYPE I—SEEDLESS RAISINS

§ 52.1845 Sizes of seedless raisins.

The size designations and measurement requirements for the respective sizes are:
(a) "Select" size raisins means that no more than 60 percent, by weight, of all the raisins will pass through round perforations $^{22}/_{64}$-inch in diameter, but not more than 10 percent, by weight, of all the raisins may pass through round perforations $^{20}/_{64}$-inch in diameter.
(b) "Small" or "midget" size raisins means that 95 percent, by weight, of all the raisins will pass through round perforations $^{24}/_{64}$-inch in diameter, and not less than 70 percent, by weight, of all raisins will pass through round perforations $^{23}/_{64}$-inch in diameter.
(c) "Mixed" size raisins means a mixture which does not meet either the requirements for "select" size or for "small" or "midget" size.

§ 52.1846 Grades of seedless raisins.

(a) "U.S. Grade A" is the quality of Seedless Raisins that have similar varietal characteristics; that have a good typical color; that have a good characteristic flavor; that show development characteristics of raisins prepared from well-matured grapes with not less than 80 percent, by weight, of raisins that are well-matured or reasonably well-matured; that contain not more than 18 percent, by weight, of moisture; and that meet the additional requirements outlined in Table I of this subpart.
(b) "U.S. Grade B" is the quality of Seedless Raisins that have similar varietal characteristics; that have a reason-

ably good typical color; that have a good characteristics flavor; that show development characteristics of raisins prepared from reasonably well-matured grapes with not less than 70 percent, by weight, of raisins that are well-matured or reasonably well-matured; that contain not more than 18 percent, by weight, of moisture; and that meet the additional requirements outlined in Table I of this subpart.

(c) "U.S. Grade C" is the quality of Seedless Raisins that have similar varietal characteristics; that have a fairly good typical color; that have a fairly good flavor; that show development characteristics of raisins prepared from fairly well-matured grapes with not less than 55 percent, by weight, of raisins that are well-matured or reasonably well-matured; that contain not more than 18 percent, by weight, of moisture; and that meet the additional requirements outlined in Table I of this subpart.

(d) "Substandard" is the quality of Seedless Raisins that fail to meet the requirements of U.S. Grade C.

TABLE I -- ALLOWANCES FOR DEFECTS IN TYPE I, SEEDLESS RAISINS AND TYPE II, GOLDEN SEEDLESS RAISINS

Defects	U.S. Grade A	U.S. Grade B	U.S. Grade C
	Maximum count (per 96 ounces)		
Pieces of stem	1	2	4
	Maximum count (per 16 ounces)		
Capstems	15	25	35
	Maximum (percent by weight)		
Sugared	5	10	15
Discolored, damaged or moldy raisins	4	6	9
Provided these limits are not exceeded:			
Damaged	2	3	5
Moldy	2	3	4
Substandard Development and Undeveloped	Total	Total	Total
Select size	1	1-1/2	2
Mixed size	1	2	3
Small (Midget) size	2	3	5
	Appearance or edibility of product:		
Slightly discolored or damaged by fermentation or any other defect not described above	May not be affected	May not be more than slightly affected	May not be materially affected
Grit, sand, or silt	None of any consequence may be present that affects the appearance or edibility of the product.		Not more than a trace may be present that affects the appearance or edibility of the product.

TYPE II—GOLDEN SEEDLESS RAISINS

§ 52.1847 Colors of golden seedless raisins.

The color of Golden Seedless Raisins is not a factor of quality for the purpose of these grades. The color requirements applicable to the respective color designations are as follows:

(a) "Well colored" means that the raisins are practically uniform in color and may range from yellow or golden to light amber color with a predominating yellow or golden color and that not more than ½ of 1 percent, by weight, of all the raisins may be definitely dark berries.

(b) "Reasonably well colored" means that the raisins are reasonably uniform in color and may range from yellow or golden or greenish yellow to light amber wherein the predominating color may be greenish yellow or light amber and that not more than 3 percent, by weight, of all the raisins may be definitely dark berries.

(c) "Fairly well colored" means that the raisins are fairly uniform in color and may range from yellow or greenish yellow to amber or light greenish amber and that not more than 6 percent, by weight, of all the raisins may be definitely dark berries.

(d) "Colored" means that the raisins may be variable in color and may range from yellowish green to dark amber or dark greenish amber; that not more than 20 percent, by weight, of all the raisins may be definitely dark berries.

(e) "Definitely dark berries" means raisins which are definitely darker than dark amber and characteristic of naturally "raisined" grapes.

§ 52.1848 Sizes of golden seedless raisins.

The size designations and measurement requirements for the respective sizes of Golden Seedless Raisins are the same as for Seedless Raisins (See § 52.1845).

§ 52.1849 Grades of golden seedless raisins.

Except for color, the grades of Golden Seedless Raisins are the same as for Seedless Raisins (See § 52.1846 and Table I).

TYPE III—RAISINS WITH SEEDS

§ 52.1850 Sizes of raisins with seeds—except layer or cluster.

The sizes of Raisins with Seeds—except for Layer or Cluster Raisins with Seeds, are not incorporated in the grades of the finished product since size, as such, is not a factor of quality for the purposes of these grades. The common size designations and measurement requirements applicable thereto include, but are not limited to, the following:

(a) *Seeded.* (1) "Select" size raisins means that not more than 70 percent, by weight, of the raisons will pass through round perforations 34/64-inch in diameter; and not more than 5 percent, by weight, of the raisins will pass through round perforations 22/64-inch in diameter.

(2) "Small" or "midget" size raisins means that all of the raisins will pass through round perforations 34/64-inch in diameter and not less than 90 percent, by weight, of all the raisins will pass through round performances 23/64-inch in diameter.

(3) "Mixed" size raisins means a mixture which does not meet either the requirements for "select" size or for "small" (or "midget") size.

(b) *Unseeded.* (1) "4 Crown" means raisins that will not pass through round perforations 42/64-inch in diameter.

(2) "3 Crown" means raisins that will pass through round perforations 42/64-inch in diameter but will not pass through round perforations 34/64-inch in diameter.

(3) "2 Crown" means raisins that will pass thorugh round perforations 34/64-inch in diameter but will not pass through round perforations 24/64-inch in diameter.

(4) "1 Crown" means raisins that will pass through round perforations 24/64-inch in diameter.

§ 52.1851 Sizes of raisins with seeds—layer or cluster.

The size of Layer or Cluster Raisins with Seeds is incorporated in the grades of the finished product. The size designation and measurement as applicable to layer or cluster raisins with seeds are:

(a) *3 Crown Size or Larger.* "3 Crown size or larger" in Layer or Cluster Raisins

with Seeds means that the raisins, exclusive of stems and branches, are such a size that they will not pass through round perforations 34/64-inhc in diameter.

§ 52.1852 Grades of raisins with seeds—except layer or cluster.

(a) "U.S. Grade A" is the quality of Raisins with Seeds that have similar varietal characteristics; that have a good typical color with not more than 10 percent, by weight, that may be dark reddish-brown berries; that have a good characteristic flavor; that show development characteristics of raisins prepared from well-matured grapes; with not less than 80 percent, by weight, of raisins that are well-matured or reasonably well-matured; that contain not more than 18 percent, by weight, of moisture, except that any seeded raisins may contain not more than 19 percent, by weight, of moisture; and meet the additional requirements as outlined in Table II of this subpart.

(b) "U.S. Grade B" is the quality of Raisins with Seeds that have similar varietal characteristics; that have a reasonably good typical color with not more than 15 percent, by weight, that may be dark reddish-brown berries; that have a good characteristic flavor; that show development characteristics of raisins prepared from reasonably well-matured grapes; with not less than 70 percent, by weight, of raisins that are well-matured or reasonably well matured; that contain not more than 18 percent, by weight, of moisture, except that any seeded raisins may contain not more than 19 percent, by weight, of moisture; and meet the additional requirements as outlined in Table II of this subpart.

(c) "U.S. Grade C" is the quality of Raisins with Seeds that have similar varietal characteristics; that have a fairly good typical color with not more than 20 percent, by weight, that may be dark reddish-brown berries; that have a fairly good flavor; that show development characteristics of raisins prepared from fairly well-matured grapes; that contain not more than 18 percent, by weight, of moisture, except that any seeded raisins may contain not more than 19 percent, by weight, of moisture; and meet the additional requirements as outlined in Table II of this subpart .

(d) "Substandard" is the quality of Raisins with Seeds that fail to meet the requirements of U.S. Grade C.

TABLE II - ALLOWANCES FOR DEFECTS IN RAISINS WITH SEEDS - EXCEPT LAYER OR CLUSTER

Defects	U.S. Grade A	U.S. Grade B	U.S. Grade C
	Maximum count (per 32 ounces)		
Pieces of stem	1	2	3
	Maximum count (per 16 ounces)		
Capstems in other than uncapstemmed types	10	15	20
Seeds in seeded types	12	15	20
Loose capstems in uncapstemmed types	20	20	20
	Maximum (percent by weight)		
Sugared	5	10	15
Discolored, damaged, or moldy	5	7	9
Provided these limits are not exceeded:			
Damaged	3	4	5
Moldy	2	3	4
Substandard Development and Undeveloped	2	5	8
	Appearance or edibility of product		
Slightly discolored or damaged by fermentation or any other defect not described above	May not be affected.	May not be more than slightly affected.	May not be more than materially affected.
Grit, sand, or silt	None of any consequence may be present that affects the appearance or edibility of the product.		Not more than a trace may be present that affects the appearance or edibility of the product.

§ 52.1853 Grades of raisins with seeds—layer or cluster.

(a) "U.S. Grade A" is the quality of Layer or Cluster Raisins with Seeds that have similar varietal characteristics; that have a good typical color; that have a good characteristic flavor; that are uniformly cured and show development characteristics of raisins prepared from well-matured grapes; that contain not more than 23 percent, by weight, of moisture; that not less than 30 percent, by weight, of the raisins, exclusive of stems and branches, are 3-Crown size or larger; and that meet the following additional requirements as outlined in Table III of this subpart.

(b) "U.S. Grade B" is the quality of Layer or Cluster Raisins with Seeds that have similar varietal characteristics that have a reasonably good typical color; that have a good characteristic flavor; that are uniformly cured and show development characteristics of raisins prepared from reasonably well-matured grapes; that contain not more than 23 percent, by weight, of the moisture, that not less than 30 percent, by weight, of the raisins exclusive of stems and branches, are 3-Crown size or larger; and that meet the additional requirements outlined in Table III of this subpart.

(c) "Substandard" is the quality of Layer or Cluster Raisins with Seeds that fail to meet the requirements of U.S. Grade B.

TABLE III - ALLOWANCES FOR DEFECTS IN LAYER OR CLUSTER RAISINS WITH SEEDS

Defects	U.S. Grade A	U.S. Grade B
	Maximum (percent by weight)	
Sugared	5	10
Discolored, damaged, or moldy	5	7
Provided these limits are not exceeded:		
Damaged	3	4
Moldy	2	3
Substandard Development and Undeveloped	2	5
Shattered (or loose) individual berries and small clusters of 2 or 3 berries each	Practically free	Reasonably free
	Appearance or edibility of product	
Slightly discolored or damaged by fermentation or any other defect not described above	May not be affected.	May not be more than slightly affected.
Grit, sand, or silt	None of any consequence may be present that affects the appearance or edibility of the product.	

TYPE IV—SULTANA RAISINS

§ 52.1854 Sizes of Sultant raisins.

Size designations are not applicable to Sultana Raisins.

§ 52.1855 Grades of Sultana raisins.

(a) "U.S. Grade A" is the quality of Sultana Raisins that have similar varietal characteristics; that have a good typical color; that have a good characteristic flavor; that show development characteristics of raisins prepared from well-matured grapes; with not less than 80 percent, by weight, of raisins that are well-matured or reasonably well-matured; and that contain not more than 18 percent, by weight, of moisture, and that meet the additional requirements outlined in Table IV of this subpart.

(b) "U.S. Grade B" is the quality of Sultana Raisins that have similar varietal characteristics; that have a reasonably good typical color; that have a good characteristic flavor; that show development characteristics of raisins prepared from reasonably well-matured grapes; with not less than 70 percent, by weight, of raisins that are well-matured or reasonably well-matured; and that contain not more than 18 percent, by weight, of moisture, and that meet the additional requirements as outlined in Table IV of this subpart.

(c) "U.S. Grade C" is the quality of Sultana Raisins that have similar varietal characteristics; that have a fairly good typical color; that have a fairly

good flavor; that show development characteristics of raisins prepared from fairly well-matured grapes; that contain not more than 18 percent, by weight, of moisture; and that meet the additional requirements as outlined in Table IV of this subpart.

(d) "Substandard" is the quality of Sultana Raisins that fail to meet the requirements of U.S. Grade C.

TABLE IV - ALLOWANCES FOR DEFECTS IN SULTANA RAISINS

Defects	U.S. Grade A	U.S. Grade B	U.S. Grade C
	Maximum count (per 32 ounces)		
Pieces of stem	1	2	3
	Maximum count (per 16 ounces)		
Capstems	25	45	65
	Maximum (percent by weight)		
Sugared	5	10	15
Discolored, damaged, or moldy	4	6	9
Provided these limits are not exceeded:			
Damaged	2	3	5
Moldy	2	3	4
Substandard Development and Undeveloped	2	5	8
	Appearance or edibility of product:		
Slightly discolored or damaged by fermentation or any other defect not described above	May not be affected.	May not be more than slightly affected.	May not be more than materially affected.
Grit, sand, or silt	None of any consequence may be present that affects the appearance or edibility of the product.		Not more than a trace may be present that affects the appearance or edibility of the product.

TYPE V—ZANTE CURRANT RAISINS

§ 52.1856 Sizes of zante currant raisins.

Size designations are not applicable to Zante Currant Raisins.

§ 52.1857 Grades of zante currant raisins.

(a) "U.S. Grade A" is the quality of Zante Currant Raisins that have similar varietal characteristics; that have a good typical color; that have a good characteristic flavor; that show development characteristics of raisins prepared from well-matured grapes; that have not less than 75 percent, by weight, of raisins that are well-matured or reasonably well matured; that contain not more than 20 percent, by weight, of moisture; and meet the additional requirements as outlined in Table V of this subpart.

(b) "U.S. Grade B" is the quality of Zante Currant Raisins that have similar varietal characteristics; that have a reasonably good typical color; that have a good characteristic flavor; that have development characteristics of raisins prepared from reasonably well-matured and/or fairly well matured grapes; that contain not more than 20 percent, by weight, of moisture; and meet the additional requirements as outlined in Table V of this subpart.

(c) "Substandard" is the quality of Zante Currant Raisins that fail to meet the requirements of U.S. Grade B.

TABLE V - ALLOWANCES FOR DEFECTS IN ZANTE CURRANT RAISINS

Defects	U.S. Grade A	U.S. Grade B
	Maximum count	
Pieces of stem	1 per 24 ounces	1 per 16 ounces
Seeds (in Seeded style)	12 per 16 ounces	15 per 16 ounces
	Maximum (percent by weight)	
Capstems - Zantes with capstems and loose capstems (include one Zante with each loose capstem)	1-1/2	2
Sugared	5	10
Discolored, damaged, or moldy	5	7
Provided these limits are not exceeded:		
Damaged	2	3
Moldy	3	4
Substandard Development and Undeveloped	2	5
	Appearance or edibility of product:	
Slightly discolored or damaged by fermentation or any other defect not described above	May not be affected.	May not be more than slightly affected.
Grit, sand, or silt	None of any consequence may be present that affects the appearance or edibility of the product.	

TYPE VI—MIXED TYPES OF RAISINS

§ 52.1858 Grades of mixed types or varieties of raisins.

The grade of a lot of mixed types of processed raisins shall be the lower (or lowest) grade of any varietal type in the mixture based on the respective requirements for each type, except for moisture, in accordance with this subpart. Mixed types of processed raisins of U.S. Grade A, U.S. Grade B, or U.S. Grade C may contain not more than 18 percent, by weight, of moisture. Mixed types of processed raisins that as a mixture exceed 18 percent, by weight, of moisture are "Substandard."

Dated: August 11, 1976.

WILLIAM T. MANLEY,
Acting Administrator.

[FR Doc.76-23942 Filed 8-16-76;8:45 am]

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

[Amdt. 25]

PART 220—SCHOOL BREAKFAST PROGRAM

Child Nutrition Programs

On February 17, 1976, there was published in the FEDERAL REGISTER (41 F.R. 7138) a proposed amendment to the regulations governing the School Breakfast Program. The purpose of the proposed amendment was the implementation of Public Law 94-105, and to make other administrative changes.

Inasmuch as the proposed Breakfast regulations paralleled the changes in the National School Lunch Program resulting from Public Law 94-105, only fourteen respondents commented on the Breakfast regulations. All of the comments received have been carefully considered. The most substantive comments and recommendations affecting portions of the proposed regulations, together with the resulting changes in the proposal or reasons for not accepting the suggestions, are discussed below.

Five of the fourteen respondents opposed the limitation of Federal reimbursement to one breakfast per child per day. However, inasmuch as this regulation reflects the philosophy of the Department in school nutrition programs and the proposed concept as presented in the lunch program regulations was found to be objectionable to a considerable number of respondents, the Department is issuing regulations which are consistent with its philosophy limiting Federal reimbursement to one breakfast per child per day, but which also will reflect a practical approach to situations in which breakfasts have been prepared in excess of one breakfast per child. This approach will acknowledge fluctuations in participation brought about by sickness, absenteeism, and other factors. The regulations will require that School Food Authorities plan and prepare breakfasts in accordance with participation trends, with the objective of providing one breakfast per child per day. School Food Authorities must maintain records which will demonstrate positive action toward this objective. However, in order to allow some latitude where excessive breakfasts are prepared, yet remain consistent with the Department's philosophy and the intent of Congress to reduce food waste, reimbursement will be allowed for more than one breakfast per child where it can be demonstrated by School Food Authorities that breakfasts were planned on the basis of one breakfast per child per day. However, reimbursement cannot be claimed for free and reduced price breakfasts in excess of the number of children approved for free and reduced price meals.

Resultant of comments received from the general public, changes to the infant breakfast pattern were made which increase flexibility and strengthen nutritional integrity.

Some respondents suggested that all milk should be fortified with vitamins A and D. The Department has decided to encourage the fortification of milk with vitamins A and D, according to the Food and Drug Administration's Standards of Identity and consistent with State and local standards for such milk.

Three respondents objected to not allowing milk as a substitute for iron-fortified formula for children less than eight months of age. The Department is not authorizing this substitution because milk contains insufficient iron to provide the levels recommended by the National Research Council, National Academy of Sciences.

Eight respondents submitted comments regarding the nutritional integrity of the meal requirements for children over one year of age. The Department, recognizing this necessity, has initiated a thorough review of the Breakfast Program. Any revised meal patterns which meet minimum nutritional requirements based on tested nutritional research will be published as proposed regulations consistent with the public rule making process.

Several nonsubstantive changes have been made for the purpose of clarification and consistent treatment of similar provisions.

Accordingly, this part is amended as set forth below:

1. The title of Part 220 is revised to read "School Breakfast Program". The Nonfood Assistance Program and State Administrative Expenses regulations are being reissued as Parts 230 and 235, respectively.

2. § 220.11a is redesignated as § 220.12, § 220.24 through § 220.26a are redesignated as § 220.13 through § 220.16, and § 220.27 and § 220.28 are redesignated as § 220.17 and § 220.18 respectively, a new

§ 220.19 and § 220.20 are added, and § 220.29 is designated as § 220.21.

3. The Table of Contents is revised to read as follows:

Sec.
220.1 General purpose and scope.
220.2 Definitions.
220.3 Administration.
220.4 Payment of funds to States and FNSROs.
220.5 Method of payment to States.
220.6 Use of funds by State agencies.
220.7 Requirements for school participation.
220.8 Requirements for breakfast.
220.9 Reimbursement payments.
220.10 Effective date for reimbursement.
220.11 Reimbursement procedure.
220.12 Competitive food services.
220.13 Special responsibilities of State agencies.
220.14 Claims against School Food Authorities.
220.15 Management evaluations and audits.
220.16 Procurement standards.
220.17 Prohibitions.
220.18 Other provisions.
220.19 Free and reduced price breakfasts.
220.20 Grant closeout procedures.
220.21 Program information.

AUTHORITY: Secs. 4 and 10, 80 Stat. 866, 889 (42 U.S.C. 1773, 1779).

4. § 220.1 is revised to read as follows:

§ 220.1 General purpose and scope.

This part announces the policies and prescribes the regulations necessary to carry out the provisions of section 4 of the Child Nutrition Act of 1966, as amended, which authorizes payments to the States to assist them to initiate, maintain, or expand nonprofit breakfast programs in schools.

5. § 220.2 is revised to read as follows:

§ 220.2 Definitions.

For the purpose of this part the term:

(a) "Act" means the Child Nutrition Act of 1966, as amended.

(b) "Breakfast" means a meal served to a school child at the beginning of the child's day at the school, which meets the nutritional requirements set out in this part.

(c) "Child" means a person under 21 chronological years of age in schools as defined in § 220.2(u) (2) and (3) or a student of high school grade or under as determined by the State educational agency in schools as defined in § 220.2 (u) (1).

(d) "CND" means the Child Nutrition Division of the Food and Nutrition Service of the Department.

(e) "Department" means the U.S. Department of Agriculture.

(f) "Distributing agency" means a State, Federal, or private agency which enters into an agreement with the Department for the distribution of commodities pursuant to Part 250 of this chapter.

(g) "Fiscal year" means the period of 15 calendar months beginning July 1, 1976, and ending September 30, 1977; and the period of 12 calendar months beginning October 1, 1977, and each October 1 of any calendar year thereafter and ending September 30 of the following calendar year.

(h) "FNS" means the Food and Nutrition Service of the Department.

(i) "FNSRO" means the appropriate Food and Nutrition Service Regional Office of the Food and Nutrition Service of the Department.

(j) "Free breakfast" means a breakfast for which neither the child nor any member of his family pays or is required to work in the school or in the school's food service.

(k) "Infant cereal" means any iron fortified dry cereal especially formulated and generally recognized as cereal for infants that is routinely mixed with formula or milk prior to consumption.

(l) "Infant formula" means any iron-fortified infant formula intended for dietary use solely as a food for normal healthy infants excluding those formulas specifically formulated for infants with inborn errors of metabolism or digestive or absorptive problems. Infant formula, as served, must be in liquid state at recommended dilution.

(m) "Long-term care facility" means any hospital, skilled nursing facility, intermediate care facility, or distinct part thereof, which is intended for the care of children confined for 30 days or more.

(n) "Milk" means pasteurized fluid types of unflavored or flavored whole milk, lowfat milk, skim milk, or cultured buttermilk which meet State and local standards for such milk except that, in the meal pattern for infants (0 to 1 year of age) milk means unflavored types of whole fluid milk or an equivalent quantity of reconstituted evaporated milk which meet such standards. In Alaska, Hawaii, American Samoa, Guam, Puerto Rico, the Trust Territory of the Pacific Islands, and the Virgin Islands, if a sufficient supply of such types of fluid milk cannot be obtained, "milk" shall include reconstituted or recombined milk. All milk should contain vitamins A and D at levels specified by the Food and Drug Administration and consistent with State and local standards for such milk.

(o) "National School Lunch Program" means the Program authorized by the National School Lunch Act.

(p) "Nonprofit" means exempt from income tax under Section 501(c)(3) of the Internal Revenue Code of 1954 as amended; or, in the Commonwealth of Puerto Rico, certified as nonprofit by its Governor.

(q) "OA" means the Office of Audit of the Department.

(q–1) "OI" means the Office of Investigation of the Department.

(r) "Program" means the School Breakfast Program.

(s) "Reduced price breakfast" means a breakfast which meets all of the following criteria: (1) The price shall be less than the full price of the breakfast, (2) the price shall be 10 cents or lower, and (3) neither the child nor any member of his family shall be required to supply an equivalent value in work for the school or the school's food service.

(t) "Reimbursement" means financial assistance paid or payable to participating schools for breakfasts meeting the requirements of § 220.8 served to eligible children at rates assigned by the State agency, or FNSRO where applicable. The term "reimbursement" also includes financial assistance made available through advances to School Food Authorities.

(u) "School" means (1) An educational unit of high school grade or under operating under public or nonprofit private ownership in a single building or complex of buildings. The term "high school grade or under" includes classes of preprimary grade when they are conducted in a school having classes of primary or higher grade, or when they are recognized as a part of the educational system in the State, regardless of whether such preprimary grade classes are conducted in a school having classes of primary or higher grade. (2) With the exception of residential summer camps which participate in the Summer Food Service Program for Children and private foster homes, any distinct part of a public or nonprofit private institution or any public or nonprofit child care institution, which (i) maintains children in residence, (ii) operates principally for the care of children, and (iii) if private, is licensed to provide residential child care services under the appropriate licensing code by the State or a subordinate level of government. The term "child care institution" includes, but is not limited to: homes for the mentally retarded, the emotionally disturbed, the physically handicapped, and unmarried mothers and their infants; group homes; halfway houses; orphanages; temporary shelters for abused children and for runaway children; long-term care facilities for chronically ill children; and juvenile detention centers. (3) With respect to the Commonwealth of Puerto Rico, nonprofit child care centers certified as such by the Governor of Puerto Rico.

(v) "School Breakfast Program" means the program authorized by section 4 of the Child Nutrition Act of 1966.

(w) "School Food Authority" means the governing body which is responsible for the administration of one or more schools and which has legal authority to operate a breakfast program therein.

(x) "Secretary" means the Secretary of Agriculture.

(y) "State" means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

(z) "State agency" means (1) the State educational agency or (2) such other agency of the State as has been designated by the Governor or other appropriate executive or legislative authority of the State and approved by the Department to administer the Program in schools as defined in § 220.2(u)(2) of this section.

(z–1) "State educational agency" means, as the State legislature may determine, (1) the chief State school officer (such as the State Superintendent of Public Instruction, Commissioner of Education, or similar officer), or (2) a board of education controlling the State department of education.

6. § 220.3 is revised to read as follows:

§ 220.3 Administration.

(a) Within the Department, FNS shall act on behalf of the Department in the administration of the Program covered by this Part. Within FNS, CND shall be responsible for administration of the Program.

(b) Within the States, responsibility for the administration of the Program in schools as defined in § 220.2 (u) (1) and (u) (3) shall be in the State educational agency, except that FNSRO shall administer the Program with respect to nonprofit private schools as defined in § 220.2(u) (1) of any State wherein the State educational agency is not permitted by law to disburse Federal funds paid to it under the Act to such schools.

(c) Within the States, responsibility for the administration of the Program in schools as defined in § 220.2(u) (2) shall be in the State educational agency, or if the State educational agency cannot administer the Program in such schools, such other agency of the State as has been designated by the Governor or other appropriate executive or legislative authority of the State and approved by the Department to administer the Program in such schools: *Provided, however,* That FNSRO shall administer the Program in such schools if the State agency is not permitted by law to disburse Federal funds paid to it under the Act to such schools.

(d) References in this part to "FNSRO where applicable" are to FNSRO as the agency administering the Program.

(e) Each State agency desiring to take part in any of the programs shall enter into a written agreement with the Department for the administration of the Program in the State in accordance with the provisions of this Part. Such agreement shall cover the operation of the Program during the period specified therein and may be extended at the option of the Department.

7. § 220.5 is revised to read as follows:

§ 220.5 Method of payment to States.

Funds to be paid to any State for the School Breakfast Program shall be made available by means of Letters of Credit issued by FNS in favor of the State agency. The State agency shall: (a) Obtain funds needed for reimbursement to School Food Authorities through presentation by designated State officials of a payment Voucher on Letter of Credit in accordance with procedures prescribed by FNS and approved by the U.S. Treasury Department; (b) submit requests for funds only at such times and in such amounts, as will permit prompt payment of claims or authorized advances; and (c) use the funds received from such requests without delay for the purpose for which drawn.

8. In § 220.7, paragraph (f) is deleted and the first sentence of paragraph (d) is revised to read as follows:

§ 220.7 Requirements for participation.

* * * * *

(d) Any School Food Authority may employ a food service management company (or other nonprofit agency or nonprofit organization) in the conduct of its feeding operations, in one or more of its schools. * * *

* * * * *

9. § 220.8 is revised to read as follows:

§ 220.8 Requirements for breakfast.

(a) (1) Except as otherwise provided in this section, and in any appendix to this part a breakfast eligible for Federal cash reimbursement shall contain, as a minimum, the following food components in the amounts indicated:

(i) One-half pint of fluid milk served as a beverage or on cereal or used in part for each purpose.

(ii) A one-half cup serving of fruit or full-strength fruit or vegetable juice.

(iii) One slice of whole-grain or enriched bread, or an equivalent serving of cornbread, biscuits, rolls, muffins, etc., made of whole-grain or enriched meal or flour, or three-fourths cup (volume) or one ounce (weight), whichever is less of whole-grain cereal or enriched or fortified cereal, or an equivalent quantity of any combination of any of these foods.

(2) To improve the nutrition of the participating children over 1 year of age, breakfasts shall also include as often as practicable meat or meat alternates such as a one ounce serving (edible portion as served) of meat, poultry, or fish; or one ounce of cheese; or one egg; or two tablespoons of peanut butter; or an equivalent quantity of any combination of any of these foods.

(b) (1) This paragraph, in subdivision (2), sets forth the requirements for breakfasts eligible for Federal cash reimbursement which are designed to provide nutritious breakfasts for infants aged up to 1 year, and in subdivision (3) for children aged 1 to 6 years.

(2) When infants aged up to 1 year participate in the Program an infant breakfast shall be offered. Foods within the infant breakfast pattern shall be of texture and consistency appropriate for the particular age group being served. The amount of food in the breakfast may be offered to the infant during a span of time consistent with the infant's eating habits. The infant breakfast pattern shall contain, as a minimum, each of the following components in the amounts indicated for the appropriate age groups:

(i) 0 to 4 months—four to six fluid ounces of infant formula; and zero to one tablespoon of infant cereal.

(ii) 4 to 8 months—six to eight fluid ounces of infant formula; and one to three tablespoons of infant cereal.

(iii) 8 months to 1 year—six to eight fluid ounces of infant formula, or six to eight fluid ounces of whole fluid milk and zero to three fluid ounces of full-strength fruit juice; and two to four tablespoons of infant cereal.

(3) When children aged 1 year to 6 years participate in the Program, a preschool breakfast shall be offered, which shall contain, as a minimum, each of the following food components in the amounts indicated for the appropriate age group

(i) 1 to 3 years—one-half cup of fluid milk served as a beverage or on cereal or used in part for each purpose; and a one-fourth cup serving of fruit or full-strength fruit or vegetable juice; and one-half slice of whole-grain or enriched bread, or an equivalent serving of cornbread, biscuits, rolls, muffins, etc., made of whole-grain or enriched meal or flour, or one-quarter cup (volume) or one-third ounce (weight), whichever is less, of whole-grain cereal or enriched or fortified cereal or an equivalent quantity of any combination of any of these foods.

(ii) 3 to 6 years—three-fourths cup of fluid milk served as a beverage or on cereal or used in part for each purpose; and a one-half cup serving of fruit or full-strength fruit or vegetable juice; and one-half slice of whole-grain or enriched bread, or an equivalent serving of cornbread, biscuits, rolls, muffins, etc., made of whole-grain or enriched meal or flour, or one-third cup (volume) or one-half ounce (weight) whichever is less, of whole-grain cereal or enriched or fortified cereal or an equivalent quantity of any combination of any of these foods.

(c) Additional foods may be served with breakfasts as desired to participating children over 1 year of age.

(d) If emergency conditions prevent a school normally having a supply of milk from temporarily obtaining delivery thereof, the State agency, or FNSRO where applicable, may approve reimbursement for breakfast served without milk during the emergency period.

(e) FNS may approve variations in the food components of the breakfast on an experimental or on a continuing basis in any school where there is evidence that such variations are nutritionally sound and are necessary to meet ethnic, religious, economic or physical needs.

(f) Substitutions may be made in foods listed in paragraphs (a) and (b) of this section if individual participating children are unable, because of medical or other special dietary needs, to consume such foods. Such substitutions shall be made only when supported by a statement from a recognized medical authority which includes recommended alternate foods.

(g) The inability of a school to obtain a supply of milk on a continuing basis to meet the breakfast requirements in paragraphs (a) and (b) of this section shall not bar it from participation in the Program. In such cases the State agency, or FNSRO were applicable, may approve the service of breakfasts without milk: *Provided, however,* That an equivalent amount of canned, whole dry, or nonfat dry milk is used in the preparation of the components of the breakfast patterns listed in (a) (1) and (b) (3) of this section.

(h) For the period ending September 30, 1977, the Secretary, with the concurrence of officials of the Trust Territory of the Pacific Islands, shall establish a breakfast pattern or patterns which are consonant with local food consumption patterns and which, given available food supplies and food service equipment and facilities, provide optimum nutrition consistent with sound dietary habits for participating children, for use in the Trust Territory in lieu of the breakfast patterns listed in paragraphs (a) and (b) of this section. The requirements for such patterns shall be attached to and made a part of the written agreement required under § 220.3 of this part.

10. In § 220.9, paragraph (a) is revised to read as follows:

§ 220.9 Reimbursement payments.

(a) State agencies, or FNSROs where applicable, shall make reimbursement payments to schools only in connnection with breakfasts meeting the requirements of § 220.8. School Food Authorities shall plan for and prepare breakfasts on the basis of participation trends, with the objective of providing one breakfast per child per day. Production and participation records shall be maintained to demonstrate positive action toward this objective. In recognition of the fluctuation in participation levels which makes it difficult to precisely estimate the number of breakfasts needed and to reduce the resultant waste, any excess breakfasts that are prepared may be served to eligible children and may be claimed for reimbursement unless the State agency, or FNSRO where applicable, determines that the School Food Authority has failed to plan and prepare breakfasts with the objective of providing one breakfast per child per day. In no event shall the School Food Authority claim reimbursement for free and reduced price breakfasts in excess of the number of children approved for free and reduced price meals.

* * * * *

§ 220.11 [Amended]

11. In § 220.11, paragraph (b), the words "§ 220.24(b)" and changed to read "§ 220.13(b)".

§ 220.14 [Amended]

12. In redesignated § 220.14, paragraph (h) is amended to delete the words "other than paragraph (a)(1) thereof" and to insert the words "(a)(1), (b)(2), and (b)(3)" in lieu thereof.

13. In redesignated § 220.15, paragraph (b), the words "§ 220.26(a)" are changed to read "§ 220.15(a)", and the first sentence of paragraph (f) is revised to read as follows:

§ 220.15 Management evaluations and audits.

* * * * *

(f) In making management evaluations or audits for any fiscal year, the State agency, FNS, or OA may disregard any overpayment which does not exceed $35 or, in the case of State agency administered programs, does not exceed the amount established under State law, regulations, or procedure as a minimum amount for which claim will be made for State losses generally. * * *

14. In redesignated § 220.16, the words "or School Food Authority", "or School Food Authority's" and "or School Food Authorities" are deleted wherever they appear, and paragraph (a) is revised to read as follows:

§ 220.16 Procurement standards.

(a) *General purpose and scope.* This section provides standards for use by State agencies in establishing procedures for the procurement of supplies, equipment, and other services with Program funds. These standards are furnished to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal law and Executive Orders. State agencies may use their own procurement regulations which reflect applicable State and local law, rules, and regulations, provided that procurements made with Program funds adhere to the standards set forth in this section.

* * * * *

§ 220.17 [Amended]

15. In redesignated § 220.17, paragraph (a) is amended to delete the words "either program" and to insert the words "the Program" in lieu thereof.

§ 220.18 [Amended]

16. In redesignated § 220.18, paragraph (a) is amended to delete the words "either program" and the words "that program" and to insert the words "the Program" in lieu thereof; paragraph (b) is deleted; paragraph (c) is amended to delete the words "either program" and to insert the words "the program" in lieu thereof.

17. § 220.19 is added to read as follows:

§ 220.19 Free and reduced price breakfasts.

The determination of the children to whom free and reduced price breakfasts are to be served because of inability to pay the full price thereof, and the serving of the breakfasts to such children, shall be effected in accordance with Part 245 of this chapter.

18. § 220.20 is added to read as follows:

§ 220.20 Grant closeout procedures.

(a) Grant closeout procedures for the Program shall be in accordance with Attachment L of Federal Management Circular 74-7 (34 CFR Part 256).

(b) FNS may terminate a State agency's participation in the Program in whole, or in part, whenever it is determined that the State agency has failed to comply with the conditions of the Program. FNS shall promptly notify the State agency in writing of the termination and the reasons for the termination, together with the effective date. A State agency or FNSRO where applicable, shall terminate a school's participation in the Program by written notice whenever it is determined by FNS or the State agency that the school has failed to comply with the conditions of the Program. When participation in the Program has been terminated for cause, any payments made to the State agency or any recoveries by FNS from the State agency or a school shall be in accordance with the legal rights and liabilities of the parties.

(c) FNS or the State agency may terminate the State agency's participation in the Program in whole, or in part, when both parties agree that the continuation of the Program would not produce beneficial results commensurate with the further expenditure of funds. The two parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated. The State agency shall not incur new obligations for the terminated portion after the effective date, and shall cancel as many outstanding obligations as possible. FNS shall allow full credit to the State agency for the Federal share of the noncancellable obligations, properly incurred by the State agency prior to termination. A State agency, or FNSRO where applicable, may terminate a school's participation in accordance with these provisions.

§ 220.21 [Amended]

19. In redesignated § 220.21, the words "these programs" are deleted and the words "the Program" are inserted in lieu thereof.

NOTE: The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.

Effective date: This amendment shall become effective on July 1, 1976.

Dated: August 13, 1976.

RICHARD L. FELTNER,
Assistant Secretary.

[FR Doc.76-24227 Filed 8-16-76;8:45 am]

SUBCHAPTER C—FOOD STAMP PROGRAM

[Amdt. No. 90]

PART 271—PARTICIPATION OF STATE AGENCIES AND ELIGIBLE HOUSEHOLDS

Procedures for Exchange of Old Series Coupons and Eligibility and Certification of Supplemental Security Income Recipients

Pursuant to the authority contained in the Food Stamp Act of 1964, as amended (78 Stat. 703, as amended; 7 U.S.C. 2011-2026), regulations governing the operation of the Food Stamp Program are hereby amended. The sections on procedures for the exchange of old series food coupons for new series coupons and the eligibility and certification of Supplemental Security Income recipients currently provide for their expiration on June 30, 1976. Also, as of July 1, 1976, SSI recipients in three States, previously ineligible for food stamps because they received the food stamp bonus in the form of increased State supplemental payments, resume food stamp eligibility as these States lose their "cash-out" status. This amend-

ment revises these sections accordingly. Section 271.6(i) is amended to eliminate the June 30, 1976, expiration date, thereby extending indefinitely procedures for the exchange of the old series coupons to the new series coupons. When the new series coupons were introduced in March 1975, it was anticipated that all exchanges could be completed by June 30, 1976. However, requests for exchange are still being received.

Since old series coupons are obligations of the United States which may not have an expiration date, it is appropriate to remove the June 30 deadline and leave the exchange procedures in effect for as long as they are needed. In addition, this amendment gives the State agency the option of exchanging old series coupons at the local level or forwarding the coupons to FNS for exchange.

Section 271.10 is amended to extend through June 30, 1977, the provisions on the eligibility of SSI recipients, to redefine the States in which SSI recipients are ineligible due to having their food stamp bonus "cashed-out" by inclusion of that amount in their State supplemental payments, and to waive certain certification procedures in those States where SSI recipients will become eligible July 1, 1976.

Pub. L. 93–233 has been amended to extend the food stamp eligibility of all SSI recipients except those in "cash-out" States for one year o runtil such earlier date as Congress may make modifications relevant to the eligibility of SSI recipients. Therefore, § 271.10(a) is amended by revising the last sentence to extend the SSI eligibility provisions through June 30, 1977.

Sections 271.10(c) (1) and (2) are amended to reflect the determination by the Secretary of the Department of Health, Education, and Welfare that, as of July 1, 1976, only Massachusetts meets the qualification of Pub. L. 93–233 for a "cash-out" State. The previous "cash-out" status of Nevada was limited to the aged and blind. Thus, as of July 1, 1976, all categories of SSI recipients in New York and California, and aged and blind SSI recipients in Nevada are eligible for food stamp benefits. Handicapped SSI recipients in Nevada are not affected by the change in status and continue to be eligible. To assist affected SSI recipients in these States in making the transition to the Food Stamp Program, the State agency will, subject to FNS approval, be given the option of waiving the interview and the completion of the standard application form for certain households containing SSI recipients. The waivers will be permitted during the three months immediately following the approval by FNS of the State agency's request for waiver authority, when application processing will be the heaviest. An interview and standard application form will be required within the six month period immediately following the date of the FNS approval of the State agency's request for waiver authority. These options are provided for in § 271.10(c) (2) (iii).

It is the policy of the Department that the public be given the opportunity to comment on regulatory changes before issuance. However, because of the need for timely implementation of all aspects of this amendment, and since the amendment relating to SSI recipients reflects statutory obligations and a determination of the Secretary of Health, Education, and Welfare pursuant thereto, it is determined to be contrary to the public interest to give notice of proposed rulemaking with respect to these amendments.

Because the Department feels that the public should have an opportunity to comment on these amendments, comments are solicited through September16, 1976. Written comments suggestions, or objections should be submitted to Nancy Snyder, Director, Food Stamp Division, Food and Nutrition Service, United States Department of Agriculture, Washington, D.C. 20250. Amendments to or revisions in this amendment will be made if, after due consideration of comments, suggestions or objections received, it is determined that such revisions or amendments are necessary or appropriate.

Accordingly, Part 271 of Chapter II, Title 7 of the Code of Federal Regulations is hereby amended as follows:

(1) In § 271.6, paragraph (i) is revised to read:

§ 271.6 Methods of distributing, issuing and accounting for coupons and receipts.

* * * * *

(i) Households were permitted to use old series 50-cent, 2-dollar, and 5-dollar coupons to purchase eligible food at authorized retail food stores and meal services until August 31, 1975. After August 31, 1975, households shall be entitled to a dollar for dollar exchange of old series coupons for new series coupons except that when only a 50-cent coupon is offered for exchange or the coupons offered include an odd number of 50-cent coupons, a new series 1-dollar coupon will be given for the odd 50-cent coupon. Households in possession of old series coupons shall submit the coupons and a request for exchange to the State agency. State agencies may make direct exchange to claimants or request FNS to make the exchange in accordance with instructions provided by FNS.

* * * * *

(2) In § 271.10, paragraphs (a) and (c) (1) (i) are revised; (c) (1) (ii) is deleted and (c) (1) (iii) is amended and relettered (c) (1) (ii); and a new paragraph (c) (2) (iii) is added. The amended and new paragraphs read as follows:

§ 271.10 Eligibility and certification of supplemental security income recipients.

(a) Notwithstanding any other provisions of this subchapter, recipients of supplemental security income (SSI) payments shall be treated according to the provisions of this section for purposes of determining eligibility for and certification in the program. The provisions of this section will expire June 30, 1977, unless earlier rescinded or modified.

* * * * *

(c) *Food stamp eligibility of SSI recipients*—(1) *Ineligible SSI recipients.* (i) No SSI recipient shall be considered a household member or an elderly person for food stamp program purposes if he resides in the State of Massachusetts. The Secretary of Health, Education, and Welfare has determined, pursuant to the provisions of Pub. L. 93–233, as amended, that Massachusetts provides State supplementary payments which have been specifically increased to include the value of bonus food coupons. (ii) In Massachusetts, the income and resources of an SSI recipient who resides with eligible household members or elderly persons shall not be considered available to the household members or elderly persons (except as provided in paragraph (c) (3) (ii) of this section), nor shall his presence be considered in determining the household coupon allotment and purchase requirement. In such instances any payment for deductible expense made on behalf of the household by the ineligible SSI recipient shall not be counted as income to the household nor shall the household be allowed a deduction for such expense. If deductible household expenses are shared among household members and an ineligible SSI recipient, the household shall be granted a deduction based on that proportion of the expense which is actually borne by the household.

(2) *Eligible SST recipients.* * * *

(iii) Effective July 1, 1976, California, Nevada (applies to aged and blind only), and New York will no longer be considered "cash-out" States. With prior approval from FNS, State agencies in such States, may, as provided in (A) and (B) of this subdivision, elect to waive the standard nonassistance application for and the interview requirement for certain households containing SSI recipients during the three month period immediately following the approval by FNS of the State agency's request for waiver authority. With respect to Nevada, this waiver authority applies only to the aged and the blind.

(A) The State agency may use an abbreviated application form approved by FNS for households consisting of SSI recipients, or SSI and non-SSI recipients, provided that verification of the income of SSI recipients is readily available from information supplied by the Social Security Administration. The form shall be used to determine if a group containing both SSI recipients and non-SSI recipients is a single household or qualifies as separate households. If such a group is a single household, and the non-SSI recipients are not already participating in the Food Stamp Program or receiving public or general assistance, a standard application and an interview shall be required. Households consisting solely of SSI recipients, essential persons or non-SSI recipients already receiving food stamps or public or general assistance may be certified with the abbreviated application form. The abbreviated applica-

tion form shall also contain other nonfinancial food stamp eligibility criteria, deductions, and the attestation statement from the standard nonassistance application which the head of the household must sign. All households initially certified on the basis of an abbreviated application form must complete the standard nonassistance application or affidavit and interview process within the six month period immediately following the approval by FNS of the State agency's request for waiver authority.

(B) The State agency may waive the interview requirement under the same conditions listed in (A) of this subdivision for waiver of the standard application form. State agencies electing to waive the interview requirement and/or the standard application form may do so for all households eligible for the waiver or on an individual case basis. If the waiver is elected on an individual case basis, the following factors must be considered in determining if a household should be certified without an interview or a standard application form: (*1*) Accessibility of information on potential eligibles; (*2*) the accuracy and currentness of the information from existing case records within the local welfare office; (*3*) the difficulty in scheduling an interview with the household; and (*4*) the stability of the individual household's situation.

* * * * *

(78 Stat. 703, as amended; (7 U.S.C. 2011–2026))

Effective date. This amendment shall become effective July 1, 1976.

(Catalog of Federal Domestic Assistance Programs No. 10,551 National Archives Reference Services)

Dated: August 9, 1976.

RICHARD L. FELTNER,
Assistant Secretary.

[FR Doc.76-24051 Filed 8-16-76;8:45 am]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Pear Reg. 6, Amdt. 1]

PART 917—FRESH PEARS, PLUMS, AND PEACHES GROWN IN CALIFORNIA

Grade and Size Requirements

This amended regulation, issued under the amended marketing agreement and Order No. 917 (7 CFR Part 917), continues the currently effective grade and size requirements on the handling of California Bartlett, Max-Red Bartlett, and Red Bartlett variety pears through July 31, 1977. Unless amended, that regulation would expire on August 20, 1976. The regulation requires that such pears grade at least U.S. Combination, with not less than 80 percent grading at least U.S. No. 1 grade. It also requires that pears be not smaller than size 165 as verified by 12-pound random samples which must contain not more than 43 pears. Containers of all pears must be marked with the name of the variety or, if the variety is not known, the words "unknown variety." This regulation is necessary to assure the shipment of only those pears which will be of suitable quality and size in the interest of consumers and producers. The marketing agreement and Order No. 917, as amended (7 CFR Part 917; 41 FR 17529), are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674).

Notice was published in the FEDERAL REGISTER issue of July 21, 1976 (41 FR 30027), that this Department was giving consideration to a proposal to amend § 917.440 (Pear Regulation 6; 41 FR 28287) effective under the marketing agreement and Order No. 917, as amended (7 CFR Part 917; 41 FR 17528), which regulate the handling of fresh pears, plums, and peaches grown in California. Under that proposal the amended regulation would continue to be effective, without change, on all shipments of fresh California pears of the Bartlett, Max-Red Bartlett, and Red Bartlett varieties during the 1976 season. The notice invited interested persons to submit written data, views, or arguments, through Augut 6, 1976, for consideration relative to the proposed extension. No such material was submitted.

After consideration of all relevant matter presented, including the proposal set forth in the aforesaid notice, the recommendations and information submitted by the Pear Commodity Committee, established under the amended marketing agreement and order, and other available information, it is found that continuing through July 31, 1977, the currently effective grade and size requirements on the handling of such pears, as hereinafter provided, will tend to effectuate the declared policy of the act.

It is further found that good cause exists for not postponing the effective date of this amendment until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553) in that (1) shipments of pears are currently in progress and this amendment should be applicable to all such shipments occurring during the effective period specified herein in order to effectuate the declared policy of the act; (2) the amendment is the same as that specified in the notice to which no exceptions were filed; (3) the regulatory provisions are the same as those currently in effect; (4) compliance with this amended regulation will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time hereof; and (5) this regulation, as amended, was unanimously recommended by the Pear Commodity Committee members in an open meeting at which all interested persons were afforded an opportunity to submit their views.

Order. Paragraph (b) preceding subparagraph (1) thereof § 917.440 is amended to read as follows:

§ 917.440 Pear Regulation 6.

* * * * *

(b) During the period July 12, 1976, through July 31, 1977, no handler shall ship: * * *

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended; (7 U.S.C. 601–674).)

Dated: August 12, 1976.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.76-23943 Filed 8-16-76;8:45 am]

[Grapefruit Reg. 16—Amdt. 7]

PART 944—FRUITS; IMPORT REGULATIONS

Grade and Size Requirements for Imports of Grapefruit

This amendment increases grade and size requirements applicable to imported grapefruit during the period August 23 through September 26, 1976. The requirements are the same as those applicable to grapefruit produced in Florida and regulated pursuant to Marketing Order No. 905.

Notice was published in the FEDERAL REGISTER on July 12, 1976 (41 FR 28528), that consideration was being given to a proposal to amend Grapefruit Import Regulation 16 (§ 944.112; 40 FR 42529, 49787, 41 FR 15829, 18674, 19965, 23186, 24577), pursuant to Part 944—Fruits; Import Regulations (7 CFR Part 944). The notice provided that all written data, views, or arguments in connection with the proposed amendment be submitted by August 4, 1976. None were received.

This amendment is consistent with Section 8e of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This section requires that whenever specified commodities, including grapefruit, are regulated under a federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality or maturity requirements as those in effect for the domestically produced commodity. This amendment fixes the same minimum grade and size requirements on imported grapefruit as are effective under Marketing Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida.

After consideration of all relevant matters presented, including the proposal set forth in the aforesaid notice, and other available information, it is hereby found that the grade and size requirements in effect pursuant to the said amended marketing agreement and order shall apply to grapefruit to be imported.

It is hereby further found that good cause exists for not postponing the effective time of the regulatory provisions of this amendment, as hereinafter set forth, beyond that hereinafter specified (5 U.S.C. 553) in that (a) the requirements of this import regulation are im-

posed pursuant to section 8e of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), which makes such requirements mandatory; (b) the grade and size requirements of this import regulation are the same as those being made applicable to domestic shipments of grapefruit grown in Florida under Grapefruit Regulation 76 (§ 905.563); (c) notice that such action was being considered was published in the July 12, 1976, issue of the FEDERAL REGISTER (41 FR 28528), and no objection to this regulation was received; (d) except for the later effective date of August 23, 1976, the provisions of this import regulation are the same as those contained in said notice; and (e) notice hereof in excess of three days, the minimum prescribed by said section 8e, is given with respect to this import regulation by prescribing an effective date of August 23, 1976.

Order. In § 944.112 (Grapefruit Regulation 16; 40 FR 42529, 49787; 41 FR 15829, 18674, 19965, 23186, 24577) the provisions of paragraph (a) are amended to read as follows:

§ 944.112 Grapefruit Regulation 16.

(a) During the period August 23, 1976, through September 26, 1976, the importation into the United States of any grapefruit is prohibited unless such grapefruit is inspected and meets the following requirements:

(1) Seeded grapefruit shall grade at least U.S. No. 1 and be of a size not smaller than $3^{12}/_{16}$ inches in diameter, except that a tolerance for seeded grapefruit smaller than such minimum size shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances, specified in § 51.761 of the United States Standards for Grades of Florida Grapefruit; and

(2) Seedless grapefruit shall grade at least Improved No. 2 and be of a size not smaller than $3^{9}/_{16}$ inches in diameter, except that a tolerance for seedless grapefruit smaller than such minimum size shall be permitted, which tolerance shall be applied in accordance with the provisions for the application of tolerances, specified in § 51.761 of the United States Standards for Grades of Florida Grapefruit. ("Improved No. 2" shall mean grapefruit grading at least U.S. No. 2 and also meeting the requirements of the U.S. No. 1 grade as to shape (form) and color.)

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended; (7 U.S.C. 601–674).)

Dated: August 11, 1976, to become effective August 23, 1976.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.76-23944 Filed 8-16-76;8:45 am]

proposed rules

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

DEPARTMENT OF DEFENSE

Department of the Army

[32 CFR Part 505]

[Army Reg. 340-21]

PRIVACY ACT OF 1974

Exemption Rules for Systems of Records

The Secretary of the Army proposes to amend § 505.9 of the adopted exemption rules for systems of records published in the FEDERAL REGISTER of November 28, 1975 (40 FR 55551) FR Doc 75-32158. Interested parties are invited to submit written comments, suggestions, or objections regarding the proposed amendments to The Adjutant General, Department of the Army, ATTN: DAAG-AMR-R, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20314 on or before September 16, 1976. All relevant material received will be considered. All written comments will be available for public inspection during normal business hours at the above address.

R. S. SEEBERG,
Lieutenant Colonel, U.S. Army, Acting Director, Admin Management.

MAURICE W. ROCHE,
Director, Correspondence and Directives OASD (Comptroller).

AUGUST 11, 1976.

PART 505—PERSONAL PRIVACY AND RIGHTS OF INDIVIDUALS REGARDING THEIR PERSONAL RECORDS

§ 505.9 Exemption rules for Army systems of records. [Amended]

1. The following exemption rules are amended:

a. So much of exemption rule ID-AO224.05DAIG, SYSNAME - Inspector General Complaint Files (40 FR 55573) is amended to read ID-AO224.05aDAIG.

b. So much of exemption rule ID-AO225.01.1DAPE, SYSNAME—Military Police Management Information System (MPMIS): Vehicle Registration System (VRS) and Correctional Reporting System (CRS) portions only (40 FR 55573) is amended to read ID—AO225.01aDAIG, SYSNAME-Vehicle Registration System (VRS) and Correctional Reporting System (CRS).

c. So much of example rule ID-AO501.08USACIDC, SYSNAME-Informant Register (40 FR 55574) is amended to read ID-AO501.08e USACIDC.

d. So much of exemption rule ID-AO501.08bDAMI, SYSNAME-Interception of Wire and Oral Communications Quarterly Reports and Motions for Discovery (40 FR 55573) is amended to read as follows:

SYSNAME—Technical Surveillance Index.

Exemption—So much of the exemption as reads: "* * * (k) (1), (2) and (5)" is amended to read: "* * *(k)(1), (2) or (5)"; and adds "(c)(3)" before ",d(" and "(e)(1)" before the remainder of the sentence.

Reasons—Delete from the second sentence on beginning with: "Files will contain * * *" and substitute the following: "Disclosure of documents or the disclosure accounting record may compromise the effectiveness of the operation, and negate specialized techniques used to support intelligence or criminal investigative programs, or otherwise interfere with the orderly conduct of intelligence operations or criminal investigations."

The complete revised exemption rule, as amended now reads as follows:

EXEMPTED RECORD SYSTEM

(SPECIFICATION EXEMPTIONS)

ID-A0501.08bDAMI.
SYSNAME—Technical Surveillance Index.
Exemption—All portions of this system of records which fall within 5 U.S.C. 552(k)(1), (2) or (5) are exempt from the following provisions of Title 5 U.S.C. section 552a: (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I).
Authority—5 U.S.C. 552a(k)(1), (2) or (5).
Reasons—The material contained in this record system contains data concerning sensitive sources and operational methods whose dissemination must be strictly controlled because of national security intelligence considerations. Disclosure of documents or the disclosure accounting record may compromise the effectiveness of the operation, and negate specialized techniques used to support intelligence or criminal investigative programs, or otherwise interfere with the orderly conduct of intelligence operations or criminal investigations.

e. So much of exemption rule ID-A0502.10DAMI, SYSNAME — United States Army Intelligence Agency (USAINTA) Investigative File System (40 FR 55575) is amended to read:

ID-A0502.10aDAMI, SYSNAME-USAINTA Investigative File System.

f. So much of exemption rule ID-A0503.06DAMI, SYSNAME-Counterintelligence Operations File (40 FR 55576) is amended to read: ID-A0503.06aDAMI.

g. So much of exemption rule ID-A0508.07USACIDC, SYSNAME-Criminal Investigation Accreditation Files (40 FR 55576) is amended to read: ID-A0508.07a USACIDC.

h. So much of exemption rule ID-A0508.11USACIDC, SYSNAME-Criminal Investigation Case Files, Crime Laboratory Reporting Files, and Indices Thereto (40 FR 55577) is amended to read: ID-A0508.11aUSACIDC, SYSNAME-Criminal Investigation and Crime Laboratory Files.

i. So much of exemption rule ID-A0508.24DAPE, SYSNAME-Serious Incident Reporting Files (40 FR 55577) is amended to read: ID-A0508.24aDAPE.

j. So much of exemption rule ID-A0509.09DAPE, SYSNAME-Traffic Law Enforcement Files (40 FR 55578) is amended to read: ID-A0509.09aDAPE.

k. So much of exemption rule ID-A0509.18DAPE, SYSNAME-Expelled or Barred Person Files (40 FR 55578) is amended to read: ID-A0509.18bDAPE.

l. So much of exemption rule ID-A0721.11DAPE, SYSNAME-Individual Correctional Treatment Files (40 55579) is amended to read: ID-A0721.11aDAPE.

2. The following exemption rules are added:

a. Insert before exemption rule ID-A0202.08DAAG, SYSNAME-Request for Information Files (40 FR 55572):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-AO201.08cOSA.
SYSNAME—Central Files, Office Secretary of the Army (SAAA).
Exemption—All portions of this system of records which fall within 5 U.S.C. 552a (k)(1) through (7) are exempted from the following provisions of Title 5 U.S.C. section 552a: (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (f).
Authority—5 U.S.C. 552a(k)(1), (2), (3), (4), (5), (6), and (7).
Reasons—This system contains documents pertaining to any function or subject which may require involvement of the Department of the Army. Documents in this file are generated by other elements of the Army or are received from other agencies and individuals. Because of the broad scope of the contents of this file, and since the introduction of documents included there is largely unregulatable, the specific portions or documents in this system which may require an exemption cannot be predetermined. Therefore, and to the extent that such material is received and maintained, selected individual documents may be exempted from disclosures under any of the provisions of subsection (k)(1) through (7), Title 5 U.S.C. 552a.

b. Insert before exemption rule ID-AO508.07USACIDC, SYSNAME—Criminal Investigation Accreditation Files (40 FR 55576):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-AO506.01fDAMI.
SYSNAME—Security Clearance Information Files.
Exemption—All portion of this system which fall within 5 U.S.C. 552a(k)(1), (2) or (5) are exempt from the following provisions of Title 5 U.S.C. section 552a: (d), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f).
Authority—5 U.S.C. 552a(k)(1), (2) and (5).
Reasons—Material contained in this record which is properly and currently classified under the Executive Order 11652 includes

data concerning sensitive source and operational methods whose dissemination must be strictly controlled because of its relationship to national security intelligence considerations. Additionally, in the conduct of operations which produce these records, at times the methods and arrangements with our Allies pertinent to the conduct of intelligence operations are relevant to this issue of national security interests and must be safeguarded. Further, the disclosure of unclassified data within this record system is exempt only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of 5 U.S.C. 552a, under an implied promise that the identity of the source would be held in confidence. These assurances are essential to the purposes of these investigations. Confidence in the integrity of the Government's assurance must be maintained or the investigative process will be severely damaged. Exemption from access necessarily includes exemption from the other requirements.

c. Insert before exemption rule ID-A0508.16DAPE, SYSNAME—Absentee Case Files (40 FR 55577):

EXEMPTED RECORD SYSTEM

(GENERAL EXEMPTIONS)

ID-A0508.11bUSACIDC.

SYSNAME—Criminal Information Reports and Cross Index Card Files.

Exemption—All portions of this system of records which fall within 5 U.S.C. 552a(j)(2) are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5), (e)(8), (f), and (g). All portions of this system of records which fall within 5 U.S.C. 552a(k)(1) and (2) are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (d), (e)(4)(G), (e)(4)(H), and (f).

Authority—5 U.S.C. 552a(j)(2) and (k)(1) and (2).

Reasons—From subsection (c)(3) because the release of accounting of disclosures would place the subject of an investigation on notice that he is under investigation and provide him with significant information concerning coordinated investigative effort and techniques and the nature of the investigation, resulting in a serious impediment to criminal law enforcement activities or the compromise of properly classified material.

From subsection (c)(4), (d), (e)(4)(G), (e)(4)(H), (f), and (g) because access might compromise ongoing investigations, reveal investigatory techniques and the identity of confidential informants, and invade the privacy of persons who provide information in connection with a particular investigation. The exemption from access necessarily includes exemption from amendment, certain agency requirements, relating to access and amendment of records, and civil liability predicated upon agency compliance with those specific provisions of the Privacy Act. In addition, subsections (d)(e)(4)(G), (e)(4)(H) and (f) are necessary to protect the security of information properly classified in the interest of national and foreign policy.

From subsection (e)(1) because the nature of the criminal investigative function creates unique problems in prescribing specific perimeters in a partimular case what information is relevant or necessary. Also, due to close liaison and working relationships with other federal, state, local and foreign national law enforcement agencies, information may be received which may relate to a case then under the investigative jurisdiction of another government agency but it is necessary to maintain this information in order to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of both the CID and other agencies.

From subsection (e)(2) because collecting information from the subject of criminal investigations would thwart the investigative process by placing the subject of the investigation on notice thereof.

From subsection (e)(3) because supplying an individual with a form containing the information specified could result in the compromise of an investigation, tend to inhibit the cooperation of the individuals queried, and render ineffectual investigative techniques and methods utilized by USACIDC in the performance of their criminal law enforcement duties.

From subsection (e)(5) because this requirement would undly hamper the criminal investigative process due to the great volume of records maintained and the necessity for rapid information retrieval and dissemination. Also, in the collection of information for law enforcement purposes, it is impossible to determine what information is then accurate, relevant, timely and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light. In the criminal investigative process accuracy and relevance of information can only be determined in a court of law. The restrictions imposed by subsection (e)(5) would restrict the ability of trained investigators to exercise their judgment in reporting on investigations and impede the development of criminal intelligence necessary for effective law enforcement.

From subsection (e)(8) because the notice requirements of this provision could present a serious impediment to criminal law enforcement by revealing investigative techniques, procedures, and the existence of confidential investigations.

d. Insert before exemption rule ID-A0508.25bUSACIDC, SYSNAME-Index to Case Files—Republic of Vietnam CY70-CY73 (see below):

EXEMPTED RECORD SYSTEM

(GENERAL EXEMPTIONS)

ID-A0508.25aUSACIDC.

SYSNAME—Index to Criminal Investigative Case Files.

Exemption—All portions of this system of records which fall within 5 U.S.C. 552a(j)(2) are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5), (e)(8), (f), and (g). All portions of this system of records which fall within 5 U.S.C. 552a (k) (1) and (2) are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (d), (e)(4)(G), (e)(4)(H), and (f).

Authority—5 U.S.C. 552a(j)(2) and (k)(1) and (2).

Reasons—From subsection (c)(3) because the release of accounting of disclosures would place the subject of an investigation on notice that he is under investigation and provide him with significant information concerning coordinated investigative effort and techniques and the nature of the investigation, resulting in a serious impediment to criminal law enforcement activities or the compromise of properly classified material.

From subsection (c)(4), (d), (e)(4)(G), (e)(4)(H), (f), and (g) because access might compromise ongoing investigations, reveal investigatory techniques and the identity of confidential informants, and invade the privacy of persons who provide information in connection with a particular investigation. The exemption from access necessarily includes exemption from amendment, certain agency requirements relating to access and amendment of records, and civil liability predicated upon agency compliance with those specific provisions of the Privacy Act. In addition, subsections (d), (e) (4)(G), (e)(4)(H) and (f) are necessary to protect the security of information properly classified in the interest of national and foreign policy.

From subsection (e)(1) because the nature of the criminal investigative function creates unique problems in prescribing specific perimeters in a particular case what information is relevant or necessary. Also, due to close liaison and working relationships with other federal, state local and foreign national law enforcement agencies, information may be received which may relate to a case then under the investigative jurisdiction of another government agency but it is necessary to maintain this information in order to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of both the CID and other agencies.

From subsection (e)(2) because collecting information from the subject of criminal investigations would thwart the investigative process by placing the subject of the investigation on notice thereof.

From subsection (e)(3) because supplying an individual with a form containing the information specified could result in the compromise of an investigation, tend to inhibit the cooperation of the individuals queried, and render ineffectual investigative techniques and methods utilized by USACIDC in the performance of their criminal law enforcement duties.

From subsection (e)(5) because this requirement would unduly hamper the criminal investigative process due to the great volume of records maintained and the necessity for rapid information retrieval and dissemination. Also, in the collection of information for law enforcement purposes, it is impossible to determine what information is then accurate, relevant, timely and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light. In the criminal investigative process accuracy and relevance of information can only be determined in a court of law. The restrictions imposed by subsection (e)(5) would restrict the ability of trained investigators to exercise their judgment in reporting on investigations and impede the development of criminal intelligence necessary for effective law enforcement.

From subsection (e)(8) because the notice requirements of this provision could present a serious impediment to criminal law enforcement of revealing investigative techniques, procedures, and the existence of confidential investigations.

e. Insert before exemption rule ID-A0509.08DAPE, SYSNAME—Registration and Permit Files (40 FR 55578):

EXEMPTED RECORD SYSTEM

(GENERAL EXEMPTIONS)

ID-A0508.25bUSACIDC.

SYSNAME—Index to Case Files—Republic of Vietnam CY70-CY73.

Exemption—All portions of this system of records which fall within 5 U.S.C. 552a(j)(2) are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)

(5), (e)(8), (f), and (g). All portions of this system of records which fall within 5 U.S.C. 552a (k)(1) and (2) are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (d), (e)(4)(G), (e)(4)(H), and (f).

Authority—5 U.S.C. 552a(j)(2) and (k)(1) and (2).

Reasons—From subsection (c)(3) because the release of accounting of disclosures would place the subject of an investigation on notice that he is under investigation and provide him with significant information concerning coordinated investigative effort and techniques and the nature of the investigation, resulting in a serious impediment to criminal law enforcement activities or the compromise of properly classified material.

From subsection (c)(4), (d), (e)(4)(G), (e)(4)(H), (f), and (g) because access might compromise ongoing investigations, reveal investigatory techniques and the identity of confidential informants, and invade the privacy of persons who provide information in connection with a particular investigation. The exemption from access necessarily includes exemption from amendment, certain agency requirements relating to acess and amendment of records, and civil liability predicated upon agency compliance with those specific provisions of the Privacy Act. In addition, subsections (d), (e)(4)(G), (e)(4)(H), and (f) are necessary to protect the security of information properly classified in the interest of national and foreign policy.

From subsection (e)(1) because the nature of the criminal investigative function creates unique problems in prescribing specific perimeters in a particular case what information is relevant or necessary. Also, due to close liaison and working relationships with other federal, state, local and foreign national law enforcement agencies, information may be received which may relate to a case then under the investigtive jurisdiction of another government agency but it is necessary to maintain this information in order to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of both the CID and other agencies.

From subsection (e)(2) because collecting information from the subject of criminal investigations would thwart the investigative process by placing the subject of the investigation on notice thereof.

From subsection (e)(3) because supplying an individual with a form containing the information specified could result in the compromise of an investigation, tend to inhibit the cooperation of the individuals queried and render ineffectual investigative techniques and methods utilized by USACIDC in the performance of their criminal law enforcement duties.

From subsection (e)(5) because this requirement would unduly hamper the criminal investigative process due to the great volume of records maintained and the necessity for rapid information retrieval and dissemination. Also in the collection of information for law enforcement purposes, it is imposible to determine what information is then accurate, relevant, timely, and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light. In the criminal investigative process accuracy and relevance of information can only be determined in a court of law. The restrictions imposed by subsection (e)(5) would restrict the ability of trained investigators to exercise their judgment in reporting on investigations and impede the development of criminal intelligence necessary for effective law enforcement.

From subsection (e)(8) because the notice requirements of this provision could present a serious impediment to criminal law enforcement by revealing investigative technique, procedures, and the existence of confidential investigations.

f. Insert before exemption rule ID-A0702.08aDASG, SYSNAME — Army Medical Procurement Applicant Files (see below):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-A0702.03aUSAREC.

SYSNAME—Enlistment Eligibility Files.

Exemption—All portions of this system of records which fall within 5 U.S.C. 552a (k)(5) are exempt from the provisions of Title 5 U.S.C. section 552a(d).

Authority—5 U.S.C. 552a(k)(5).

Reasons—It is imperative that the confidential nature of evaluations and investigatory material on applicants applying for enlistment furnished to the US Army Recruiting Command under an express promise of confidentiality, be maintained to insure the candid presentation of information necessary in determinations of enlistment and suitability for enlistment into the United States Army.

g. Insert before exemption rule ID-A0704.10bUSAREC, SYSNAME—Armed Services Vocational Aptitude Battery (ASVAB) System (see below):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-A702.08aDASG

SYSNAME—Army Medical Procurement Applicant Files

Exemption—All portions of this system of records which fall within 5 U.S.C. 552a(k)(5) are exempt from the following provisions of Title 5 U.S.C. section 552a: (d).

Authority—5 U.S.C. 552a(k)(5).

Reasons—It is imperative that the confidential nature of evaluation and investigatory material on applicants furnished to the Army Medical Procurement Program under an express promise of confidentiality, be maintained to insure that candid presentation of information neecssary in determinations involving selection for AMEDD training programs and for suitability for commissioned service and future promotion.

h. Insert before exemption rule ID-AO709.01aDAPE, SYSNAME—United States Military Academy Candidate Files (40 FR 55579):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-A0704.10bUSAREC.

SYSNAME—Armed Services Vocational Aptitude Battery (ASVAB) System.

Exemption—All portions of this system which fall within 5 U.S.C. 552a(k)(6) are exempt from the following provisions of Title 5 U.S.C. section 552a: (d).

Authority—5 U.S.C. 552a(k)(6).

Reasons—Exemption is needed for the portion of records which pertain to individual item response on tests, to preclude compromise of scoring keys.

i. Insert before exemption rule ID-A0720.04aDAPE, SYSNAME—Individual Correctional Treatment Files (40 FR 55579):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-A0709.03bDAPE.

SYSNAME—United States Corps of Cadets Personnel Records.

Exemption—All portions of this system which fall within 5 U.S.C. 5522a(k)(5) and (7) are exempt from the following provisions of Title 5 U.S.C. 552a: (d).

Authority—5 U.S.C. 552a(k)(5) and (7).

Reasons—It is imperative that cadet evaluation reports, rendered by other cadets under the promise of confidentiality, be maintained in a confidential nature to insure candid evaluations necessary in counseling cadets on their performance and in determining their suitability for commissioned service.

j. Insert before exemption rule ID-A1012.04aDAPE, SYSNAME—USMAPS Training Files (see below):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-A1012.01bDAPE.

SYSNAME-USMAPS Admissions File.

Exemption—All portions of this system which fall within 5 U.S.C. 552a(k)(5) and (7) are exempt from the following provisions of Title 5 U.S.C. 552a: (d).

Authority—5 U.S.C. 552a(k)(5) and (7).

Reasons—It is imperative that the confidential nature of evaluation material on candidates, furnished to the United States Military Academy Preparatory School, under an express promise of confidentiality, be maintained to insure the candid presentation of information necessary in determinations involving admission to the United States Military Academy Preparatory School and suitability for commissioned service.

k. Insert before exemption rule ID-A1015.06DAAG, SYSNAME—School Employee File (40 FR 55580):

EXEMPTED RECORD SYSTEM

(SPECIFIC EXEMPTIONS)

ID-A1012.04aDAPE.

SYSNAME-USMAPS Training Files.

Exemptions—All portions of this system which fall within 5 U.S.C. 552a(k)(5) and (7) are exempt from the following provisions of Title 5 U.S.C. section 552a: (d).

Authority—5 U.S.C. 552a(k)(5) and (7).

Reasons—It is imperative that the confidential nature of evaluation material on candidates, furnished to the United States Military Academy Preparatory School, under an express promise of confidentiality, be maintained to insure the candid presentation of information necessary in determinations involving retention at the United States Military Academy Preparatory School and admission to the United States Military Academy and suitability for commissioned service.

[FR Doc.76-24043 Filed 8-16-76;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 953]

IRISH POTATOES GROWN IN SOUTHEASTERN STATES

Proposed Change in Fiscal Period

Consideration is being given to a proposal to change the fiscal period, currently April 1 through March 31, to June 1 through May 31. The proposal was recommended by the Southeastern Potato Committee, established pursuant to Marketing Agreement No. 104 and Order No. 953, both as amended (7 CFR Part 953). This program regulates the handling of potatoes grown in designated counties in North Carolina and Virginia

and is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.).

Statement of consideration. The fiscal period presently begins on April 1 of each year. However, the committee does not customarily hold its organizational meeting to recommend regulations until early April, and final regulations are usually not published before late May. During this two-month period the committee may incur some financial obligations. Since shipments from the production area usually begin in early June, this change would result in the fiscal period more closely conforming to actual operations under the order, thus improving the functioning of the committee and the administration of the order.

All persons who desire to submit written data, views, or arguments in connection with this proposal may file the same in duplicate with the Hearing Clerk, Room 112–A, U.S. Department of Agriculture, Washington, D.C. 20250, not later than September 10, 1976. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The proposal is as follows:

§ 953.122 Fiscal period.

The fiscal period, pursuant to § 953.9, which began on April 1, 1976, shall end on May 31, 1977. Thereafter, each fiscal period shall begin on June 1 of each year and end on May 31 of the following year, both dates inclusive.

Dated: August 11, 1976.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.76-23941 Filed 8-16-76;8:45 am]

Farmers Home Administration

[7 CFR Part 1823]

[FmHA Instruction 442.1]

ASSOCIATION LOANS AND GRANTS

Community Facilities, Development Conservation and Utilization

Notice is hereby given that the Farmers Home Administration has under consideration the proposed amendments of §§ 1823.2, 1823.3, 1823.4, 1823.5, 1823.6, 1823.7, 1823.9, 1823.11, 1823.13, 1823.14, 1823.25, 1823.28, 1823.29, 1823.42 and the deletion of § 1823.15 of Subpart A of Part 1823, Title 7, Code of Federal Regulations (38 FR 19026 as amended at 39 FR 12729; 39 FR 17971–17972; 39 FR 41829–41831; 40 FR 24517; 40 FR 29263; 40 FR 30930; 40 FR 6951; 40 FR 24517; 40 FR 29263; 44 FR 30930; 40 FR 54338; 41 FR 1490). As proposedfi the changes to incorporate certain substantive procedural and editorial changes read as follows:

1. Section 1823.2 is revised and restructured to clarify the section; to require the facilities to be located in rural areas; to require the applicat to be responsible for operating, maintaining and managing the facility; to require that nonprofit organizations have significant ties to the local commurity and to give consideration to projects needing improvements to comply with the Safe Drinking Water Act.

2. Section 1823.3 (b) and (c)(2), (9) and (11) are revised to clarify eligible loan purposes for industrial parks; to clarify the refinancing of debts; and to provide that utility-type projects may be located in either rural or nonrural areas in certain circumstances.

3. Section 1823.4 is revised to delete paragraph (c)(3) in reference to extensions to serve industrial areas; to add paragraph (e) to require nonpublic body borrowers to have cerain convenants in the articles of incorporation or loan agreement.

4. Section 1823.5 (b) is amended to require the term of the loan not exceed the useful life of the facility, or 40 years, whichever is less.

5. Section 1823.6(b)(1) (iv) and (v) are combined and revised to allow public bodies to pledge as security facility revenues and to give liens on real and personal property when legally permissible; paragraph (c) (1), (2) and (3) of this section are revised to take title clearance steps as necessary, or required by FmHA, to assign water rights as security when legally permissible, and to clarify membership authorization.

6. Section 1823.7 (a) (1) and (3), and (b) are revised to require the applicant to develop a user connection program prior to loan closing or the commencement of construction, whichever occurs first, and to allow for FmHA financing to the eligible applicant in certain developing areas; paragraph (c) is added to provide guidance and requirements for financial feasibility reports.

7. Section 1823.9 is amended to add a new paragraph (c) setting forth the provisions to require malpractice insurance for health care facilities; former paragraphs (c) through (f) are redesignated as (d) through (g) without change; a new paragraph (h) is added to outline requirements when the applicant is leasing a site.

8. Section 1823.11(a) is revised to add paragraph heading and to include appraisers in the group who may be necessary for their professional services; paragraphs (b) and (c) are amended to add paragraph headings.

9. Section 1823.13 is revised to include requirements regarding content of loan resolutions to be adopted by the applicant; provide for the use of multiple advances of loan funds in conjunction with interim commercial financing when needed; require the applicant to deposit applicant contribution funds prior to loan closing or start of construction, whichever occurs first; provide that supervised bank accounts which exceed the F.D.I.C. coverage be collateralized pursuant to Treasury Circular No. 176; provide that funds remaining after completion of the project be returned to FmHA as payment on the loan in a proportionate amount of the FmHA loan to the total project costs. The revision of this section involves new paragraphs, redesignation and revision of others. Where no change of text is involved only the redesignated paragraph and heading is shown.

10. Section 1823.14 is revised to provide more flexibility in the submission of management reports and audit reports.

11. Section 1823.15 is deleted.

12. In § 1823.24, the text and paragraph (a) are revised to extend the requirements for water purchase contracts so as to make these contract requirements applicable when other utility services are purchased.

13. In § 1823.28, the last sentence is amended to update the cross-reference.

14. In § 1823.29, the heading is revised and the following paragraphs are redesignated and revised as indicated:

(a) Former redesignated paragraph (c) (1) through (7) is now redesignated (b) (3) (i) through (vii) without change;

(b) Former redesignated paragraph (c)(8) (i) through (x) is now redesignated paragraph (b)(4) (i) through (x), with revisions in paragraphs (b)(4) and (b)(4)(ii), to update cross-references.

(c) New paragraph (b)(5) is added to set forth requirements for applicants awarding construction contracts prior to filing preapplications with FmHA.

(d) Former redesignated paragraph (d) (1) through (8) is now redesignated paragraph (c) (1) through (8) with revisions in paragraphs (c) (7) and (8), to expand requirements to comply with Section 114 of the Clean Air Act and section 308 of the Water Pollution Control Act; and to note supplemental general conditions in contracts in excess of $2.500 contained in FmHA Guide 18.

15. In § 1823 42, a new paragraph (k) is added to require a preliminary approving opinion of bond counsel when multiple advances are used and if a final unqualified opinion cannot be obtained; former paragraph (k) is redesignated as paragraph (l) without change.

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed amendment to the Chief, Directives Management Branch, Farmers Home Administration, U.S. Department of Agriculture, Room 5316, South Building, Washington, DC 20250, on or before September 18, 1976.

All written submissions made pursuant to this notice will be made available for public inspection at the office of the Chief, Directives Management Branch, during regular business hours. (8:15 a.m.–4:45 p.m.)

As proposed, the various amendments and additions read as follows:

§ 1823.2 Applicant eligibility and priority.

Facilities financed by FmHA shall primarily serve rural residents, and be located in rural areas except as provided in § 1823.3(c)(11). The terms "rural" and "rural area" shall not include any area in any city or town having a population in excess of 10,000 inhabitants according to the latest decennial census of the United States.

(a) *Eligibility.* (1) Applicants eligible for loans include but are not limited to municipalities, counties, other political subdivisions of a State and other organizations operated on a not-for-profit basis such as:

(i) Districts.

(ii) Authorities.

(iii) Associations, cooperatives and corporations operated on a not-for-profit basis.

(iv) Indian tribes on Federal and State reservations and other Federally recognized Indian Tribes.

(v) Existing private corporations. Applicants organized under the general profit corporation laws may be eligible if they actually will be operated on a not-for-profit basis under their charter, bylaws, mortgage, or supplementary agreement provisions as may be required as a condition of loan approval.

(2) Applicants must certify in writing and FmHA shall determine that the applicant is unable to finance the proposed project from their own resources or through commercial credit at reasonable rates and terms.

(3) Each applicant must have or will obtain the legal authority necessary for constructing, operating, and maintaining the proposed facility or service and for obtaining, giving security for, and repaying the proposed loan. The applicant shall be responsible for operating, maintaining and managing the facility and for providing for its continued availability and use at reasonable rates and terms. This responsibility shall be exercised by the applicant even though the facility may be operated, maintained or managed by a third party under contract, management agreement or written lease. Leases may be used when this is the only feasible way to provide the service and is the customary practice.

(4) FmHA shall require an agreement that if at any time it shall appear to the Government that the borrower is able to refinance the amount of the indebtedness then outstanding, in whole or in part, by obtaining a loan for such purposes from responsible cooperative or private credit sources at reasonable rates and terms for loans for similar purposes and periods of time, the borrower will upon request of the Government, apply for and accept such loan in sufficient amount to repay the Government and will take all such actions as may be required in connection with such loan.

(5) Preference for available loan funds will normally be given to public bodies. When this is not practicable:

(i) Loans for facilities providing a utility type service such as water and sewer systems, natural gas distribution systems, and cable TV may be made to other than public body type organizations, when operated on a not-for-profit basis. Security for such loans will be obtained in accordance with § 1823.6(a).

(ii) Loans for services and facilities basic to social, cultural, recreational needs, public health and safety, such as fire and rescue facilities, hospitals, and health clinics, community and other public buildings, and similar facilities may be made to other than public body-type organizations when (A) such facilities are fully available to the public, (B) it is not practicable for the public entity they serve to finance them, and (C) the proposal meets appropriate security requirements of section 1823.6.

(b) *Nonprofit organization eligibility.* A private nonprofit organization to be eligible for a community facility loan, must have significant ties with the local rural community. Such ties are necessary to insure to the greatest extent possible that a facility under private control will carry out a public purpose and continue to primarily serve the local rural residents. Such ties may be evidenced by such items as:

(1) Association with or control by a local public body or bodies, or broadly based ownership and control by members of the community;

(2) Substantial public funding through taxes, revenue bonds, or other local Government sources, and/or, substantial voluntary community funding such as would be obtained through a community-wide funding campaign.

(c) *Project priority.* In selecting projects, FmHA shall give due consideration to State development strategies, projects needing improvements to comply with the Safe Drinking Water Act, clearinghouse comments and priority recommendations and assign priorities in accordance with the following:

(1) Water and sewer system applications for any municipality or other public agency (including an Indian tribe on a Federal or State reservation or other Federally recognized Indian tribal group) in a rural community having a population not in excess of 5,500 having an inadequate water or sewer system.

(2) Those projects which will enlarge, extend, or otherwise modify existing facilities to provide service to additonal rural residents.

(3) Those projects which involve the merging of ownership, management, and operation of smaller facilities thereby providing for more efficient management and economical service to more rural communities and residents and more orderly development of the rural area in which the facilities are located.

§ 1823.3 Eligible loan purposes.

Funds may be used:

* * * * *

(b) To construct, enlarge, extend, or otherwise improve community facilities providing essential service to rural residents. Such facilities include but are not limited to those providing or supporting overall community development such as fire and rescue services; transportation; traffic control; community, social, cultural, and recreational benefits; supplemental and supporting structures for rural electrification or telephone systems or facilities such as headquarters and office buildings, storage facilities, and maintenance shops only when they are not eligible for Rural Electrification Administration financing. Funds may be used for development of industrial park sites, consisting of land and land improvements (e.g. clearing, grading, drainage, etc.), necessary access ways and utility extensions to and throughout the site when the park is determined to be an integral part of community development. Funds may not be used in connection with industrial parks to finance on-site utility systems, or business and industrial buildings.

(c) * * *

(2) Paying interest installments in connection with loans to be repaid from facility revenue until such time as the facility is generating sufficient revenue to be self-supporting. Ordinarily, this will be limited to an amount sufficient to pay not more than 3 years interest after the estimated loan closing date. Funds may be included for interest installments for loans secured by general obligation bonds through the period when taxes are available for payment, ordinarily not to exceed 2 years.

* * * * *

(9) Refinancing debts incurred by or on behalf of a community when all of the following conditions exist.

(i) The debt being refinanced is only an incidental portion of the total loan.

(ii) The debts were incurred for the facility or part thereof or service to be installed or improved with the loan.

(iii) Arrangements cannot be made with the creditors to extend or modify the terms of the debt so that a sound basis will exist for making a loan.

* * * * *

(11) FmHA loan funds may be used alone or in connection with funds provided by the applicant or from other sources. When the utility is to serve both rural and urban areas, FmHA loan funds may be used to finance that portion of a utility project serving rural residents regardless of location of the facility. Since "matching funds" are not a requirement for FmHA loans, shared revenues may be used with such loans for project construction. Applicants expecting funds from other Agencies for use in completing projects being partially financed with FmHA funds will present evidence that funds from such other Agencies will be available at the time needed for construction of the project before closing the FmHA loan or the commencement of construction, whichever occurs first.

§ 1823.4 Facilities for public use.

* * * * *

(c) * * *

(3) [Deleted].

* * * * *

(e) Before a loan is made to an applicant other than a public body, the articles of incorporation or loan agreement will include the following condition:

In the event of dissolution of this corporation, or in the event it shall cease to carry out the objectives and purposes herein set forth, all business, property and assets of the corporation shall go and be distributed to one or more nonprofit corporations or public bodies as may be selected by the board of directors of this corporation and approved by

at least 75% of users or members, to be used for, and devoted to, the purpose of a community facility project or other purpose to serve the public welfare of the community. In no event shall any of the assets or property, in the event of dissolution thereof, go or be distributed to members, directors, stockholders, or others having financial or managerial interest in the corporation either for the reimbursement of any sum subscribed, donated or contributed by such members or for any other purposes, provided that nothing herein shall prohibit the corporation from paying its just debts.

§ 1823.5 Rates and terms.

* * * * *

(b) Loans will ordinarily be scheduled for repayment on terms similar to those used in the State for financing such facilities but in no case shall they exceed 40 years from the date of the note(s) or bond(s) or the useful life of the facility, whichever is less.

* * * * *

§ 1823.6 Security.

* * * * *

(b) *Public Bodies.* * * *

(1) * * *

(iv) Pledges of facility revenue and when permitted by State law liens on real and personal property.

(v) [Deleted.]

* * * * *

(c) *Public bodies and other than public bodies*—(1) *Title for right-of-way or easement.* When a lien will be taken on a site for structures such as a reservoir or pumping station, and the applicant is able to obtain only a right-of-way or easement on such site rather than a fee simple title, the applicant will furnish a title report thereon by the applicant's attorney showing the ownership of the land and all mortagges or other liens, defects, or encumbrances, if any. Consents, releases, or subordinations will be obtained from the holders of outstanding liens or mortgages as may be necessary to give FmHA the required security. The applicant wil take such title clearance steps as may be necessary or required by FmHA.

(2) *Water rights.* When legally permissible, an assignment will be taken on water rights owned or to be acquired by the applicant and the following will be furnished as applicable:

* * * * *

(3) *Membership authorization.* For organizations other than public bodies, the membership will authorize a utility-type project and its financing, except that the State Director may, with the concurrence of the Office of the General Counsel, accept the loan resolution without such membership authorization when State statutes and the organization's charter and bylaws do not require such authorization; and:

§ 1823.7 Economic feasibility requirements.

(a) Applicants for loans for utility facilities dependent on user fees for debt payment shall base their income and expense forecast on realistic user estimates in accordance with the following:

(1) In estimating the number of users and establishing rates or fees on which the loan will be based for new systems and for extensions or improvements to existing systems, consideration should be given to the following:

* * * * *

(3) User connection program. In those cases where all or a part of the borrower's debt repayment ability revenues will come from user fees, applicants must provide a positive program to encourage connection by all users as soon as service is available for review and approval by FmHA before loan closing or the commencement of construction, whichever occurs first. Such a program shall include:

* * * * *

(b) *Facilities for new or developing communities or areas.* Developers are normally expected to provide essential community facilities in new or developing areas and such facilities shall be installed in compliance with appropriate State statutes and regulations. FmHA financing will be considered to an eligible applicant in such cases when failure to complete development would result in an adverse economic condition for the rural area (not the community being developed); the proposal is necessary to the success of an area development plan; and loan repayment can be assured by:

* * * * *

(3) Developers paying cash for the increased capital cost and any increased operating expenses until the developing area will support the increased costs; or

* * * * *

(c) *Financial feasibility reports.* Applicants will provide a financial feasibility report prepared by a qualified firm or individual. Projects for other than utility-type facilities, dependent on revenues from the facility to repay the loan and proposing modifications which will significantly affect the applicant's financial operations, will be prepared by a qualified firm or individual not having a direct interest in the management or construction of the facility. For other projects the financial feasibility report will normally be included as a part of the preliminary engineer/architectural report unless additional information is specifically requested by FmHA. Guides outlining the minimum content requirements of financial feasibility reports are available at local FmHA offices.

§ 1823.9 General requirements.

* * * * *

(c) *Malpractice insurance.* The need for and requirements for malpractice insurance will be carefully and thoroughly considered in connection with each health care facility financed. The applicant will maintain such insurance as determined necessary by the governing body, with the advice of the applicant attorney and concurred in by FmHA.

* * * * *

(h) *Lease agreements.* Where the right of use or control of real property not owned by the applicant/borrower is essential to the successful operation of the facility during the life of the loan, such right will be evidenced by written agreements or contracts between the owner(s) of the property and the applicant/borrower. Lease agreements shall not contain provisions for restricted use of the site or facility, forfeiture or summary cancellation clauses, and shall provide for the right to transfer the lease without restriction. Lease agreements will ordinarily be written for a term at least equal to one and one-half times the term of the loan. Such lease contracts or agreements will be approved by the FmHA loan approving official with the advice and counsel of the Regional Attorney, Office of the General Counsel, as to the legal sufficiency of such documents. A copy of the lease contract or agreement will be included in the loan docket.

* * * * *

§ 1823.11 Professional services and contracts related to the facility.

(a) *Professional services.* Applicants will be responsible for providing the services necessary to plan projects including design of facilities, preparation of cost and income estimates, development of proposals for organization and financing, and overall operation and maintenance of the facility. Professional services of the following may be necessary: Engineer, architect, attorney, bond counsel, accountant, auditor as defined in § 1823.14(e)(3)(i), appraisers, and financial advisory or fiscal agent (if desired by the applicant). Contracts or other forms of agreement between the applicant and its professional and technical representatives are required and are subject to FmHA concurrence. Form FmHA 442–19, "Agreement for Engineering Services," may be used when appropriate. Guide 14 may be used in the preparation of the legal services agreement.

(b) *Contracts for other services.* * * *

(c) *Fees.* * * *

* * * * *

§ 1823.13 Closing loans and fund delivery.

(a) *Loan resolutions.* Loan resolutions will be adopted by both public and other-than-public bodies using Forms FmHA 442–47, "Loan Resolutions (Public Bodies)," and FmHA 442–9, "Association Loan Resolution (Security Agreement)," respectively. These resolutions will supplement or add to provisions included elsewhere in this subpart. The association will agree:

(1) To indemnify the Government for any payments made or losses suffered by the Government on behalf of the association. Such indemnification shall be payable from the same source of funds pledged to pay the bonds or any other legally permissible source.

(2) To comply with applicable local, State and Federal laws, regulations and ordinances.

(3) To provide for the receipt of adequate revenues to meet the require-

ments of debt service, operation and maintenance, establishments of adequate reserves and to continually operate and maintain the facility in good condition. No free service or use of the facility will be permitted.

(4) To acquire and maintain such insurance coverage, including fidelity bonds, as may be required by the Government.

(5) To establish and maintain such books and records relating to the operation of the facility and its financial affairs and to provide for required audit thereof in such a manner as may be required by the Government to provide the Government without its request, a copy of each such audit and to make and forward to the Government such additional information and reports as it may, from time to time, require.

(6) To provide the Government, at all reasonable times, access to all books and records relating to the facility and access to the property of the system so that the Government may ascertain that the association is complying with the provisions hereof and instruments incident to the making or insuring of the loan.

(7) To serve any applicant within the service area who desires services and can be feasibly and legally served, and to obtain the concurrence of the FmHA prior to refusing services to such applicant. Upon the failure to provide such services which are feasible and legal, such applicant shall have a direct right of action against the association under this agreement.

(8) To have prepared on its behalf and to adopt an ordinance or resolution for the issuance of its bonds or notes or other lien instruments containing such items and in such form as are required by State statutes and as are agreeable and acceptable to the Government.

(9) To refinance the unpaid balance, in whole or in part, of its bonds or notes upon the request of the government if at any time it should appear to the Government that the association is able to refinance its bonds by obtaining a loan for such purposes from responsible cooperative or private sources at reasonable rates and terms.

(10) To provide for, execute, and comply with Form FmHA 400–4, "Nondiscrimination Agreement," and Form FmHA 400–1, "Equal Opportunity Agreement," including an "Equal Opportunity Clause," which clause is to be incorporated in or attached as a rider to each construction contract and subcontract involving an amount in excess of $10,000.

(11) To place the proceeds of the loan on deposit in an account in a bank and in a manner approved by the Government.

(12) Not to sell, transfer, lease, or otherwise encumber the facility or any portion thereof or interest therein; not to permit others to do so, without the prior written consent of the Government.

(13) Not to borrow any money from any source, enter into any contract or agreement, or incur any other liabilities in connection with making enlargements, improvements or extensions to, or for any other purpose in connection with the facility (exclusive of normal maintenance) without the prior written consent of the Government, if such undertaking would involve the source of funds pledged to pay the bonds or notes.

(14) That upon default in the payments of any principal and accrued interest on the bonds or in the performance of any covenant or agreement contained herein or in the instruments incident to making or insuring the loan, the Government, at its option, may:

(i) Declare the entire principal amount then outstanding and accrued interest, immediately due and payable;

(ii) For the account of the association (payable from the source of funds pledged to pay the bonds or notes or any other legally permissible source), incur and pay reasonable expenses for repair, maintenance, and operation of the facility and such other reasonable expenses as may be necessary to cure the cause of default; and/or

(iii) Take possession of the facility, repair, maintain and operate, rent or otherwise dispose of the facility. Default under the provisions of the resolution or any instrument incident to the making or insuring of the loan may be construed by the Government to constitute default under any other instrument held by the Government and executed or assumed by the association, and default under any such instrument may be construed by the Government to constitute default hereunder.

(b) *Interim financing.* In all loans, exceeding $50,000, where it is possible for funds to be borrowed at reasonable interest rates on an interim basis from commercial sources for the construction period, such interim financing will be obtained so as to preclude the necessity for multiple advances of FmHA funds. When interim commercial financing is used, the application will be processed, including obtaining construction bids, to the stage where the FmHA loan would normally be closed, that is immediately prior to the start of construction. When the interim financing funds have been expended, the FmHA loan will be closed. Multiple advances may be used in conjunction with interim commercial financing when the applicant is unable to obtain sufficient funds through interim commercial financing in an amount equal to the loan. The FmHA loan proceeds (including advances) will be used to retire the interim commercial indebtedness. Before the FmHA loan is closed, the applicant will be required to provide FmHA with statements from the contractor, engineer, architect, and attorney that they have been paid to date in accordance with their contracts or other agreements and, in the case of the contractor, that he has paid his suppliers and subcontractors.

(c) *Multiple advances.* * * *

* * * * *

(2) Advances will be requested in sufficient amounts to insure that ample funds will be on hand to pay costs of construction, rights-of-way and land, legal, engineering, interest, and other expenses as needed. The applicant will prepare Form FmHA 440–11, "Estimate of Funds needed," to show the amount of funds needed during the 30-day period. Form AD–627, "Report of Federal Cash Transactions," will be prepared and submitted with each Form FmHA 440–11 after the initial advance of funds is made.

(d) *Applicant contribution.* Applicants contributing funds toward the project cost shall deposit these funds in its construction account on or before loan closing or start of construction, whichever occurs first. Project costs, paid prior to the required deposit time, with applicant funds shall be appropriately accounted for.

(e) *Supervised bank account.* Loan funds and any funds furnished by the applicant may be deposited in a supervised bank account in a bank having Federal Deposit Insurance Corporation (FDIC) coverage. Funds placed in a supervised bank account are public monies under 12 U.S.C. 265, and therefore any amount which exceeds the FDIC coverage will require a collateral pledge pursuant to Treasury Circular No. 176. If a supervised bank account is not used, arrangements will be agreed upon for the prior approval by FmHA of the bills, or vouchers upon which warrants will be drawn, so that the necessary control of payments from loan funds can be maintained and FmHA records can be kept current. Periodic audits of nonsupervised accounts shall be made by FmHA at such times and in such manner as the FmHA State Director prescribes in the conditions of loan approval. Mandatory State Laws regulating the depositories to be used shall be complied with.

(f) *Payment for construction.* Payment for construction will be made in accordance with the construction contract in amounts approved on Form FmHA 424–18, "Partial Payment Estimate." Advances for contract retainage will not be made until such retainage is due and payable under the terms of the contract. Form AD–629, "Outlay Report and Request for Reimbursement for Construction Programs," will be used to account for funds expended in the last 30-day period. Each payment estimate must be approved by the governing body of the borrower. The review and acceptance of partial payment estimates by FmHA does not attest to the correctness of the quantities shown or that the work has been performed in accordance with the plans and specifications. A final Form AD–627 will be submitted to FmHA to include the final advance and all other advances not later than 90 days after the final advance has been made.

(g) *Funds remaining after construction is completed.* Should loan funds remain available, including obligated funds not advanced, after all costs incident to the basic project have been paid or provided for, such funds may be used

for needed extensions, enlargements and improvements of the project with the prior permission of the FmHA State Director. If the additional work is to be undertaken by the contractor(s) already engaged in the construction of the project, the additional work may be authorized by a change order. Remaining project funds not needed for authorized extensions, enlargements, or improvements shall be returned to FmHA as a repayment on the loan in a proportionate amount of the FmHA loan to the total planned project cost, unless other disposition is required by the bond ordinance or resolution or by State statutes.

(h) *Obtaining insurance and fidelity bonds.* * * *

(i) *Distribution of recorded documents.* * * *

* * * * *

§ 1823.14 Borrower accounting methods, management reporting and audits.

(a) *Accounting methods and records*—(1) *Method of accounting.* The methods of accounting will be such that separate accounts are to be maintained on the individual project being financed by FmHA when it is a unit of a larger organization. Borrowers shall maintain their accounting records on the accrual basis unless State statutes or regulatory Agencies provide otherwise, or this requirement is waived by FmHA.

(i) *Waiver of accrual method.* The State Director may approve a basis of accounting other than accural when the resulting financial statements will present fairly the financial position and results of operations of the organization. For organizations who have audits by independent public accountants, whether or not required by paragraph (c) of this section, the basis of accounting other than accrual must have the written approval of the organization's auditor before granting a waiver so that the basis of accounting will not be a factor in keeping the auditor from rendering an unqualified opinion.

(2) *Records.* Each borrower shall retain all records, books, and supporting material for a period of 3 years after the issuance of the audit reports and financial statements in paragraphs (c) and (d) of this section. This material will be available upon request to FmHA, the Comptroller General, or to their representatives.

(3) *Approval requirements.* Prior to loan closing or commencing with construction, whichever shall occur first, each borrower shall provide and obtain approval from the FmHA State Director for its accounting and financial reporting system, including the agreement with its auditor, if an auditor is required as determined in paragraph (c)(1) of this section.

(b) *Management reports.* These reports will furnish the management with a means of evaluating prior decisions and serve as a basis for planning future operations and financial conditions. In those cases where revenues from multiple sources are pledged as security for an FmHA loan, two reports will be required; one for the project being financed by FmHA and one combining the entire operation of the borrower. In those cases where FmHA loans are secured by general obligation bonds or assessments and the borrower combines revenues from all sources, one management report combining all such revenues will suffice. The following management data will be submitted:

(1) *Financial Information.* Form FmHA 442–2, Schedule 1, "Statement of Budget, Income and Equity," and Schedule 2, "Projected Cash Flow."

(i) Prior to be beginning of each fiscal year, two copies, with data entered in column three only of page one, annual budget of schedule 1 and all of schedule 2, will be submitted to the County Supervisor. Twenty(20) days after the end of each of the first three quarters of each year, two copies with all information furnished will be submitted. More frequent submissions may be required by FmHA when necesary. For the fourth quarter of each year, submit together with the year-end financial requirements of paragraphs (c) and (d) of this section. The submission dates to the County Supervisor will be 90 days following year-end requirements for audited statements, and 60 days following year-end requirements for unaudited statements. The fourth quarter submission may serve the dual purpose of management report and year-end financial requirement for Statement of Income. Refer to paragraph (d) of this section and Form FmHA 442–2.

(2) *Additional Information.* (i) Together with the other year-end requirements, submit to the County Supervisor a letter listing the names and addresses of all members, partners, director, etc., as appropriate, also indicating the officers and their term of office.

(ii) Borrowers delinquent on their payment to FmHA or experiencing financial problems, will develop a positive action plan to resolve its financial problems. The plan will be reviewed with FmHA and updated at least quarterly. A guide for developing a positive action plan is available at the local FmHA office.

(3) *Waiver of management reports.* In those cases where FmHA loans are secured by the general obligation of the public body or tax assessments which total 100 percent of the debt service requirements, the State Director may authorize an annual audit to be substituted in lieu of management reports.

(c) *Audits and financial statements.*—(1) *Audit requirements.* Audits are required annually of borrowers as follows:

(i) Where gross annual income exceeds $50,000.

(ii) Others as the FmHA State Director may require.

(2) *Public body borrowers.* Audit reports prepared in accordance with State statutes or regulatory Agencies are acceptable, provided they contain the financial information necessary and are prepared on a frequency sufficient to furnish borrowers and FmHA the information for proper loan analysis. A copy of the audit will be submitted to the County Supervisor as soon as possible but in no case later than 90 days following the period covered by the audit. Public bodies should refer to the FmHA audit guide in paragraph (c)(3)(ii) of this section for certain required information.

(3) *Other borrowers.* Borrowers other than public bodies and public bodies where the State has no audit requirements are required to have their records audited by an independent public accountant on an annual basis. A copy of the audit will be submitted to the County Supervisor as soon as possible, but in no case later than ninety (90) days following the period covered by the audit.

(i) *Independent public accountant defined.* Audits shall be conducted in accordance with generally accepted auditing standards by independent certified public accountants or by independent licensed public accountants who are certified or licensed by a regulatory authority of a State or other political subdivision of the United States.

(ii) *Audit guide.* Audits will be prepared in accordance with the requirements of the handbook, "Instructions to Independent Certified Public Accountants and Licensed Public Accountants Performing Audits of Farmers Home Administration Borrowers and Grantees." The handbook is available at all FmHA offices.

(d) *Borrowers not required to have audits.* Borrowers whose gross annual income for a full year of operation is less than $50,000, and who do not have an annual audit made by an independent public accountant, will within 60 days following the end of each fiscal year, furnish the FmHA with annual financial statements, consisting of a verification of the organization's balance sheet and statement of income and expense by an appropriate official of the organization. The "Statement of Budget, Income and Equity," Form FmHA 442–2, and the "Balance Sheet," Form FmHA 442–3, may be used. For borrowers using Form FmHA 442–2, the dual purpose of fourth-quarter management report, when required, and annual statement of income, will be met with this one submission.

§ 1823.15 [Deleted]

§ 1823.24 Utility purchase contracts.

Applicants proposing to purchase water or other utility service from private or public sources shall have written contracts for such supply, and all such contracts will be reviewed and approved by FmHA prior to their execution by the applicant. Form FmHA 422–30, "Water Purchase Contract," may be used. Such contracts will:

(a) Include a definite commitment by the supplier to furnish at a specified point a specified minimum quantity of water or other service and provide that in case of shortages, all of the supplier's users will share the shortages proportionately. If it is impossible to obtain a firm commitment for a minimum supply at all times, a contract may be executed and approved, if adequate evidence is provided to enable FmHA to

make a positive determination that the supplier has adequate supply and treatment facilities to furnish its other users and the applicant for the foreseeable future, and that a suitable alternative supply could be arranged within the repayment ability of the borrower if it should ever become necessary.

* * * * *

§ 1823.28 Performing construction.

Payments for construction will be handled in accordance with § 1823.13(f).

* * * * *

§ 1823.29 Procurement, bidding and contracting.

(b) * * *

(4) Procurement records or files for purchases not handled in accordance with paragraph (b) (3) (v) and (vi) of this section and those in excess of $50,000 shall provide at least the following pertinent information:

* * * * *

(ii) A written consent from the FmHA making an exception to the requirements contained in paragraph (b) (3) (i) and (vi) and paragraph (d) of this section in regards to formal competitive bidding and the architect/engineer-contractor relationship. Such consent shall not be given when FmHA financing includes a grant.

* * * * *

(5) Applicants awarding construction contracts prior to filing a preapplication with FmHA must comply with the following:

(i) Provide conclusive evidence that the contract was entered into without intent to circumvent the requirements of FmHA regulations. Such evidence will consist of at least the following:

(A) The lapse of a reasonable period of time between the date of contract award and the date of filing the preapplication which clearly indicates an irreconcilable failure of previous financial arrangements or,

(B) A written statement explaining initial plans for financing the project and reasons for failure to obtain the planned credit.

(ii) Modify the outstanding contract to conform with the provisions of this appendix. Where this is not possible, modifications will be made to the extent practicable and as a minimum the contract must comply with all State and local laws and regulations as well as statutory requirements and executive orders related to the FmHA financing. Where all construction is complete and it is impractical to modify the contracts, the applicant must provide the certification required by paragraph (b) (5) (iv) of this section. Any exceptions to full compliance with this appendix must be approved by FmHA with the advise of the Office of the General Counsel.

(iii) Provide a certification by its engineer or architect certifying that any construction performed complies with the plans and specifications.

(iv) Provide a certification that the applicant and their contractor(s) complied with all statutory and executive order requirements relating to FmHA financing for construction already performed even though these requirements may not have been included in the contract documents.

(c) * * *

(7) If the contract exceeds $100,000, the contractor agrees to comply with all requirements of section 114 of the Clean Air Act (42 U.S.C. 1957–g) and section 308 of the Water Pollution Control Act (33 U.S.C. 1318) relating to inspection, monitoring entry, reports, and information, as well as all other requirements specified in section 114 of the Clean Air Act and section 308 of the Water Pollution Control Act and all regulations and guidelines issued thereunder after the award of the contract. Such regulations and guidelines can be found at 40 CFR 15.4 and 40 FR 17126 dated April 16, 1975.

(i) The contract should contain provisions obligating the contractor as a condition for the award of the contract.

(A) To notify the owner of the receipt of any communication form the Environmental Protection Agency (EPA) indicating that a facility to be utilized for the contract is under consideration to be listed on the EPA list of Violating Facilities. Prompt notification is required prior to contract award.

(B) To certify that any facility to be utilized in the performance of any nonexempt contractor subcontact is to be listed on the EPA list of Violating Facilities pursuant to 40 CFR 15.20 as of the date of contract award.

(C) To include or cause to be included, the above criteria and requirements in every nonexempt subcontract, and, that he will take such action as the Government may direct as a means of enforcing such provisions.

(ii) The term "facility" means any building, plant, installation, structure, mine, vessel or other floating craft, location, or site of operations, owned, leased, or supervised by a grantee, cooperator, contractor, or subcontractor, to be utilized in the performance of a grant, agreement, contract, subgrant, or subcontract. Where a location or site of operations contains or includes more than one building, plant, installation, or structure, the entire location shall be deemed to be a facility except where the Director, Office of Federal Activities, Environmental Protection Agency, determines that independent facilities are located in one geographical area.

(8) Each contract in excess of $2,500 shall contain FmHA supplemental general conditions. These conditions are contained in Guide FmHA 18 "Supplemental General Conditions," and may be obtained from the local FmHA office.

* * * * *

§ 1823.42 Bond transcript documents.

* * * * *

(k) For loans involving multiple advances of FmHA loan funds, a preliminary approving opinion of bond counsel if a final unqualified opinion cannot be obtained. The preliminary opinion for the entire issue shall be delivered on or before the first advance of loan funds and state that the applicant has the legal authority to issue the bonds, construct, operate and maintain the facility, and repay the loan subject only to changes during the advance of funds such as litigation resulting from the failure to advance loan funds, and receipt of closing certificates.

(l) [Redesignated].

* * * * *

(7 U.S.C. 1989, delegation of authority by the Secretary of Agriculture, 7 CFR 2.23, delegation of authority by the Assistant Secretary for Rural Development, 7 CFR 2.70)

Dated: August 9, 1976.

JOSEPH R. HANSON,
Acting Administrator,
Farmers Home Administration.

[FR Doc.76–23945 Filed 8–16–76;8:45 am]

Office of the Secretary

[7 CFR Part 1260]

[Docket No. BRIA–1]

BEEF RESEARCH AND INFORMATION

Hearing on Proposed Order

Notice is hereby given of a public hearing on a proposed national research and information order for beef. Hearing sessions will be held at six locations beginning on the dates listed below:

1. September 14, 1976—Dallas, TX 75201, Baker Hotel, 1400 Commerce Street.
2. September 28, 1976—Pittsburgh, PA 15222, 1112 Federal Building, 1000 Liberty Avenue.
3. September 30, 1976—Atlanta, GA 30324, Holiday Inn, I 85 & Monroe Drive, 1944 Piedmont Circle.
4. October 5, 1976—Denver, CO 80225, Denver Federal Center, Bldg. 56, Entrance A, West 6th Avenue & Kipling Street.
5. October 7, 1976—San Francisco, CA 94111, Conference Room 503, U.S. Custom House, 555 Battery Street.
6. October 12, 1976—Des Moines, IA 50309, Federal Building, Room 113, 210 Walnut Street.

Each day's session of the hearing will commence at 9:30 a.m., local time, unless the judge otherwise specifies during the course of the hearing. Any of the sessions may be continued beyond 1 day if necessary. The hearing is called pursuant to the Beef Research and Information Act (90 Stat. 529–538, (7 U.S.C. 2901 et seq.)), and in accordance with the applicable rules of practice and procedure governing proceedings to formulate an order (7 CFR Part 1260).

The public hearing is for the purpose of : (a) Receiving evidence with respect to the economic and marketing conditions which relate to the proposed order set forth herein and to any appropriate modifications thereof; (b) determining the extent of need for an order to implement a nationwide coordinated beef research and information program; and (c) determining whether provisions specified in the proposed order or some other provisions appropriate to the terms of the Beef Research and Information Act (90 Stat. 529–538, (7 U.S.C. 2901 et seq.)) will tend to effectuate the declared policy of the Act.

The proposed order, set forth below, has not received the approval of the Secretary of Agriculture.

The proposed order was submitted to the Secretary of Agriculture, with a request for a public hearing thereon, by the Beef Development Taskforce composed of representatives from national beef organizations and State cattlemen's associations. The Taskforce indicates that the proposed order is endorsed by a total of 81 State and national beef and dairy organizations.

The provisions of the proposed Beef Research and Information Order are:

PART 1260—BEEF RESEARCH AND INFORMATION

Subpart—Beef Research and Information Order

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AUTHORITY: Beef Research and Information Act (7 U.S.C. 2901 et seq.).

DEFINITIONS

§ 1260.101 Secretary.

"Secretary" means the Secretary of Agriculture or any other officer or employee of the Department of Agriculture to whom there has heretofore been delegated, or to whom there may hereafter be delegated, the authority to act in his stead.

§ 1260.102 Act.

"Act" means the Beef Research and Information Act (7 U.S.C. 2901 et. seq.) and any amendments thereto.

§ 1260.103 Person.

"Person" means any individual, group of individuals, partnership, corporation, association, cooperative, or any other entity.

§ 1260.104 Cattle.

"Cattle" means live domesticated bovine quadrapeds.

§ 1260.105 Beef.

"Beef" means the flesh of cattle.

§ 1260.106 Beef products.

"Beef products" means products produced in whole or in part from cattle, exclusive of milk and products made therefrom.

§ 1260.107 Fiscal period.

"Fiscal period" is the 12-month budgetary period and means the USDA's fiscal year unless the Beef Board, with the approval of the Secretary, selects some other 12-month budgetary period.

§ 1260.108 Beef Board or Board.

"Beef Board" or "Board" or other designatory term adopted by such Board, with the approval of the Secretary, means the administrative body established pursuant to § 1260.136.

§ 1260.109 Executive Committee.

"Executive committee" means the members of the Beef Board, from 7 to 11 in number, who are elected by the Board to handle administrative matters, to make policy recommendations to the Board, and to conduct routine business within the policies determined by the Board.

§ 1260.110 Producer.

"Producer" means any person who owns or acquires ownership of cattle other than one who acquires cattle solely from the purpose of slaughter: *Provided*, That a person shall not be considered to be a producer if his only share in the proceeds of a sale of cattle or beef is a sales commission, handling fee, or other service fee.

§ 1260.111 Producer-buyer.

"Producer-buyer" means a producer who buys cattle.

§ 1260.112 Producer-seller.

"Producer-seller" means a producer who sells cattle.

§ 1260.113 Slaughterer.

"Slaughterer" means any person who slaughters cattle, including cattle of his own production.

§ 1260.114 United States.

"United States" means the 50 States of the United States of America and the District of Columbia.

§ 1260.115 Marketing.

"Marketing" means the sale or other disposition of cattle, beef, or beef products in any channel of commerce.

§ 1260.116 Commerce.

"Commerce" means interstate, foreign, or intrastate commerce.

§ 1260.117 Producer organization or eligible organization.

"Producer organization" or "eligible organization" means any organization which has been certified by the Secretary pursuant to this order.

§ 1260.118 Producer information.

"Producer information" means facts, data, and other information that will assist producers in making decisions that lead to increased efficiency, lower cost of production, a stable supply of cattle, and the development of new markets.

§ 1260.119 Consumer information.

"Consumer information" means facts, data, and other information that will assist consumers and other persons in making evaluations and decisions regarding the purchasing, preparation, and utilization of beef and beef products.

§ 1260.120 Promotion.

"Promotion" means any action to advance the image or desirability of beef and beef products.

§ 1260.121 Research.

"Research" means any type of research to advance the desirability, marketability, production, or quality of cattle, beef, and beef products, or the evaluation of such research.

§ 1260.122 Transaction.

"Transaction" means the transfer of ownership of cattle or beef through a sale, trade, or other means of exchange.

§ 1260.123 Contracting party.

"Contracting party" means any individual, group of individuals, partnership, corporation, association, cooperative, or other entity, public or private, with which the Beef Board may enter into a contract or agreement pursuant to § 1260.146(c).

§ 1260.124 Marketing year.

"Marketing year" means the calendar year ending on December 31 or any

other consecutive 12-month period designated by the Board, with the approval of the Secretary.

§ 1260.125 Part and subpart.

"Part" means 7 CFR Part 1260, containing rules, regulations, orders, supplemental orders, and similar matters concerning the Beef Research and Information Act. "Subpart" refers to any portion or segment of this part.

BEEF BOARD

§ 1260.136 Establishment and membership.

There is hereby established a Beef Board composed of not more than 68 beef producers, each of whom shall have an alternate, appointed by the Secretary from nominations submitted by eligible producer organizations within geographic areas certified pursuant to § 1260.176 or by producers in a manner authorized by the Secretary pursuant to § 1260.138(a). Each geographic area as designated by the Secretary shall be represented by at least one member and his alternate.

§ 1260.137 Term of office.

The members of the Board and their alternates shall serve for terms of 3 years, except appointments to the initial Board shall be, proportionately, for terms of 1, 2, and 3 years. Each member and alternate member shall continue to serve until his successor is appointed by the Secretary and has accepted. No member shall serve more than 6 consecutive years: *Provided,* That those members appointed to the initial Board for 1 or 2 year terms are eligible to serve two additional consecutive terms.

§ 1260.138 Nominations.

All nominations to the Beef Board authorized under § 1260.136 shall be made in the following manner:

(a) Within 90 days of the announcement of approval of this order, unless a longer period of time is prescribed by the Secretary, nominations for each member and each alternate member to be appointed shall be submitted to the Secretary for each geographic area as specified in paragraph (d) of this section by eligible organizations, certified pursuant to §1260.176: *Provided,* That if there is no eligible organization certified for a geographic area, or if the Secretary determines that a substantial number of producers are not members or, if their interests are not represented by, any such eligible organization, then nominations shall be submitted in a manner authorized by the Secretary;

(b) After the establishment of the Board, the nominations for subsequent Board members and alternates shall be submitted to the Secretary not less than 60 days prior to the expiration of the terms of the members and alternates previously appointed to the Board;

(c) Where there is more than one eligible organization within a geographic area, they may caucus for the purpose of jointly nominating qualified persons for each member and for each alternate member to be appointed. If joint agreement is not reached with respect to any such nominations, or if no caucus is held within a defined geographic area, each eligible organization may submit to the Secretary nominations for each appointment to be made;

(d) For purposes of nominating members and their alternates to the Board, the United States shall be divided into geographic areas so as to reflect the proportion of cattle in each geographic area: *Provided,* That such designated geographic area shall be entitled to at least one member on the Board and one alternate member. The Secretary shall redefine the geographic areas if he finds, upon recommendation of the Board or otherwise, that the existing geographic area designations interfere with proper effectuation of the Act and the subpart;

(e) The initial geographic areas and the number of members and alternates on the Beef Board from each area shall be: Alabama 1, Arizona 1, Arkansas 1, Colorado 2, Florida 1, Georgia 1, Idaho 1, Illinois 2, Indiana 1, Iowa 3, Kansas 3, Kentucky 2, Louisiana 1, Michigan 1, Minnesota 2, Mississippi 1, Missouri 3, Montana 2, Nebraska 3, Nevada 1, New Mexico 1, New York 1, North Carolina 1, North Dakota 1, Ohio 1, Oklahoma 3, Oregon 1, Pennsylvania 1, South Carolina 1, South Dakota 2, Tennessee 2, Texas 7, Utah 1, Virginia 1, West Virginia 1, Wisconsin 2, Wyoming 1. Additional geographic areas, comprised of combined States, shall be: California-Hawaii 2, Washington-Alaska 1, Maryland-Dalaware-New Jersey-District of Columbia 1, Maine-Vermont-New Hampshire-Massachusetts-Rhode Island-Connecticut 1. This distribution of membership was determined based on the definition of a geographic area as a State or combination of States with 500,000 head of cattle or more. Each geographic area was entitled to one member on the Beef Board, plus one additional member for each additional 2.5 million head of cattle; and

(f) After the establishment of the Board, the geographic areas provided for in paragraph (d) of this section, including, the area distribution of members of the Board and their alternates, shall be reviewed within 5 years and at any time not to exceed 5 years from the date of the last review by the Board or by a person or agency designated by the Board to perform such review to consider cash assessments, cash receipts for cattle, cattle numbers, and other factors, and the results shall be reported to the Secretary along with any recommendations by the Board regarding whether the delineation of the areas and the area distribution of the Board should continue without change, or whether changes should be made in either the areas or the number of board members to be appointed from each area: *Provided,* That each area shall be represented by at least one Board member and any action recommended shall be subject to the approval of the Secretary.

§ 1260.139 Appointments.

From the nominations made pursuant to §§ 1260.136 and 1260.138, the Secretary shall appoint the members of the Board and an alternate for each member, on the basis of the representation provided for in §§ 1260.136, 1260.137, and 1260.138.

§ 1260.140 Acceptance.

Any person appointed by the Secretary as a member, or as an alternate member, of the Board shall notify the Secretary of his acceptance in a manner prescribed by the Secretary.

§ 1260.141 Vacancies.

To fill any vacancy occasioned by the death, removal, resignation, or disqualification of any member or alternate member of the Board, a successor for the unexpired term of such member or alternate member of the Board shall be nominated and appointed in a manner specified in §§ 1260.136, 1260.137, 1260.138 (b), and 1260.140, except that replacement of a Board member or alternate with an unexpired term of less than six months is not necessary.

§ 1260.142 Alternate members.

An alternate member of the Board, during the absence of the member for whom he is the alternate, shall act in the place and stead of such member and perform such other duties as assigned. In the event of the death, removal, resignation, or disqualification of a member, his alternate shall act for him until a successor for such member is appointed.

§ 1260.143 Procedure.

(a) A majority of the members of the Board, including alternates acting for members of the Board, shall constitute a quorum, and any action of the Board shall require the concurring votes of at least a majority of those present and voting. At assembled meetings all votes shall be cast in person.

(b) For matters which do not require deliberation and the exchange of views, and in matters of an emergency nature when there is not enough time to call an assembled meeting of the Board, the Board may also take action upon the concurring votes of a majority of its members by mail, telegraph, or telephone, but any such telephone vote shall be confirmed promptly in writing.

§ 1260.144 Compensation and reimbursement.

The members of the Board, and alternates when acting for members, shall serve without compensation but shall be reimbursed for necessary and reasonable expenses incurred by them in the performance of their duties under this subpart.

§ 1260.145 Powers of the Board.

The Board shall have the following powers:

(a) To administer the provisions of this subpart in accordance with its terms and provisions;

(b) To make rules and regulations to effectuate the terms and provisions of this order;

(c) To receive, investigate, and report to the Secretary complaints of violations of the provisions of this subpart;

(d) To appoint from its members an Executive Committee, consisting of not less than 7 or more than 11 members, with authority to employ a staff and conduct routine business within the policies determined by the Beef Board. The membership of the Executive Committee shall be broadly representative of the cattle industry and shall reflect, to the extent practicable, approximately the same proportion of cattle production by geographic location as the membership of the Beef Board itself; and

(e) To recommend to the Secretary amendments to this subpart.

§ 1260.146 Duties of the Board.

The Board shall have the following duties:

(a) To meet and organize and to select from among its members a chairman and such other officers as may be necessary, to select committees and subcommittees of Board members, to adopt such rules for the conduct of its business as it may deem advisable, and it may establish advisory committees of persons other than Board members;

(b) To prepare and submit to the Secretary for his approval budgets on a fiscal period basis of its anticipated expenses and disbursements in the administration of this subpart, including probable costs of research, information, advertising, promotion, and developmental projects, with the Board's recommendations with respect thereto. The Board shall also submit informational copies of such budgets to the House Committee on Agriculture and the Senate Committee on Agriculture and Forestry;

(c) To enter into contracts or agreements, with the approval of the Secretary, with appropriate contracting parties for the development and carrying out of the activities of the Board as authorized by § 1260.151, and for the payment of the costs thereof with funds collected pursuant to § 1260.162. Any such contract or agreement shall provide that such contracting parties shall develop and submit to the Board a plan or project, together with a budget or budgets which shall show the estimated cost to be incurred for such plan or project, and that any such plan or project shall become effective upon approval by the Secretary. Any such contract or agreement shall also provide that the contracting parties shall keep accurate records of all of their activities with respect to the contract or agreement, and make periodic reports to the Board of activities carried out and an accounting for funds received and expended, and such other reports as the Secretary or Board may require;

(d) To set aside up to 10% of net assessments from each State for use in the next fiscal year by the qualifying State beef council, beef board, or other beef promotion entity. The amount of net assessments from each State shall be computed by the Beef Board to reflect total assessments in such State less a deduction for refunds to producers in such State. Any request for funds shall be made by a State beef promotion entity which meets qualifications specified in § 1260.157, and shall be accompanied by budgets, plans, and specifications for research, information, education, and/or promotion programs for which such funds will be used, as well as a plan for reporting on how the funds were used. Approval of the request shall be based upon the apparent ability of the programs to further the purposes of the Act and this order and complement the natural research, information, education, and/or promotion efforts: *Provided,* That nothing herein shall prevent the Beef Board from entering into further contracts or agreements with any State beef promotion entity according to paragraph (c) of this section;

(e) To develop and submit to the Secretary plans or projects, together with the Board's recommendations with respect to the approval thereof by the Secretary;

(f) To maintain such books and records and prepare and submit such reports from time to time to the Secretary as he may prescribe and to make appropriate accounting with respect to the receipt and disbursement of all funds entrusted to it;

(g) To prepare and make public, at least each fiscal period, a report of activities carried out and an accounting for funds received and expended;

(h) To cause its books to be audited by a public accountant at least once each fiscal period and at such other times as the Secretary may request and to submit a copy of each such audit to the Secretary;

(i) To give the Secretary the same notice of meetings of the Board as is given to members in order that he or his representative may attend such meetings; and

(j) To submit to the Secretary such information pursuant to this subpart as he may request.

Research, Information, Education, and Promotion

§ 1260.151 Research, information, education, and promotion.

(a) The Beef Board shall in the manner prescribed in § 1260.146 establish or provide for:

(1) The establishment, issuance, effectuation, and administration of plans or projects for advertising, promotion, education, producer information, and consumer information with respect to the use of cattle, beef, and beef products and for the disbursement of necessary funds for such purposes;

(2) The establishment and carrying on of research, market development projects, and studies with respect to the production, growing, sale, processing, distribution, marketing, or utilization of cattle, beef, and beef products and the creation of new products thereof, in accordance with section 7(b) of the Act, to the end that the production, marketing, and utilization of cattle, beef, or beef products may be encouraged, expanded, improved, or made more efficient and/or acceptable and the data collected by such activities may be disseminated, and the disbursement of necessary funds for such purposes; and

(3) The development and expansion of foreign markets and uses for cattle, beef, or beef products.

(b) Each program or project authorized under paragraph (a) of this section shall be periodically reviewed or evaluated by the Board to insure that each such plan or project contributes to a coordinated program of research, information, education, and promotion. If it is found by the Board that any such program or project does not further the purposes of the Act, then the Board shall terminate such program or project.

(c) No reference to a private brand or trade name shall be made if the Secretary determines that such reference will result in undue discrimination against the cattle, beef, or beef products of other persons. No such advertising, consumer education, or sales promotion programs shall make use of false or misleading claims in behalf of cattle, beef, or beef products, or false or misleading statements with respect to quality, value, or use of any competing product.

State Beef Councils

§ 1260.156 Continuation.

Nothing in the Act or this order shall be construed to preempt, eliminate, or interfere with any beef board, beef council, or other beef promotion entity organized and operating within and by authority of any of the several States.

§ 1260.157 Qualifications.

To qualify for the receipt of funds, pursuant to § 1260.146(d), a State beef board, beef council, or other beef promotion entity shall (a) be organized pursuant to legislative authority within the State or be organized by State charter, with goals and purposes complementary to the goals and purposes of this Act and order, and (b) demonstrate ability to provide research, information, education, or promotion consistent with this Act and order. In no event shall more than one such entity qualify within a State. If more than one entity applied for qualification within a State, the Beef Board, with approval of the Secretary, shall choose the one most qualified to fulfill the purposes of this Act and order.

Expenses and Assessments

§ 1260.161 Expenses.

(a) The Board is authorized to incur such expenses as the Secretary finds are reasonable and likely to be incurred by the Board for its maintenance and functioning and to enable it to exercise its powers and perform its duties in accordance with the provisions of this subpart. The funds to cover such expenses shall be paid from assessments received pursuant to § 1260.162.

(b) The Board shall reimburse the Secretary, from producer assessments, for all the expenses and expenditures, excluding salaries, which the Secretary determines were incurred by the Government in the preparation of an original order and the conduct of the referendum considering its approval.

(c) The Board shall reimburse the Secretary, from producer assessments, for administrative costs, including salaries, incurred by the Government with respect to this subpart after the order becomes effective.

§ 1260.162 Assessments.

Each cattle producer-seller, upon sale or transfer of ownership of any cattle, except as provided below, shall pay to the producer-buyer or slaughterer thereof, pursuant to regulations issued by the Board, and such producer-buyer or slaughter shall colect from the producer-seller an assessment based on the value of the cattle involved in the transaction as follows:

(a) The Beef Board, with the approval of the Secretary, may set the amount of assessment, not to exceed five-tenths (5/10) of one percent of the sale price;

(b) The assessment rate for the first three years shall not exceed three-tenths (3/10) of one percent of the sale price;

(c) In the event that no sales transaction occurs at the point of slaughter or other transfer, a fair market value shall be attributed to the cattle for the purpose of determining the assessment;

(d) Cattle slaughtered for his own home consumption by a producer who has been the sole owner of such cattle shall not be subject to assessments provided in the Act and this order;

(e) The Beef Board may exempt or adjust the assessment value on transactions of breeding animals or classes of breeding animals until time of slaughter so as not to exceed commercial market values;

(f) Each slaughterer shall remit assessment(s) collected to the Beef Board at such times and in such manner as prescribed by regulations issued by the Board, including any assessment(s) due at time of slaughter on cattle of his own production;

(g) Failure of the slaughterer to collect the assessment(s) on each animal shall not relieve the slaughterer of his obligation to remit the assessment(s) to the Beef Board as required in this subpart;

(h) The Beef Board may collect directly from any producer any assessment(s) that he collected under the provisions of the Act and this order or otherwise due which are not passed along in the usual manner due to the loss in value of the cattle or due to the export of the cattle or due to other reasons; and

(i) The Beef Board may accumulate a reasonable reserve of approximately the average yearly collections to maintain continuity of programs and fulfill other obligations and expenses.

§ 1260.163 Producer refund.

Any producer-seller against whose cattle any assessment is made and collected from him under the authority of the Act shall have the right to demand and receive from the Beef Board a refund of such assessment upon submission of proof satisfactory to the Board that the producer-seller paid the assessment for which refund is sought. Any such demand shall be made by such producer-seller in accordance with regulations and on a form prescribed by the Board and approved by the Secretary. Such demands shall be made within 60 days after the end of the month in which the transaction occurred upon which said refund is based. Refund shall be made within 60 days after the submission of proof satisfactory to the Board that the producer-seller paid the assessment for which refund is sought: *Provided*, That no producer shall claim or receive a refund of any portion of an assessment which he collected from other producers.

§ 1260.164 Influencing governmental action.

No funds collected by the Board under this subpart shall in any manner be used for the purpose of influencing governmental policy or action except as provided in this subpart.

REPORTS, BOOKS, AND RECORDS

§ 1260.171 Reports.

Each slaughterer subject to this subpart shall be required to report to the Beef Board periodically such information as may be required by regulations established by the Board, which information may include but is not limited to the following:

(a) Number of cattle slaughtered;

(b) Total value of cattle on which assessments were collected;

(c) Number and value of cattle in each transaction on which an assessment was collected;

(d) Name and address of person(s) from whom he has collected assessment(s);

(e) Date collection was made on each transaction;

(f) Number and value of cattle slaughtered of his own production; and

(g) Number, value, and ownership of cattle slaughtered on a custom basis.

§ 1260.172 Books and records.

Each slaughterer shall maintain and make available for inspection by the Beef Board and the Secretary such books and records as are necessary to carry out the provisions of this subpart and the regulations issued thereunder, including such records as are necessary to verify any reports required. Such records shall be retained for at least two years beyond the marketing year of their applicability.

§ 1260.173 Confidential treatment.

All information obtained from such books, records, or reports required to be maintained under §§ 1260.171 and 1260.172 shall be kept confidential by all officers and employees of the Beef Board and of the Department of Agriculture, and only such information so furnished or acquired as the Secretary deems relevant shall be disclosed by them, and then only in a suit or administrative hearing brought at the direction, or upon the request, of the Secretary of Agriculture, or to which any officer of the United States is a party, and involving this subpart: *Provided, however*, That nothing in this subpart shall be deemed to prohibit (a) the issuance of general statements based upon the reports of the number of persons subject to an order or satistical data collected therefrom, which statements do not identify the information furnished by any person, (b) the publication of general statements relating to refunds made by the Beef Board during any specific period, which statements do not identify any person to whom refunds are made, or (c) the publication by direction of the Secretary of the name of any person violating any order, together with a statement of the particular provisions of the order violated by such person.

CERTIFICATION OF ORGANIZATIONS

§ 1260.176 Certification of organizations.

(a) Any cattle producer organization within a designated geographic area may request the Secretary for certification of eligibility to represent cattle producers to participate in nominating members and alternate members to represent such geographic area on the Beef Board. Such eligibility shall be based, in addition to other available information, upon a factual report submitted by the organization which shall contain information deemed relevant and specified by the Secretary for the making of such determination, including but not limited to the following:

(1) Geographic area covered by the organization's active membership;

(2) Nature and size of the organization's active membership, proportion of total of such active membership accounted for by producers of cattle, and the volume of cattle produced by the organization's active membership in each such State or applicable geographic area(s);

(3) The extent to which the cattle producer membership of such organization is represented in setting the organization's policies;

(4) Evidence of stability and permanency of the organization;

(5) Sources from which the organization's operating funds are derived;

(6) Functions of the organization; and

(7) The organization's ability and willingness to further the aims and objectives of the Act.

(b) The primary consideration in determining the eligibility of an organization shall be whether its producer membership consists of a substantial number of producers who produce a substantial volume of cattle in the geographic area subject to the provisions of this subpart. The Secretary shall certify any organization which he finds to be eligible

under this section and his determination as to eligibility shall be final.

MISCELLANEOUS

§ 1260.181 Suspension and termination.

(a) The Secretary shall, whenever he finds that this subpart or any provision thereof obstructs or does not tend to effectuate the declared policy of the Act, terminate or suspend the operation of this subpart or such provision.

(b) The Secretary may conduct a referendum at any time, and shall hold a referendum on request of 10 percent or more of the number of cattle producers voting in the referendum approving this subpart, to determine whether cattle producers favor the termination or suspension of this subpart, and the Secretary shall suspend or terminate such subpart 6 months after he determines that its suspension or termination is approved or favored by a majority of the producers of cattle voting in such referendum who, during a representative period determined by the Secretary, have been engaged in the production of cattle and who produced more than 50 percent of the volume of the cattle produced by the cattle producers voting in the referendum.

§ 1260.182 Proceedings after termination.

(a) Upon the termination of this subpart, the Beef Board shall recommend not more than five of its members to the Secretary to serve as trustees, for the purpose of liquidating the affairs of the Beef Board. Such persons, upon designation by the Secretary, shall become trustees of all of the funds and property then in the possession or under control of the Board, including claims for any funds unpaid or property not delivered or any other claim existing at the time of such termination.

(b) The said trustees shall: (1) Continue in such capacity until discharged by the Secretary; (2) carry out the obligations of the Beef Board under any contracts or agreements entered into by it pursuant to § 1260.146(c); (3) from time to time account for all receipts and disbursements and deliver all property on hand, together with all books and records of the Board and of the trustees, to such person as the Secretary may direct; and (4) upon the direction of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such person full title and right to all of the funds, property, and claims vested in the Board or the trustees pursuant to this subpart.

(c) Any person to whom funds, property, or claims have been transferred or delivered pursuant to this subpart shall be subject to the same obligation imposed upon the Beef Board and upon the trustees.

(d) Any residual funds or property not required to defray the necessary expenses of liquidation shall be turned over to the Secretary to be utilized, to the extent practicable, in the interest of continuing one or more of the beef research or information programs hitherto authorized.

§ 1260.183 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this subpart or of any regulation issued pursuant thereto, or the issuance of any amendment to either thereof, shall not:

(a) Affect or waive any right, duty, obligation, or liability which shall have arisen or which may thereafter arise in connection with any provision of this subpart or any regulation issued thereunder;

(b) Release or extinguish any violation of this subpart or any regulation issued thereunder; and

(c) Affect or impair any right or remedies of the United States, or of any person, with respect to any such violation.

§ 1260.184 Amendments.

Amendments to this subpart may be proposed, from time to time, by the Board or by an organization certified pursuant to Section 15 of the Act, or by any interested person affected by the provisions of the Act, including the Secretary.

§ 1260.185 Personal liability.

No member or alternate member of the Beef Board shall be held personally responsible, either individually or jointly with others, in any way whatsoever to any person for errors in judgment, mistakes, or other acts, either of commission or omission, of such member or alternate, except for acts of dishonesty or willful misconduct.

§ 1260.186 Separability.

If any provision of this subpart is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby.

Copies of this notice may be obtained from the Livestock Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Signed at Washington, D.C., on August 11, 1976.

RICHARD L. FELTER,
Assistant Secretary.

[FR Doc.76-24052 Filed 8-16-76;8:45 am]

[7 CFR Part 16]

LIMITATION ON IMPORTS OF MEAT

Regulations With Respect To Meat Processed in Foreign-Trade Zones

Public Law 88-482, approved August 22, 1964, 19 U.S.C. 1202 note (hereinafter referred to as the Act), provides for limiting the quantity of fresh, chilled, or frozen cattle meat (TSUS 106.10) and fresh, chilled, or frozen meat of goats and sheep, except lamb (TSUS 106.20), which may be imported into the United States in any calendar year. Such limitations are to be imposed when it is estimated by the Secretary of Agriculture that imports of such articles, in the absence of limitations during such calendar year, would equal or exceed 110 percent of the estimated quantity of such articles prescribed by Section 2(a) of the Act.

Quantitive limitations on the importation of meat classified under items 106.10 and 106.20 of the Tariff Schedules of the United States (TSUS) have not been imposed to date in calendar year 1976 because the estimates of imports of meat required to be made under the Act have not exceeded 1,233.0 million pounds, 110 per centum of the adjusted base quantity determined by the Secretary pursuant to the Act. In making such estimates for the first, second, and third quarters of 1976 the Secretary relied upon the fact that trade agreements ensuring that meat imports would not exceed 110 per centum of the adjusted base quantity would remain in effect during 1976. These agreements limit the quantity of meat classifiable under TSUS 106.10 and 106.20 which may be imported into the United States. However, information available to the United States Department of Agriculture shows that in circumvention of the Act boned frozen meat shipped from countries signatory to the trade agreements is being processed in Foreign-Trade Zones of the United States to change its form. Thus at the time of its entry into the customs territory of the United States it is no longer the type of meat described in TSUS item 106.10 despite the fact that it has merely been ground, shredded, flaked or chunked and repackaged in 60 pound bags before being entered.

This meat processing operation permits greater quantities of fresh, chilled or frozen beef and veal to enter the commerce of the United States than was intended by the Meat Import Law and the trade agreements. Through July 31 approximately 21.3 million pounds of foreign beef have entered warehouses for processing in the Foreign-Trade Zone at Mayaguez, Puerto Rico. Reports from trade sources indicate another 10 million pounds is in the processing stages at Mayaguez and that 26 million pounds of meat has been contracted for delivery at Mayaguez through the end of September. Including current contracts the total quantity of boneless beef estimated to be imported through the one existing processing plant in the Foreign-Trade Zone in Mayaguez in 1976 will be about 60 million pounds. A second plant is expected to become operational within the next few weeks. As a result, imports of meat this year through the Foreign-Trade Zone at Mayaguez could reach at least 70 million pounds.

Such meat is being delivered into the Foreign-Trade Zone at prices as much as one-third less than prices for comparable manufacturing type meat entering the customs territory of the United States directly from supplying countries. Moreover, application has been made to the Foreign-Trade Zones Board to estab-

lish two special zone sites for processing meat in Metairie, Louisiana, and New Orleans, Louisiana. The application states the plants intend to process some 32 to 35 million pounds of such meat per year.

The Secretary of Agriculture is authorized under section 2(e) of the Act to issue such regulations as he determines to be necessary to prevent circumvention of the purposes of the Act. Notice is hereby given that the Secretary of Agriculture is considering the issuance of a regulation pursuant to this authority in order to prevent circumvention of the purposes of the Act through the processing of meat in the Foreign-Trade Zones. Under this regulation, in the administration of the Act and the trade agreements, any meat which is processed in a Foreign-Trade Zone from foreign meat which, if it were entered into the customs territory of the United States in the form in which it was brought into the Foreign-Trade Zone, would be classifiable as TSUS item 106.10, shall be treated for the purposes of the Act and the trade agreements as being classifiable under TSUS item 106.10 when entered, or withdrawn from warehouse, into the customs territory of the United States.

It is proposed that, if this regulation is placed in effect, the provisions thereof will be made applicable to any meat brought into a Foreign-Trade Zone subsequent to September 17, 1976.

All persons who desire to submit written data, views or arguments for consideration in connection with this proposal should file the same in duplicate, not later than September 16, 1976, with the Administrator, Foreign Agricultural Service, USDA, Room 5073, South Agriculture Building, 14th and Independence, Washington, D.C. 20250. All material received will be available for public inspection in Room 6621, South Agriculture Building, 14th and Independence, Washington, D.C., during the official hours of business 8:30 a.m. to 5:00 p.m., Monday through Friday. All material received on or before September 16, 1975 will be considered.

It is proposed that 7 CFR, Subtitle A-Office of the Secretary of Agriculture, Part 16, be amended by adding a new Subpart "Meat Import Law Regulations," as follows:

Subpart—Meat Import Law Regulations

§ 16.20 Meat processed in Foreign-Trade Zones.

Any meat which is processed in a Foreign-Trade Zone from foreign meat, which if it were entered into the customs territory of the United States in the form in which it was brought into the Foreign-Trade Zone would be classifiable as TSUS item 106.10, shall be treated for the purposes of Meat Import Law, P.L. 88-482 (19 U.S.C. 1202 note), and the trade agreements entered into by the United States with the supplying countries of such meat pursuant to section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), as being classifiable under TSUS item 106.10 when entered, or withdrawn from warehouse, into the customs territory of the United States. The section shall be applicable to any foreign meat brought into a Foreign-Trade Zone subsequent to September 17, 1976).

(Sec. 2, Pub. L. 88-482 (19 U.S.C. 1202 note).)

Issued at Washington, D.C. this 14th date of August, 1976.

EARL L. BUTZ,
Secretary of Agriculture.

[FR Doc.76-24261 Filed 8-16-76;9:30 am]

ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION

[10 CFR Part 705]

PROTECTION OF HUMAN SUBJECTS

Proposed Regulations

This notice offers interested parties an opportunity to comment on a proposed regulation relating to the protection of human subjects in research, development, and related activities supported by Energy Research and Development Administration (ERDA) agreements including, but not limited to, grants and contracts.

The policies and procedures provided by the proposed regulation are substantially the same as those adopted by the Department of Health, Education, and Welfare for the protection of human subjects (40 FR 11854, March 13, 1975). The proposed regulation provides that safeguarding the rights and welfare of human subjects in research activities supported by ERDA agreements, including grants and contracts, is primarily the responsibility of the institution which receives, or is accountable to ERDA for, the funds awarded for support of the activity. In general, the adequate discharge of this institutional responsibility requires that no activity within the United States and its territories that will be supported by ERDA funds and that will involve human subjects at risk shall be undertaken unless an Institutional Review Board has reviewed and approved such activity, and the institution has submitted to ERDA a certification of such review and approval.

Interested parties should submit their written comments concerning this proposed regulation to the Director, Division of Biomedical and Environmental Research, U.S. Energy Research and Development Administration, Washington, D.C. 20545, on or before October 18, 1976.

Dated at Washington, D.C., this 10th day of August, 1976.

JAMES L. LIVERMAN,
Assistant Administrator for Environment and Safety.

The proposed regulationi s as follows:

PART 705—PROTECTION OF HUMAN SUBJECTS

Sec.

705.1 Applicability.
705.2 Policy.
705.3 Definitions.
705.4 Submission of assurances.
705.5 Types of assurances.
705.6 Minimum requirements for general assurances.
705.7 Minimum requirements for special assurances.
705.8 Evaluation and disposition of assurances.
705.9 Obligation to obtain informed consent; prohibition of exculpatory clauses.
705.10 Documentation of informed consent.
705.11 Submission and certification of applications and proposals—general assurances.
705.12 Submission and certification of applications and proposals—special assurances.
705.13 Applications and proposals lacking definite plans for involvement of human subjects.
705.14 Applications and proposals submitted with the intent of not involving human subjects.
705.15 Evaluation and disposition of applications and proposals.
705.16 Cooperative activities.
705.17 Investigation new drug 30-day delay requirement.
705.18 Institution's executive responsibility.
705.19 Institution's records; confidentiality.
705.20 Reports.
705.21 Early termination of awards; evaluation of subsequent applications proposals.
705.22 Conditions.

AUTHORITY: Sec. 105(a) Energy Reorganization Act of 1974, Public Law 93-438.

§ 705.1 Applicability.

(a) The regulations in this part are applicable to all Energy Research and Development Administration (ERDA) agreements including, but not limited to, grants and contracts supporting research, development, and related activities within the United States and its territories in which human subjects are involved.

(b) For agreements supporting activities outside the United States and its territories in which human subjects are involved, the requirements of this part shall apply to the maximum extent practicable as determined by the Administrator on a case-by-case basis, taking into account the relevant laws and practices of the foreign nation in which the activity will be conducted.

(c) The Administrator may, from time to time, determine in advance whether specific programs, methods, or procedures to which this part is applicable place subjects at risk, as defined in § 705.3(b). Such determinations will be published as notices in the FEDERAL REGISTER and will be included in an appendix to this part.

§ 705.2 Policy.

(a) Safeguarding the rights and welfare of subjects at risk in activities supported under ERDA agreements is primarily the responsibility of the institution which receives, or is accountable to ERDA for, the funds awarded for the support of the activity. In order to provide for the adequate discharge of this institutional responsibility, it is the policy of ERDA that no activity involving human subjects within the United States

and its territories to be supported by ERDA agreements shall be undertaken unless an Institutional Review Board has reviewed and approved such activity, and the institution has submitted to ERDA a certification of such review and approval, in accordance with the requirements of this part.

(b) This review shall determine whether these subjects will be placed at risk, and, if risk is involved, whether:

(1) the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;

(2) the rights and welfare of any such subjects will be adequately protected;

(3) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part; and

(4) the conduct of the activity will be reviewed at timely intervals.

(c) No agreement involving human subjects at risk shall be awarded to an individual unless he is affiliated with or sponsored by an institution which can and does assume responsibility for the subjects involved.

§ 705.3 Definitions.

(a) "Institution" means any public or private institution or agency (including Federal, State, and local government agencies).

(b) "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

(c) "Informed consent" means the knowing consent of an individual or his legally authorized representative so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) a description of any attendant discomforts and risks reasonably to be pected;

(3) a description of any benefits reasonably to be expected;

(4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) an offer to answer any inquiries concerning the procedures; and

(6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

(d) "ERDA" means the Energy Research and Development Administration.

(e) "Administrator" means the Administrator of ERDA or any other officer or employee of ERDA to whom authority has been delegated.

(f) "Agreement" means a grant, contract, cooperative agreement, or any other instrument under which ERDA provides funds or other resources for projects or efforts involving human subjects.

(g) "Approved assurance" means a document that fulfills the requirements of this part and is approved by the Administrator.

(h) "Certification" means the official institutional notification to ERDA in accordance with the requirements of this part that a project or activity involving human subjects at risk has been reviewed and approved by the institution in accordance with the "approved assurance" on file at ERDA.

(i) "Legally authorized representative" means an individual or judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

§ 705.4 Submission of assurances.

(a) Recipients or prospective recipients of ERDA support under any agreement involving subjects at risk shall provide written assurance acceptable to ERDA that they will comply with ERDA policy as set forth in this part. Each assurance shall embody (1) A statement of compliance with ERDA requirements for initial and continuing Institutional Review Board review of the supported activities; and (2) A set of implementing guidelines, including identification of the Board and a description of its review procedures; or, in the case of special assurance concerned with single activities or projects, a report of initial findings of the Board and of its proposed continuing review procedures.

(b) Such assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this part, and shall be filed in such form and manner as the Administrator may require.

§ 705.5 Types of assurances.

(a) *General assurances.* A general assurance describes the review and implementation procedures applicable to all ERDA-supported activities conducted by an institution, regardless of the number, location, or types of its components or field activities. General assurances will be required from institutions having a significant number of concurrent ERDA-supported projects or activities involving human subjects.

(b) *Special assurances.* A special assurance will, as a rule, describe those review and implementation procedures applicable to a single activity or project. A special assurance will not be solicited or accepted from an institution which has on file with ERDA an approved general assurance.

§ 705.6 Minimum requirements for general assurances.

General assurances shall be submitted in such form and manner as the Administrator may require. The institution must include, as part of its general assurance, implementing guidelines that specifically provide for:

(a) A statement of principles which will govern the institution in the discharge of its repsonsibilities for protecting the rights and welfare of subjects. This may include appropriate existing codes or declarations, or statements formulated by the institution itself. It is to be understood that no such principles supersede ERDA policy or applicable law.

(b) An Institutional Review Board or Board structure which will conduct initial and continuing reviews in accordance with the policy outlined in § 705.2. Such a Board or Board structure shall meet the following requirements:

(1) The Board must be composed of not less than five persons with varying backgrounds to assure complete and adequate review of activities commonly conducted by the institution. The Board must be sufficiently qualified through the maturity, experience, and expertise of its members, and diversity of its membership, to insure respect for its advice and counsel for safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the Board must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. The Board must, therefore, include persons whose conerns are in these areas.

(2) The Board members shall be identified to ERDA by name; earned degrees, if any; position or occupation; representative capacity; and by other pertinent indications of experience, such as board certification, licenses, etc., sufficient to describe each member's chief anticipated contributions to Board deliberations. Any employment or other relationship between each member and the institution shall be identified, i.e., full-time employee, part-time employee, member of governing panel or board, paid consultant, or unpaid consultant. Changes in Board membership shall be reported to ERDA in such form and at such times as the Administrator may require.

(3) No member of a Board shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to provide information requested by the Board.

(4) No Board shall consist of a majority of persons who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the Board.

(5) No Board shall consist entirely of members of a single professional group.

(6) The quorum of the Board shall be defined, but may in no event be less than a majority of the total membership duly convened to carry out the Board's re-

sponsibilities under the terms of the assurance.

(c) Procedures which the institution will follow in its initial and continuing review of applications, proposals, and activities.

(d) Procedures which the Board will follow: (1) To provide advice and counsel to activity directors and investigators with regard to the Board's actions, (2) To insure prompt reporting to the Board of proposed changes in an activity, and of unanticipated problems involving risk to subjects or others, and (3) To insure that any such problems, including adverse reactions to biologicals, drugs, radioisotope-labelled drugs, or to medical devices, are promptly reported to ERDA.

(e) Procedures which the institution will follow to maintain an active and effective Board and to implement its recommendations.

§ 705.7 Minimum requirements for special assurances.

Special assurances shall be submitted in such form and manner as the Administrator may require. An acceptable special assurance shall:

(a) Identify the specific agreement involved by its full title and by the name of the activity or project director, principal investigator, fellow, or other person immediately responsible for the conduct of the activity.

(b) Include a statement, executed by an appropriate institutional official, indicating that the institution has established an Institutional Review Board satisfying the requirements of § 705.6(b).

(c) Describe the makeup of the Board and the training, experience, and background of its members as required by § 705.6(b)(2).

(d) Describe, in general terms, the risks to subjects that the Board recognizes as inherent in the activity, and justify its decision that these risks are so outweighed by the sum of the benefit to the subject, and the importance of the knowledge to be gained, as to warrant the Board's decision to permit the subject to accept these risks.

(e) Describe the informed consent procedures to be used, and attach documentation as required by § 705.10.

(f) Describe procedures which the Board will follow to insure prompt reporting to the Board of proposed changes in the activity, and of any unanticipated problems involving risks to subjects or others, to insure that any such problems, including adverse reactions to biologicals, drugs, radioisotope-labelled drugs, or to medical devices, are promptly reported to ERDA.

(g) Indicate at what time intervals the Board will meet to provide for continuing review. Such review must occur no less than annually.

(h) Be signed by the individual members of the Board and be endorsed by an appropriate institutional official.

§ 705.8 Evaluation and disposition of assurances.

(a) All assurances submitted in accordance with §§ 705.6 and 705.7 shall be evaluated by the Administrator through such officers and employees of ERDA as he determines to be appropriate. The Administrator's evaluation shall take into consideration, among other pertinent factors, the adequacy of the proposed Institutional Review Board in light of the anticipated scope of the applicant institution's activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(b) On the basis of his evaluation of an assurance, pursuant to paragraph (a) of this section, the Administrator shall (1) Approve, (2) Enter into negotiations to develop a more satisfactory assurance, or (3) Disapprove. With respect to approved assurances, the Administrator may determine the period during which any particular assurance or class of assurances shall remain effective or otherwise condition or restrict his approval. With respect to negotiations, the Administrator may, pending completion of negotiations for a general assurance, require an institution, otherwise eligible for such an assurance, to submit special assurances.

§ 705.9 Obligation to obtain informed consent; prohibition of exculpatory clauses.

Any institution proposing to place any subject at risk is obligated to obtain and document legally effective informed consent. No such informed consent, oral or written, obtained under an assurance provided pursuant to this part shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, including any release of the institution or its agents from liability for negligence.

§ 705.10 Documentation of informed consent.

The actual procedure utilized in obtaining legally effective informed consent and the basis for Institutional Review Board determinations that the procedures are adequate and appropriate shall be fully documented. The documentation of consent will employ one of the following three forms:

(a) Provision of a written consent document embodying all of the basic elements of informed consent. This may be read to the subject or to his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or his legally authorized representative. Sample copies of the consent form, as approved by the Board, are to be retained in its records.

(b) Provision of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his legally authorized representative. Written summaries of what is to be said to the patient are to be approved by the Board. The short form is to be signed by the subject or his legally authorized representative and by an auditor witness to the oral presentation and to the subject's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent and by the auditor witness. Sample copies of the consent form and of the summaries as approved by the Board are to be retained in its records.

(c) Modification of either of the primary procedures outlined in paragraphs (a) and (b) of this section. Granting of permission to use modified procedures imposes additional responsibility upon the Board and the institution to establish: (1) That the risk to any subject is minimal, (2) That use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and (3) That any reasonable alternative means for attaining these objectives would be less advantageous to the subjects. The Board's reasons for permitting the use of modified procedures must be individually and specifically documented in the minutes and in reports and Board actions to the files of the institution. All such modifications should be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation, as appropriate.

§ 705.11 Submission and certification of applications and proposals—general assurances.

(a) *Timely review.* Any institution having an approved general assurance shall indicate in each application or proposal for support of activities covered by this part (or in a separate document submitted with such application or proposal) that it has on file with ERDA such an assurance. In addition, unless the Administrator otherwise provides, each such application or proposal must be given review and, when found to involve subjects at risk, approval, prior to submission to ERDA. In the event the Administrator provides for the performance of institutional review of an application or proposal after its submission to ERDA, processing of such application or proposal by ERDA will under no circumstances be completed until such institutional review and approval has been certified. Except where the institution determines that human subjects are not involved, the application or proposal should be appropriately certified in the spaces provided on forms, or one of the following certifications, as appropriate, should be typed on the lower or right-hand margin of the page bearing the name of an official authorized to sign or execute applications or proposals for the institution.

Human Subjects: Reviewed, Not at Risk

(Date)

Human Subjects: Reviewed, at Risk, Approved.

(Date)

(b) *Applications and proposals not certified.* Applications and proposals not properly certified, or submitted as not involving human subjects and found by the operating agency to involve human subjects, will be returned to the institution concerned.

§ 705.12 Submission and certification of applications and proposals, special assurances.

(a) Except as provided in paragraph (b) of this section, institutions not having an approved general assurance shall submit in or with each application or proposal for support of activities covered by this part a separate special assurance and certification of its review and approval.

(b) If the Administrator so provides, the assurance which must be submitted in or with the application or proposal under paragraph (a) of this section need satisfy only the requirements of § 705.7(a) and (b) of this Part. Under such circumstances, processing of such application or proposal by ERDA will not be completed until a further assurance satisfying the remaining requirements of § 705.7 has been submitted to ERDA.

(c) An assurance and certification prepared in accordance with this part and approved by ERDA shall be considered to have met the requirement for certification for the initial agreement period concerned. If the terms of the agreement recommend additional support periods, each application or proposal for continuation or renewal of support must satisfy the requirements of this section or 705.11, whichever is applicable at the time of its submission.

§ 705.13 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications or proposals are submitted with the knowledge that subjects are to be involved within the support period, but definite plans for this involvement would not normally be set forth in the application or proposal. These include such activities as (a) Institutional-type grants where selection of projects is the responsibility of the institution, (b) Training grants where training projects remain to be selected, and (c) Research, pilot, or developmental studies in which involvement depends upon such things as the completion of instruments, or of prior animal studies, or upon the purification of compounds. Such applications or proposals shall be reviewed and certified in the same manner as more definitive applications or proposals. The initial certification indicates institutional approval of the applications or proposals as submitted and commits the institution to later review of the plans when completed. Such later review and certification to ERDA should be completed prior to the beginning of the budget period during which actual involvement of human subjects is to begin. Review and certification to ERDA must in any event be completed prior to involvement of human subjects.

§ 705.14 Applications and proposals submitted with the intent of not involving human subjects.

If an application or proposal does not anticipate involving or intend to involve human subjects, no certification should be included with the initial submission of the application or proposal. In those instances, however, when later it becomes appropriate to use all or part of awarded funds for one or more activities which will involve subjects, each such activity shall be reviewed and approved in accordance with the assurance of the institution prior to the involvement of subjects. In addition, no such activity shall be undertaken until the institution has submitted to ERDA: (a) A certification that the activity has been reviewed and approved in accordance with this part, and (b) A detailed description of the proposed activity (including any protocol, revised statement of work or similar document). Also, where support is provided by project grants or contracts, subjects shall not be involved prior to certification and institutional receipt of ERDA approval and, in the case of contracts, prior to negotiation and formal amendment of the contract statement of work.

§ 705.15 Evaluation and disposition of applications and proposals.

(a) Notwithstanding any prior review, approval, and certification by the institution, all applications or proposals submitted to ERDA involving human subjects at risk shall be evaluated by the Administrator for compliance with this part through such officers and employees of ERDA as he determines to be appropriate. This evaluation may take into account, among other pertinent factors, the apparent risks to the subjects, the adequacy of protection against these risks, the potential benefits of the activity to the subjects and to others, and the importance of the knowledge to be gained.

(b) Disposition. On the basis of his evaluation of an application or proposal, pursuant to paragraph (a) of this section, and subject to such approval or recommendation by or consultation with appropriate councils, committees, or other bodies as may be required by law, the Administrator shall (1) Approve, (2) Defer for further evaluation, or (3) Disapprove support of the proposed activity in whole or in part. With respect to any grant or contract award or other agreement, the Administrator may impose conditions, including restrictions on the use of certain procedures or certain subject groups, or requiring use of specified safeguards or informed consent procedures when in his judgment such conditions are necessary for the protection of human subjects.

§ 705.16 Cooperative activities.

Cooperative activities are those which involve institutions in addition to the institution having an agreement with ERDA (herein referred to as, though not limited to, a grantee or prime contractor). Examples of cooperative activities are those of a contractor under a grantee or of a subcontractor under a prime contractor. If, in such instances, the grantee or prime contractor obtains access to all or some of the subjects involved through one or more cooperating institutions, the basic ERDA policy applies and the grantee or prime contractor remains responsible for safeguarding the rights and welfare of the subjects.

(a) *Institutions with approved general assurances.* Initial and continuing review by the institution may be carried out by one or a combination of procedures:

(1) *Cooperating institution with approved general assurance.* When the cooperating institution has on file with ERDA an approved general assurance, the grantee or prime contractor may, in addition to its own review, request the grantee or prime contractor may, in independent review, and to report its recommendations on those aspects of the activity that concern individuals for whom the cooperating institution has responsibility under its own assurance to the grantee's or prime contractor's Institutional Review Board. The grantee or prime contractor may, at its discertion, concur with or further restrict the recommendations of the cooperating institution. It is the responsibility of the grantee or prime contractor to maintain communication with the Boards of the cooperating institution. However, the cooperating institution shall promptly notify the grantee or contracting institution whenever the cooperating institution finds the conduct of the project or activity within its purview to be unsatisfactory.

(2) *Cooperating institution with no approved general assurance.* When the cooperating institution does not have an approved general asusrance on file with ERDA, ERDA may require the submission of a general or special assurance which, if approved, will permit the grantee or prime contractor to follow the procedure outlined in the preceding subparagraph.

(3) *Interinstitutional joint review.* The grantee or prime contracting institution may wish to develop an agreement with cooperating institutions to provide for an Institutional Review Board with representatives from cooperating institutions. Representatives of cooperating institutions may be appointed as ad hoc members of the grantee or contracting institution's existing Institutional Review Board or, if cooperating is on a frequent or continuing basis, as between a medical school and a group of affiliated hospitals, appointments for extended periods may be made. All such cooperative arrangements must be approved by ERDA as part of a general assurance, or as an amendment to a general assurance.

(b) *Institutions with special assurances.* While responsibility for initial and continuing review necessarily lies with the grantee or prime contracting insti-

tution, ERDA may also require approved assurance from those cooperating institutions having immediate responsibility for subjects. If the cooperating institution has on file with ERDA an approved general assurance, the grantee or prime contractor shall request the cooperating institution to conduct its own independent review of those aspects of the project or activity which will involve human subjects for which it has responsibility. Such a request shall be in writing and should provide for direct notification of the grantee's or pmime contractor's Institutional Review Board in the event that the cooperating institution's Board finds the conduct of the activity to be unsatisfactory. If the cooperating institution does not have an approved general assurance on file with ERDA, it must submit to ERDA a general or special assurance which is determined by ERDA to comply with the provisions of this part.

§ 705.17 Investigational new drug 30-day delay requirement.

Where an institution is required to prepare or to submit a certification under §§ 705.11, 705.12, 705.13, or 705.14, and the application or proposal involves an investigational new drug within the meaning of The Food, Drug, and Cosmetic Act, the drug shall be identified in the certification, together with a statement that the 30-day delay required by 21 CFR 312.1(a)(2) has elapsed and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects; or that the Food and Drug Administration has waived the 30-day delay requirement; provided, however, that in those cases in which the 30-day delay interval has neither expired nor been waived, a statement shall be forwarded to ERDA upon such expiration, or upon receipt of a waiver. No certification shall be considered acceptable until such statement has been received.

§ 705.18 Institution's executive responsibility.

Specific executive functions to be conducted by the institution include policy development and promulgation and continuing indoctrination of personnel. Appropriate administrative assistance and support shall be provided for the Board's functions. Implementation of the Board's recommendations through appropriate administrative action and follow-up is a condition of ERDA approval of an assurance. Board approvals, favorable actions, and recommendations are subject to review and to disapproval or further restriction by the institution officials. Board disapprovals, restrictions, or conditions cannot be rescinded or removed except by action of a Board described in the assurance approved by ERDA.

§ 705.19 Institution's records; confidentiality.

(a) Copies of all documents presented, or required for initial and continuing review by the Institutional Review Board, and documents such as Board minutes, records of subject's consent, transmittals on actions, instructions, and conditions resulting from Board deliberations addressed to the activity director, are to be retained by the institution permanently unless permission is obtained from the Administrator to destroy specific records. Upon termination of the life of the Institution, the foregoing documents will be transferred to ERDA for further retention.

(b) Except as otherwise provided by law, information in the records or possession of an institution acquired in connection with an activity covered by this part, which information refers to or can be identified with a particular subject, may not be disclosed except:

(1) with the consent of the subject or his legally authorized representative; or

(2) as may be necessary for the Administrator to carry out his responsibilities under this part.

§ 705.20 Reports.

Each institution with an approved assurance shall provide the Administrator with such reports and other information as the Administrator may, from time to time, prescribe.

§ 705.21 Early termination of awards; evaluation of subsequent applications and proposals.

(a) If, in the judgment of the Administrator, an institution has failed materially to comply with the terms of this policy with respect to a particular ERDA agreement, he may require that said agreement be terminated or suspended in the manner prescribed in applicable regulations.

(b) In evaluating applications or proposals for support of activities covered by this part, the Administrator may take into account, in addition to all other eligibility requirements and program criteria, such factors as: (1) Whether the applicant or offeror has been subject to a termination or suspension under paragraph (a) of this section, (2) Whether the applicant, offeror, or the person who would direct the scientific and technical aspects of an activity has, in the judgment of the Administrator, failed materially to discharge his, her, or its responsibility for the protection of the rights and welfare of subjects in his, her, or its care (whether or not ERDA funds were involved, and (3) Whether, where past deficiencies have existed in discharging such responsibility, adequate steps have, in the judgment of the Administrator, been taken to eliminate these deficiencies.

§ 705.22 Conditions.

The Administrator may, with respect to any agreement or any class of agreements, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary for the protection of human subjects.

[FR Doc.76-23919 Filed 8-16-76;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 600-2]

STATE OF CALIFORNIA

Approval and Promulgation of Implementation Plans; Revision to Great Basin Unified Air Pollution Control District Rules and Regulations

On April 21, 1976, the State of California submitted to the Regional Administrator, Region IX, a revision of the Great Basin Unified Air Pollution Control District Regulation II—Permits. As revised, Great Basin Unified Air Pollution Control District Regulation II, Rules 200-216, will provide a procedure by which persons who wish to construct, modify or operate any article, machine, equipment, or other contrivance that may cause the issuance of air contaminants may be granted a permit to do so. A permit shall not be granted, however, if it is determined that such construction, modification, or operation would interfere with the attainment or maintenance of a National Ambient Air Quality Standard.

The State of California has submitted proof that this revision to its State Implementation Plan was adopted after a public hearing was held on March 10, 1976, in Bishop, California, after notice conforming to 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of Implementation Plans, was given.

The decision of the Administrator to approve or disapprove the proposed revision to the State Implementation Plan will be based on whether or not it meets the requirements of Clean Air Act section 110(a)(2)(A)-(H), the requirements of 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of Implementation Plans, and particularly 40 CFR 51.18.

This notice is to advise the public of receipt of this proposal and to request public comments. Copies of the proposed revision are available for public inspection during regular business hours at:

Environmental Protection Agency Region IX, Enforcement Division, 100 California Street, San Francisco, CA 94111.

State of California, Air Resources Board, 1709 11th Street, Sacramento, CA 95814.

Great Basin Unified Air Pollution Control District, 192C East Line Street, Bishop, CA 93514.

Public Information Reference Unit, Room 2922, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

Interested persons may participate in the rulemaking process by submitting written comments to Regional Administrator, attention: Enforcement Division, EPA, Region IX, 100 California Street, San Francisco, California 94111. Relevant comments received on or before September 16, 1976, will be considered. Comments received will be available for inspection during normal working hours at

the Region IX office and at the EPA Public Information Reference Unit.

This notice is issued under the authority of section 110 of the Clean Air Act, as amended (42 U.S.C. 1857c–5).

Dated: August 6, 1976.

L. RUSSELL FREEMAN,
Acting Regional Administrator,
Region IX, EPA.

[FR Doc.76-24087 Filed 8-16-76;8:45 am]

FEDERAL ENERGY OFFICE

[10 CFR Part 205]

CIVIL AND CRIMINAL PENALTY REGULATIONS

Proposed Definition of "Notice of Noncompliance"; Public Hearing and Request for Public Comments

The Energy Policy and Conservation Act ("EPCA"), which was enacted into law on December 22, 1975, among other things amended Section 5 of the Emergency Petroleum Allocation Act of 1973 ("EPAA") so as to increase substantially the penalties applicable to violations of the Federal Energy Office's mandatory price and allocation regulations. Included within those new penalty provisions was a provision, now contained in section 5(a)(4) of the EPAA which makes individual directors, officers or agents of corporations subject to the same penalties as the corporation if they have "knowingly and willfully" authorized, ordered or performed any act or practice that constitutes a violation. However, section 5(a)(4) limits a corporate official's liability for imprisonment to those cases where he also has knowledge, or reasonably should have known, of "notice of noncompliance" received by the corporation from the FEO. There is nothing in the legislative history of the EPCA that elucidates congressional intent regarding precisely what constitutes "notice of noncompliance."

On January 15, 1976, the Federal Energy Administration issued a notice of proposed rulemaking that proposed amending FEA's existing civil and criminal penalty regulations to conform them to the provisions of section 5(a). (41 FR 2249, January 15, 1976.) In that Notice, FEA proposed to define "notice of noncompliance" as "any written notice that the FEA believes the corporation to be acting in violation of the provisions of this chapter * * * or any order issued pursuant thereto, and shall include, but not be limited to a notice of probable violation * * *, a remedial order * * * or a consent order * * *."

Many comments received in response to the notice of proposed rulemaking disagreed with the FEA definition of "notice of noncompliance." The disagreement focused on FEA's inclusion of notices of probable violation ("NOPVs") or other pre-remedial order written notices as "notices of noncompliance" sufficient to trigger a corporate director's, officer's or agent's liability for imprisonment. FEA carefully evaluated the merits of the points raised by the commentators, but concluded that the comments "reflect a misunderstanding of the notice requirement" incorporated in the statute and adopted the notice definition contained in the Notice of Proposed Rulemaking.

This definition continues to be controversial, however. The principal objection raised is that the present regulations in effect require corporate officials to alter their corporation's operations to conform them to the interpretation given in an NOPV, even though the agency itself has not yet made any official determination that the NOPV correctly interprets FEO regulations, and that, if the agency does later determine that the NOPV was correct, any failure to make such alterations at the NOPV stage will subject the official to possible imprisonment for willfully violating FEO regulations. Notwithstanding the fact that the preamble to the notice adopting the final rule made it clear that the FEO does not intend to refer to the Department of Justice for criminal prosecution those cases where the official involved believes in good faith that the NOPV was erroneously issued and makes every reasonable effort to challenge it, the critics of the regulation have continued to object to the fact that this approach seems to leave the decision to prosecute entirely to the discretion of federal prosecutors, who may or may not in a particular case follow what is apparently non-binding language of the preamble.

There is some question as to whether and the extent to which FEO's civil and criminal penalty regulations themselves have any binding effect, since the statutory language is obviously controlling over the regulation language in the event there is any conflict between them. This is particularly so here, where the statute would be effective standing alone and does necessarily require the promulgation of regulations to give it meaning or effectiveness. Moreover, the ultimate decision as to whether to prosecute a particular criminal case is the Department of Justice's, not the FEO's, and it is doubtful that FEO regulations embellishing upon the terms of the statute have any binding effect on that agency, which ordinarily possesses great discreation in determining whether to prosecute actions technically constituting violations of a criminal statute. The FEO has had civil and criminal penalty regulations in effect since the beginning of the mandatory allocation and price control program, however, because of its view that such regulations would give some useful guidance to the public as to how the FEO, at least, interprets and intends to apply the statutory penalty provisions.

With this limited function of FEO regulations in this area in mind, the FEO has decided to reopen the recent rulemaking on civil and criminal penalties and propose three alternative courses of action. The first option, and the only one for which it is necessary to propose express regulatory language, would revise the current regulations to make it clear in the regulations themselves the FEO's policy that it will not recommend to the Department of Justice that it seek the imprisonment of an individual corporate officer, director or agent in any case in which that officer, director or agent has failed to conform his company's conduct to FEO regulations as interpreted in an NOPV or other pre-remedial order notice which he believes to have been erroneously issued and makes a good faith effort to challenge it. The proposed modification provides explicitly that a pre-remedial order notice will be used as the basis for referring a corporate official for prosecution leading to possible incarceration only where there is compelling evidence that the official had knowingly caused or authorized the continuation of an unlawful act after receipt of such notice and knew or had reason to know that the activity in question was a violation of a regulation whose meaning was clearly established. Moreover, in order to trigger the liability of individual corporate officials to imprisonment, the pre-remedial order notice will be required to state expressly that FEO believes the meaning of the regulation alleged to be violated has been clearly established, the basis for that belief, and the fact that continuation of the violation after receipt of the notice could subject corporate officials responsible for continuation of the violation to imprisonment, as well as to the other applicable civil and criminal penalties.

The second alternative upon which comments are solicited is to leave the regulations as they now are, thus giving the FEO the maximum amount of flexibility available under the statute to assure that potential imprisonment of corporate officials is an effective deterrent to willful violations of FEA regulations. If the FEO adopts this course, it would also reconfirm the expressions of policy made by it in preambles to the rulemaking in which the current regulation was adopted.

The third alternative is to amend the current regulations to provide that imprisonment of corporate officials will not be considered by FEO, for purposes of making referrals to the Department of Justice, to be triggered under section 5(a)(4) by any written notice other than a remedial order or consent order. The amendment would be accomplished merely by defining "notice of noncompliance" as a consent order or remedial order.

The fact that the FEO is proposing specific regulatory language for only the first of the three alternatives is because it is believed to be the only one of the three options concerning which the language itself might be controversial, and should not be viewed as an indication that the FEO has a tentative preference for that option.

Interested persons are invited to submit written data, views, or arguments with respect to these amendments to Executive Communications, Room 3309, Federal Energy Office, Box IG, the Federal Building, Washington, D.C. 20461. Comments should be identified on the outside of the envelope and on the documents submitted to the Federal Energy

Office with the designation "Notice of Noncompliance." Fifteen (15) copies should be submitted. All comments received by 4:30 p.m., August 27, 1976, will be considered by the Federal Energy Office in evaluating the revisions and amendments.

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 FEO reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

A public hearing will be held at 9:30 a.m. on September 1, 1976, and will be continued, if necessary, on September 2, 1976, in Room 2105, 2000 M Street, NW., Washington, D.C.

Any person who has an interest in the subject matter of the hearing, or who is a representative of a group or class of persons that has such an interest, may make a written request for an opportunity to make an oral presentation. Such a request should be directed to Executive Communications, FEO, and must be received before 4:30 p.m., August 25, 1976.

Such a request may be hand delivered to Room 3309, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C., between the hours of 8 a.m., and 4:30 p.m., Monday through Friday. 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 that has 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 August 31, 1976. Each person selected to be heard will be so notified by FEO before 4:30 p.m., e.d.t., August 27, 1976, and must submit 100 copies of his or her statement to the Assistant General Counsel for Compliance, FEO, Room 5308, 2000 M Street, NW., Washington, D.C. before 4:30 p.m., e.d.t., on August 31, 1976

FEO 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 FEO 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. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if 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 persons may submit questions, to be asked of any person making a statement at the hearings, to Executive Communications, FEO, before 4:30 p.m., e.d.t., August 31, 1976. Any person who wishes to ask a question at the hearings may submit the question, in writing, to the presiding officers. FEO or the presiding officer, if the question is submitted at the hearings, will determine whether the question is relevant, and whether the time limitations permit it to be presented for answer.

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

A transcript of the hearings will be made and the entire record of the hearings, including the transcript, will be retained by FEO and made available for inspection at the Freedom of Information Office, Room 2107, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

It has been determined by FEO that since the regulation proposed herein would not, if adopted, affect the quality of the environment, it is not necessary that it be submitted to the Administrator of the Environmental Protection Agency for his comments pursuant to section 7(c)(2) of the Federal Energy Administration Act of 1974, Pub. L. 93–275.

This proposal has been reviewed in accordance with Executive Order 11821 and OMB Circular No. A–107 and has been determined not to require evaluation of its inflationary impact as provided therein.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93–159, as amended, Pub. L. 93–511, Pub. L. 94–99, Pub. L. 94–133 and Pub. L. 94–163; Federal Energy Administration Act of 1974, Pub. L. 93–275; Energy Policy and Conservation Act, Pub. L. 94–163; EO 11790, 39 FR 23195; EO 11930.)

In consideration of the foregoing, it is proposed that Part 205 of Chapter II of Title 10 of the Code of Federal Regulations be amended as set forth below.

Issued in Washington, D.C., August 12, 1976.

MICHAEL F. BUTLER,
General Counsel,
Federal Energy Office.

Sections 205.202 (e)(1) and (e)(2)(B) are revised to read as follows:

§ 205.202 Sanctions.

* * * * *

(e) *Corporate personnel.* (1) Any individual director, officer or agent of a corporation who knowingly and willfully authorizes, orders or performs any of the acts or practices constituting in whole or in part a violation of any provision of the regulation issued under authority of the Emergency Petroleum Allocation Act of 1973, as amended, or any order issued pursuant thereto, shall be subject to the penalties specified in paragraphs (b) and (c) of this section with regard to any penalties to which that corporation may be subject under paragraphs (b) and (c) of this section, except that no such individual director, officer or agent shall be subject to imprisonment under paragraph (c) of this section unless he also has knowledge, or reasonably should have known, of notice of noncompliance received by the corporation from the FEO. The FEO will not seek or recommend to the Department of Justice that it seek the imprisonment of any individual director, officer or agent of a corporation under this paragraph for knowingly and willfully authorizing, ordering or performing any act or practice occuring prior to the issuance to the corporation of a remedial order or consent order pertaining to such act or practice unless it has reason to believe that such act or practice was known, or should have been known, by such individual at the time it was commited to have been in violation of such regulation or order issued pursuant thereto.

(2) For purposes of this paragraph (e):

* * * * *

(B) "notice of noncompliance" shall include any written notice that the FEO believes the corporation to be acting in violation of the provisions of this chapter issued under authority of the Emergency Petroleum Allocation Act of 1973, as amended, or any order issued pursuant thereto, and shall include, but not be limited to, a notice of probable violation issued under § 205.191, a remedial order issued under §§ 205.192 or 205.193 or a consent order issued under § 205.197: *Provided,* That any such notice other than a remedial order or a consent order shall state (*1*) that the FEO has reason to believe that the meaning of the regulation alleged to have been violated is clearly established, (*2*) the precedent, if any upon which such belief is based, and (*3*) that continuation of the alleged violation after receipt by the corporation of the notice could subject the individual officers, directors, or agents of the corporation who have knowingly and willfully authorized, ordered or performed any of the acts or practices constituting in whole or in part the alleged violation may be subject to imprisonment of up to one year in addition to the other civil and criminal penalties applicable to such violation.

[FR Doc.76–24084 Filed 8–12–76;4:39 pm]

[10 CFR Parts 210, 211 and 212]

EXEMPTION OF NAPHTHA JET FUEL FROM THE MANDATORY PETROLEUM ALLOCATION AND PRICE REGULATIONS

Notice of Proposed Rulemaking and Public Hearing

The Federal Energy Office ("FEO") hereby gives notice that, following a preliminary analysis of the impact of regulation of naphtha type aviation fuel (has defined in 10 CFR 211.142 and 212.31 and hereinafter referred to as naphtha jet fuel) pursuant to the Emergency Petroleum Allocation Act of 1973, as amended ("EPAA"), it has tentatively concluded that this product should be

exempted from its Mandatory Petroleum Allocation and Price Regulations. Therefore, by this notice of proposed rulemaking, FEO is proposing an amendment to be submitted to the Congress in accordance with the provisions of section 12 of the EPAA, to exempt naphtha jet fuel from the application of the Mandatory Petroleum Allocation and Price Regulations (10 CFR Parts 210, 211 and 212) thereby converting the EPAA to standby authority with respect to the pricing and the allocation thereof. This amendment has been issued concurrently with FEO's Preliminary Findings and Views Concerning the Exemption of Naphtha Jet Fuel from the Mandatory Petroleum Allocation and Price Regulations (the "Preliminary Findings").

FEO also gives notice that it will hold a public hearing and receive written comments with respect to this proposed exemption of naphtha jet fuel and the Preliminary Findings. If, after all comments received during the public comment period are fully considered, FEO concludes that its preliminary findings and views are correct, an amendment to exempt naphtha jet fuel from regulation will be submitted to the Congress.

Because supplies of crude oil and refined petroleum products have generally been sufficient since the end of the 1973 oil embargo, and FEO's domestic crude oil allocation (entitlements) program equalizes refiners' crude costs to a competitive range, it has been apparent for some time that the complex regulatory program created for the embargo shortage period may no longer be necessary to assure that the original objectives of the regulatory program are achieved with regard to some or all products.

On December 22, 1975, the President signed into law the Energy Policy and Conservation Act ("EPCA") which, among other things, extended the EPAA, eliminated the cumbersome exemption procedures of section 4(g)(2) and provided new and more flexible exemption procedures in section 455, which added section 12 to the EPAA. In the Conference Report to accompany S. 622, the conferees stated with respect to section 455 of the EPCA:

> The United States still faces a critical energy problem. However, the dimensions of that problem are far different from those which existed in 1973 and were addressed by the EPAA. There is no longer a general shortage of either crude oil or refined petroleum products, with the possible exemption of propanes. In many ways, the supply side of the market has returned to near the pre-embargo conditions which prevailed in 1972.
>
> In view of these changed conditions, a comprehensive regulatory structure * * * may no longer be necessary.
>
> Extension of the EPAA and its conversion to a standby authority offers, in addition, the potential for a smooth transition of petroleum markets from a closely regulated state to a large unregulated status subject to standby pricing and allocation authority. [Conference Report to Accompany S. 622, Report No. 94-516, p. 203-204, December 8, 1975.]

In February 1976, the Federal Energy Administration (FEA), whose functions were assumed by FEO, held public hearings and received written comments on the reevaluation of FEA regulations as required by § 456 of the EPCA. The overwhelming majority of comments in that proceeding advocated the exemption of all refined petroleum products from FEA regulations.

FEA has accordingly proceeded with proposals to exempt refined products from price and allocation regulations. On June 1, 1976, the exemption of residual fuel oil became effective, and on July 1 middle distillates were so exempted. In addition, the Congressional review period for FEA's proposal to exempt naphtha, gas oil, greases, lubricants, certain petrochemical feedstocks and other specialty products from regulations recently expired without disapproval of the proposal by either House of Congress and such exemption will become effective September 1, 1976.

FEO is continuing the examination of its regulations in light of the comments received in the reevaluation proceeding and other available information with a view toward the further exemption of refined petroleum products still under controls where the regulations issued pursuant to section 4(a) of the EPAA are no longer necessary to achieve the objectives of that legislation.

Section 455 of the EPCA has provided somewhat more flexibility in the exemption of products than was the case under the EPAA prior to enactment of the EPCA. Certain products or category of products may be exempted in the same proceeding, for example, and an exemption is no longer limited to 90 days in length. FEO may proposed to exempt an oil or product from the regulation prescribed under section 4(a) of the EPAA if it determines that the exemption is consistent with the attainment of the public policy objectives specified in section 4(b)(1) of the EPAA and that the regulation with the exemption provides for the attainment of those objectives, to the maximum extent practicable. An amendment exempting crude oil, residual fuel oil, or a refined petroleum product with respect to a class of persons or transactions with respect to any market level, must be submitted to the Congress before it takes effect. An exemption amendment may take effect if not disapproved by either House of Congress within 15 days under expedited Congressional review procedures.

The EPCA further provides that any amendment submitted to Congress which proposes to exempt crude oil (if permissible under and consistent with the requirements and limitations of section 8 of the EPAA), residual fuel oil, or any refined petroleum product from the allocation regulations must be accompanied by a finding that the oil or product is no longer in short supply and that the exemption would not have an adverse impact on the supply of any other oil or product. Any proposed exemption with respect to price must be accompanied by findings that competition and market forces would provide adequate protection for the consumer, and that such amendment would not result in inequitable prices for any class of user. Any exemption amendment submitted to the Congress must also be accompanied by an analysis of and FEO's views on the potential economic impact of such amendment.

Any oil or refined petroleum product which is exempted from the regulation under section 4(a) of the EPAA is subject to the reimposition of controls if FEO determines that reimposition is necessary for and consistent with the objectives specified in section 4(b)(1). Subsequent reexemption of that oil or refined petroleum product would not be subject to Congressional review.

In this notice of proposed rulemaking, FEO is considering the exemption of naphtha jet fuel from the Mandatory Petroleum Allocation and Price Regulations at this time because recent surplus supplies and market conditions appear to justify an end to controls. For purposes of this proposed exemption, naphtha jet fuel means all fuels in the heavy naphtha boiling range with an average gravity of 52.8° API and 10% to 90% distillation temperatures of 210° F. to 420° F., including JP-4 and other fuels meeting military specifications MIL-F-5624 and MIL-T-5624G, used for turbojet and turboprop aircraft engines, primarily by the military (§ 212.31), and also Type B (naphtha-base) refined petroleum fuel whose basic specification is ASTM D-1655 and is designed to operate aircraft turbine engines (§ 211.142).

Naphtha jet fuel, as defined above, constitutes only about 1.4% of total domestic refinery yield and is almost exclusively used by the Department of Defense for military purposes. This proposed exemption does not apply to kerosene jet fuel which is the principal fuel for commercial airlines.

Section 12(b)(2) of the EPAA requires that an exemption amendment apply to only one refined petroleum product or one refined product category, and specifies that all or any portion of the group of refined petroleum products (other than motor gasoline, No. 2 oils and propane) constitutes a single product category. FEO is proposing the exemption of naphtha jet fuel as a single product category in this notice of proposed rulemaking. Upon conclusion of this rulemaking, FEO will determine whether an exemption of this product category should be adopted and will, as required by Section 12 of the EPAA, submit any exemption amendment for this product category to the Congress for review of FEO's findings and views supporting such exemption.

FEO has concluded in its Preliminary Findings on the basis of currently available data that this exemption would be consistent with the attainment of the objectives set forth in secion 4(b)(1) of the EPAA, as amended by section 451 of the EPCA. Those objectives are as follows:

(A) Protection of public health (including the production of pharmaceuticals), safety and welfare (including maintenance of residential heating, such as individual homes, apartments and similar occupied dwelling units), and the national defense;

(B) Maintenance of all public services (including facilities and services provided by municipally, cooperatively, or investor owned utilities or by any State or local government or authority, and including transportation facilities and services which serve the public at large);

(C) Maintenance of agricultural operations, including farming, ranching, dairy, and fishing activities, and services directly related thereto;

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

(E) The allocation of suitable types, grades, and quality of crude oil to refineries in the United States to permit such refineries to operate at full capacity;

(F) Equitable distribution of crude oil, residual fuel oil, and refined petroleum products at equitable prices among all regions and areas of the United States and sectors of the petroleum industry, including independent refiners, small refiners, nonbranded independent marketers, branded independent marketers, and among all users;

(G) Allocation of residual fuel oil and refined petroleum products in such amounts and in such manner as may be necessary for the maintenance of exploration for, and production or extraction of—

(i) Fuels, and

(ii) Minerals essential to the requirements of the United States, and for required transportation related thereto;

(H) Economic efficiency; and

(I) Minimization of economic distortion, inflexibility, and unnecessary interference with market mechanisms.

FEO's preliminary conclusions, based on information currently available to FEO, are that since an adequate supply is anticipated, the continuation of allocation and price controls for naphtha jet fuel is not necessary to protect the public health, safety and welfare (section 4(b)(1)(A)); the maintenance of all public services (section 4(b)(1)(B)); the maintenance of agricultural operations (section 4(b)(1)(C)); or the maintenance of exploration for and production or extraction of fuels and minerals (section 4(b)(1)(G)). Adequate supply and the positive effects of increased competition should insure that the proposed exemption is consistent with the preservation of an economically sound and competitive petroleum industry (section 4(b)(1)(D)); the equitable distribution of crude oil, residual fuel oil and refined petroleum products (section 4(b)(1)(F)); economic efficiency (section 4(b)(1)(H)); and minimization of economic distortions, inflexibility, and interference with market mechanisms (section 4(b)(1)(I)). The proposed exemption should have no adverse effect on the allocation of suitable crude oil to domestic refineries (section 4(b)(1)(E)). FEO emphasizes that these conclusions are preliminary and invites specific data, views and arguments with respect to the relationship between the objectives of the EPAA and the exemption contemplated by this proposal. Any further information received with respect to the compatibility of the exemption proposed herein with these objectives will be considered by FEO in formulating its final conclusions.

FEO's specific preliminary findings and views on the exemption proposed hereby and the data and information in support thereof are set forth in its Preliminary Findings. Interested persons may obtain copies of the Preliminary Findings by writing FEO, Office of Communications and Public Affairs, Publications Distribution Center, Washington, D.C. 20461. Copies will also be available at the FEO Press Room, Room 2134, 1200 Pennsylvania Avenue, N.W., Washington, D.C.

Tentative conclusions as set forth in the Preliminary Findings include:

(1) Sufficient domestic refining capacity exists to adequately satisfy projected U.S. demand.

(2) Exemption of naphtha jet fuel from the Mandatory Petroleum Allocation and Price Regulations would not have an adverse impact on the supply of any other oil or refined product subject to the EPAA.

(3) Competition and market forces are adequate to protect consumers, following such an exemption from regulation.

(4) Such an exemption from regulation will not result in inequitable prices for any class of user of naphtha jet fuel or other products.

The Preliminary Findings also indicate FEO's tentative views concerning the potential economic impacts of exempting naphtha jet fuel from the Mandatory Petroleum Allocation and Price Regulations. It is not anticipated that there will be any adverse state or regional impacts resulting from the proposed exemption. In addition, FEO anticipates no adverse economic impacts on the availability of consumer goods or services, the gross national product, small business or the supply and availability of energy resources as fuel or feedstock for industry. FEO believes that the proposed exemption may have a positive effect on competition. The proposed exemption is likewise expected not to cause an adverse effect on employment or consumer prices. FEO's analysis concludes that there will be no effect of the proposed exemption on the rate of unemployment in the United States, on the Consumer Price Index or on the implicit price deflator for the gross national product.

Comments are requested on whether the refiners' price rules should be amended in this proceeding to limit, between now and the effective date of the exemption proposed herein, the reallocation of increased product costs and increased non-product costs (including any unrecovered increased costs which have been banked for future recovery) which is currently permitted with respect to the products proposed to be exempted.

FEO also requests comments on the method by which a limitation would be most effectively implemented, including the manner of determining which portion of the aviation jet fuel bank is properly attributable to naphtha jet fuel. Further conforming amendments to the Mandatory Petroleum Price Regulations, beyond the simple exemption proposed herein, may be necessary so that the price rules fully reflect the exemption of products pursuant to this proceeding.

Public hearings in this proceeding will be held beginning at 9:30 a.m. on Friday, September 3, 1976, in Room 2105, 2000 M Street, NW., Washington, D.C., in order to receive comments from interested persons.

Any person who has an interest in the proposed amendment, or who is a representative of a group or class of persons that has an interest in the proposed amendment, may make a written request for an opportunity to make an oral presentation. Such a request should be directed to Executive Communications, FEO, Room 3309, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C. 20461, and must be received before 4:30 p.m., August 25, 1976. Such a request may be delivered to Room 3309, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. The person making the request should describe briefly the interest concerned; if appropriate, state he or she is a proper representative of a group or class of persons that has such an interest; and give a concise summary of the proposed oral presentation and a phone number where he or she may be contacted through Friday, August 27, 1976. Each person selected to be heard will be so notified by the FEO before 4:30 p.m., EST, August 27, 1976, and must submit 100 copies of his or her statement to Regulations Management, FEO, Room 2214, 2000 M Street, NW., Washington, D.C. 20461, before 4:30 p.m., EST., on September 2, 1976.

The FEO 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 FEO 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 FEO with respect to the subject matter of the hearings will be based on all information available to the FEO. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if 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 hearings, to Executive Communications, FEO, Room 3309, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C. before 4:30 p.m., EST, September 1, 1976. Any person who makes an oral statement and who wishes to ask a question at the hearings may submit the question, in writing, to the presiding officer. The FEO or the presiding officer, if the question is submitted at the hearings, will determine whether the question is relevant, and weather time limitations permit it to be presented for answer.

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

A transcript of the hearings will be made and the entire record of hearings, including the transcript, will be retained by the FEO and made available for inspection at the Freedom of Information Office of the FEO, Room 2107, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

Interested persons are also invited to participate in this rulemaking by submitting data, views, or arguments with respect to the proposed regulations set forth in this notice to Executive Communications, Room 3309, Federal Energy Office, Box IH, Washington, D.C. 20461.

Comments should be identified on the outside envelope and on documents submitted to the FEO, Executive Communications, with the designation "Exemption of Naphtha Jet Fuel." Fifteen copies should be submitted. All comments received by September 1, 1976, and all relevant information will be considered by the FEO before final action is taken on the proposed regulations.

The inflationary impact of this proposal has been considered by the FEO, consistent with Executive Order 11821, issued November 27, 1974, and has been determined not to be of a nature that requires an evaluation of its inflationary impact.

A copy of this notice has been submitted to the Administrator of the Environmental Protection Agency for his comments concerning the impact of this proposal on the quality of the environment. The Administrator had no comments.

In addition, based on an environmental assessment of the proposed action, the Federal Energy Office (FEO) has determined that the exemption of naphtha jet fuel will not be a "major Federal action significantly affecting the quality of the human environment" (Section 102(2)(C), National Environmental Policy Act (42 U.S.C. 4332(2)(C))).

Copies of the environmental assessment will be available upon request from the FEO Office of Communications and Public Affairs, Room 2134, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461. Copies of the document will also be available for public review in the FEO Information Access Reading Room, Room 2107, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461.

Interested persons are invited to submit data, views, or arguments with respect to the environmental impacts of this proposed exemption and the environmental assessment to Executive Communications, Box IJ, Room 3309, Federal Energy Office, 12th and Pennsylvania Avenue, NW., Washington, D.C. 20461.

Comments should be identified on the outside of the envelope and on documents submitted to FEO Executive Communications with the designation, "Environmental Assessment—Naphtha Jet Fuel Decontrol." Fifteen copies should be submitted. All comments should be received by FEO by September 3, 1976, in order to receive full consideration.

Any information or data submitted pursuant to the above procedures and considered by the person furnishing it to be confidential must be so identified and submitted in one copy only. The FEO reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159, as amended by Pub. L. 94-163; E.O. 11930, (41 FR 32399, August 3, 1976))

In consideration of the foregoing, it is proposed to amend Parts 210, 211, and 212 of Chapter II, Title 10 of the Code of Federal Regulations, as set forth below.

Issued in Washington, D.C., August 12, 1976.

MICHAEL F. BUTLER,
General Counsel.

PART 210—GENERAL ALLOCATION AND PRICE RULES

1. Section 210.35 is amended by adding paragraph (g) to read as follows:

§ 210.35 Exempted products.

* * * * *

(g)(1) Aviation turbine fuel (naphtha base) as defined in § 211.142 of this chapter is exempt from the provisions of Part 211 of this chapter.

(2) Aviation fuel (naphtha-type) as defined in § 212.31 of this chapter is exempt from the provisions of Part 212 of this chapter.

PART 211—MANDATORY PETROLEUM ALLOCATION REGULATIONS

2. Section 211.1 is amended in paragraph (b) by adding new subparagraph (9) to read as follows:

§ 211.1 Scope.

* * * * *

(b) *Exclusions.*

* * * * *

(9) Notwithstanding the provisions of Subpart H of this part, aviation turbine fuel (naphtha base) is excluded from this part.

PART 212—MANDATORY PETROLEUM PRICE REGULATIONS

3. Section 212.31 is amended in the definition of "covered products" to read as follows:

§ 212.31 Definitions.

* * * * *

"Covered products" means aviation fuels (other than aviation fuel (naphtha-type)), butane, crude oil, gasoline, natural gas liquids, natural gasoline, and propane. A blend of two or more particular covered products is considered to be that particular covered product constituting the major proportion of the blend.

* * * * *

[FR Doc.76-24133 Filed 8-13-76;10:41 am]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 73]

[Docket No. 20890]

FM BROADCAST STATIONS IN GRANGER-HUNTER, UTAH

Proposed Table of Assignments

In the matter of amendment of § 73.202(b), *Table of assignments*, FM Broadcast Stations. (Granger-Hunter, Utah), Docket No. 20890, RM-2641.

1. Petitioner, Proposal, and Comments:

(a) Petition for rule making, filed January 5, 1976, by Albert E. Guthrie, proposed to assign Class C FM Channel 274 to Granger-Hunter, Utah [1] as its first aural service.

(b) This channel may be assigned without affecting any existing FM assignments.

(c) No opposition to this petition for rulemaking has been filed.

2. Demographic Data:

(a) *Location.* Granger-Hunter is located approximately 12 miles southwest of Salt Lake City, Utah.

(b) *Population.* (1970 U.S. Census)—Granger-Hunter, 9,029; Salt Lake County, 458,607. Petitioner alleges, however, that the present population of Granger-Hunter is 25,000.

(c) *Local Radio Service.* Granger-Hunter has no local aural service but receives radio service from Salt Lake City's eleven AM stations and seven FM stations.

(d) *Economic Considerations.* Petitioners alleges that Granger-Hunter has a strong need for the assignment of Channel 274 because it is a growing community. Moreover, petitioner contends that issues which are of interest only to the residents of Granger-Hunter are not presently reported by the Salt Lake City stations but would be covered by a Granger-Hunter station.

3. *Preclusions.* If Channel 274 is assigned to Granger-Hunter, then preclu-

[1] Although the petitioner refers to the community as Granger, Utah, we shall use the name Granger-Hunter because this is the name used in the 1970 U.S. Census. See discussion of the community issue in paragraph 4, infra.

sion would occur on Channels 272A, 273, 274, and 275. The most significant preclusion would occur on Channel 274 which would be precluded from use at the following Utah communities each having populations over 10,000: Roy, Layton, Clearfield, and Bountiful-Centerville. The petitioner indicates that these communities could be served by Channel 258. However, a study by the Commission's engineering staff reveals that these communities would be precluded from using Channel 258 due to the assignment of Channel 258 to Rock Springs, Wyoming. We also note that the only present aural service to any of these communities is daytime-only AM Station KBBC in Centerville and that Springville, Utah (pop. 8,790) is in the precluded area and does not have local aural service. Consequently, petitioner should submit a more precise preclusion study showing all areas that would be precluded from use of the proposed channel and the six pertinent adjacent channels, and with regard to the above named precluded communities, indicate whether any other channels are available for assignment. See "Policy to Govern Requests for Additional FM Assignments," 8 F.C.C. 2d 79 (1967).

4. *The Community Issue.* We note that the 1970 U.S. Census lists Granger-Hunter as an "unincorporated place." However, section 307(b) of the Communications Act of 1934, as amended, and §§ 73.202(a), 73.203(a), and 73.206 of the Commission's rules require that we assign FM channels to "communities." A "community" within the meaning of our rules is more than a mere geographical location. "Notice of Proposed Rule Making in Yorktown, Virginia," 38 FR 6695 (released March 12, 1973) and Sierra-Pacific Radio Corp. (KOSO), 7 F.C.C. 2d 61 (1967). Rather, we are looking to see whether there is a community of interest associated with an identifiable population grouping. The showing that petitioner must make is that "the residents function as and conceive of themselves as residents of a community around which their interests coalesce." Yorktown, Virginia, supra, at paragraph 4. However, we would like to point out that a valid showing of the existence of a community can be made even though the community is unincorporated[2] and has no concrete boundaries which can be delineated.[3] In this regard, we also request that petitioner indicate whether Granger-Hunter is one community or whether Granger and Hunter are separate communities. See footnote 1, supra.

5. *Class A vs. Class C Channel.* The Commission's rules, as well as policy, provide that Class A channels are assigned to serve relatively small communities, and the surrounding rural area, and that Class B and C channels are designed to serve urban centers. Section 73.206(a)(2) and(b)(4) of the Commission's rules: Third Report, Memorandum Opinion and Order, 40 F.C.C. 747, 758–59, paragraph 25 (1963). Since the petitioner requests the assignment of a Class C channel to a community having a population of less than 10,000 persons, petitioner should indicate in its comments whether any Class A channels are available for assignment to Granger-Hunter. In the past, the Commission has assigned Class C channels to small communities when the assignment would result in a large first or second FM service, e.g., Lyons, Kansas, 42 F.C.C. 2d 215, 216 (1973), and Lexington, Missouri, 53 F.C.C. 2d 893 (1975), when the assignment of a Class C channel would enable a large rural area to be served, e.g., Clinton, Oklahoma, 7 F.C.C. 2d 836, 839 (1967), or when there was no other place that the Class C channel might be used due to the Commission's mileage separation rules, e.g., Pensacola, Florida, 44 F.C.C. 2d 1056, 1061 (1974).

6. The Suburban Issue. In view of the fact that a Class C channel at Granger-Hunter, operating with minimum facilities, would most likely place a city grade signal over all of Salt Lake City, the petitioner, and any other party interested in operating a Class C channel at Granger-Hunter, must show that it intends to serve primarily Granger-Hunter rather than Salt Lake City. For a discussion of this suburban question, see Berwick Broadcasting Co., 12 F.C.C. 2d 8 (1968), and P.A.L. Broadcasting Co., 40 F.C.C. 2d 546, 556 (1973). To compare how the suburban issue is handled in applications for AM stations, see Policy Statement on Section 307(b) Considerations for Standard Broadcast Facilities Involving Suburban Communities 2 F.C.C. 2d 190 (1965), modified by Report and Order, Docket No. 20265, 54 F.C.C. 2d, 1, 10–11, 21–22 (1975).

7. Roanoke Rapids Report. Because petitioner is requesting a Class C channel in a place where a Class A channel would normally be assigned, petitioner should include a Roanoke Rapids report showing the number of people who would receive a first or second FM service from a Class C station in Granger-Hunter, Roanoke Rapids-Goldsboro, North Carolina, 9 F.C.C. 2d 672 (1967).

8. In view of the above, the Commission proposes to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules and regulations, with regard to Granger-Hunter, Utah, as follows:

	Channel No.	
	Present	Proposed
City: Granger-Hunter, Utah		274

We wish to point out that this proposal is made for the purpose of eliciting comments on the above discussed issues. We emphasize that Channel 274 cannot be assigned to Granger-Hunter unless we know that Granger-Hunter is a "community" within the meaning of our rules, that a Class C assignment is justified, and that a Class C channel would be used to serve Granger-Hunter rather than Salt Lake City.

9. The Commission's authority to institute rule making proceedings; showings required; cut-off procedures; and filing requirements are contained below and are incorporated herein.

10. Interested parties may file comments on or before September 23, 1976, and reply comments on or before October 13, 1976.

Adopted: August 9, 1976.

Released: August 13, 1976.

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

1. Pursuant to authority found in sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the notice of proposed rulemaking.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the notice of proposed rulemaking. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rule making. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the

[2] Mercer Broadcasting Co., 22 F.C.C. 1009, 1023–25 (1957); Musical Heights, Inc., 29 F.C.C. 1, 3–4 (1960); Seven Locks Broadcasting Co., 37 F.C.C. 82 (1964); Holston Broadcasting Corp., 45 F.C.C. 1290, 1291–92; and Holiday, Florida, 41 Fed. Reg. 20036 (released May 20, 1976), paragraph 7.

[3] Seven Locks, supra, and Hymen Lake, 46 F.C.C. 2d 560, 562–63 (1974).

person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of Section 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc.76-24028 Filed 8-16-76;8:45 am]

[Docket No. 20888]

[47 CFR Part 73]

FM BROADCAST STATIONS IN RIDGECREST AND INYOKERN, CALIF.

Proposed Table of Assignments

In the matter of amendment of § 73.202(b), *Table of Assignments*, FM Broadcast Stations. (Ridgecrest and Inyokern, California), Docket No. 20888, RM-2677.

1. *Petitioner, Proposal and Comments:*

(a) Notice of proposed rule making is hereby issued concerning the amendment of the FM Table of Assignments (§ 73.202(b) of the Commission's rules and regulations) with regard to the communities of Ridgecrest and Inyokern, California.

(b) The petition for rulemaking, of which Public Notice was given (Report No. 977), April 12, 1976, was filed on behalf of Kitchen Productions (petitioner), proposing the assignment of Channel 244A or Channel 285A to the Ridgecrest-Inyokern, California area as a second Class A assignment.

(c) Either channel could be assigned to Ridgecrest or Inyokern in complete conformity with all mileage separation requirements.

2. *Demographic Data:*

(a) *Location.* Ridgecrest is located approximately 120 miles northeast of Los Angeles and 75 miles east of Bakersfield. Inyokern is located about 6 miles from Ridgecrest.

(b) *Population.* (1970 U.S. Census)—Ridgecrest, 7,629; Inyokern, 800; Kern County, 329.162.

(c) *Present aural services.* KZIQ(AM) daytime-only, KLOA (Class IV); Channel 224A on which application is pending (BPH-9569) filed by licensee of daytime-only Station KZIQ.

(d) *Economic considerations.* Petitioner states that the 1970 U.S. Census greatly understates the Ridgecrest area population because the area has grown and an outflux of population from the Navy property has occurred, partially due to rent increases and to availability of new homes in Ridgecrest and surrounding areas. Petitioner also adds that, according to the Ridgecrest Chamber of Commerce figures for 1975, Ridgecrest's population is now estimated at 13,500.

3. *Preclusion studies:*

Channel 244A. Preclusion would occur on the co-channel and all six adjacent channels with the exception of Channel 246B. The Commission's preclusion study indicates that six communities (China Lake, 11,105; Trona, 1,500; Edwards, 10,331; Mojave, 2,573; Boron, 1,999; and California City, 1,309), would be precluded as a result of the assignment of Channel 244A to Ridgecrest.

Channel 285A. Preclusion would occur on the co-channel and all adjacent channels except Channel 287. Only three communities (China Lake, 11,105; Trona, 1,500; and Tehachapi, 4,311), would be precluded as a result of the assignment of Channel 285A to Ridgecrest.

At least two other Class A or Class B channels are available for assignment to these communities.

4. *Additional Considerations.* An opposition to the proposed assignment was filed by Space/Time Broadcasting Company (Space/Time), the applicant for Channel 224A at Ridgecrest. Space/Time states that Ridgecrest at the present time is supporting one newspaper, two radio stations and one cable television company, all of them soliciting business in this very limited market. It contends that assignment of frequencies in Inyokern, the Rand District or the Trona/Argus area means only that stations in these areas will be competing in the Ridgecrest market since these areas are incapable of sustaining radio stations or anything else. It adds that the Commission has already caused hardship of this kind by granting an AM station (KINC) to Independence, California, and an AM frequency to the Lake Isabella area. Space/Time states that it was apparent from the beginning that KINC would have to be sustained by the Ridgecrest and Bishop markets. Space/Time also contends that, since it could not maintain its station with business from the Ridgecrest area only, it managed to obtain some accounts from the Isabella area. Now, it adds, when the new AM station becomes operational in the Isabella area this business will be lost to it. It contends that spreading this market any thinner would cause both the existing stations undue hardship and could result in the demise of one or both.

5. Space/Time's objection is that the assignment of a second FM channel to Ridgecrest would cause severe economic harm to the existing AM stations at Ridgecrest. It has been long established Commission policy to make ultimate decisions with respect to Carroll issues concerning the economic questions at the time of an application for a specific station rather than in rulemaking proceedings.[1]

[1] Adrian, Michigan, Docket No. 19512, 37 F.C.C. 2d 1021 (1972).

6. A review of the petition reveals that discussion of the economic, sociological and governmental activity in Ridgecrest is lacking in petitioner's presentation. Normally, in allocation proceedings, there is a detailed discussion of the commercial and business life and structure, the sociological life and the governmental activity, in a community so as to demonstrate the importance of the community and the need of the community for the additional local radio broadcast service. Too, oftentimes, presentations are made as to how a newly proposed station will better be able to meet the needs of its principal community and area. Petitioner should have an opportunity to cure the above described deficiency in its comments to the notice of proposed rulemaking herein.

7. We are proposing the assignment of Channel 285A to Ridgecrest rather than to Inyokern since Ridgecrest has a population of 7,629 compared to that of 800 in Inyokern. However, the channel may also be used at Inyokern under the 10-mile rule (§ 73.203(b)) since the two communities are located about six miles apart. Further, Channel 285A is preferred because the Commission's preclusion study indicates that the preclusion areas would be slightly less on Channel 285A than on Channel 244A.

8. Petitioner has stated that, if a channel is granted to the Ridgecrest-Inyokern area, it will apply for the facility and, if authorized, construct an FM station.

9. In light of the above, the Commission proposes to amend the FM Table of Assignments, § 73.202(b), as follows with regard to the community listed:

	Channel No.	
	Present	Proposed
City: Ridgecrest, Calif.	224A	224A, 285A

10. The Commission's authority to institute rule making proceedings; showings required; cut-off procedures, and filing requirements are contained below and are incorporated herein.

11. Interested parties may file comments on or before September 20, 1976, and reply comments on or before October 12, 1976.

Adopted: August 6, 1976.

Released: August 12, 1976.

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and Section 0.281(b)(6) of the Commission's rules. It is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the notice of proposed rulemaking.

2. *Showings required.* Comments are invited on the proposal(s) discussed in

the notice of proposed rulemaking to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420 (d) of Commission rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rulemaking. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc.76-24029 Filed 8-16-76;8:45 am]

[47 CFR Parts 81, 83]

[Docket No. 20886; FCC 76-755]

VESSELS ON THE GREAT LAKES

Proposed Operation of a Very High Frequency Automated, Multi-Station Radiocommunications System

In the matter of amendment of Parts 81 and 83 of the rules to permit the operation of a communications system on the Great Lakes to provide very high frequency (VHF) regional, and other, public correspondence radiocommunication service to vessels, Docket No. 20886, RM-2472, RM-2476.

1. Notice of proposed rulemaking in this proceeding is hereby given.

2. On October 30, and November 7, 1974, Lorain Electronics, Inc., filed petitions for rule changes to provide for the licensing and operation of a very high frequency (VHF) automated, multi-station radiocommunications system, to serve vessels on the Great Lakes. On April 7, 1976, Lorain amended its petition with respect to the channels to be used and the specific location of the stations it intends to operate in the system. Lorain has operated shore stations providing maritime radiocommunications service to ships on the Great Lakes since 1934.

3. The Lorain petitions were placed on public notice and comments were filed by the American Telephone and Telegraph Company (AT&T) and by Waterway Communications Systems, Inc. (Watercom). Watercom now has applications pending for six public coast stations on the Mississippi River, with requests for necessary rule changes or waivers, to permit the operation of a VHF radiocommunications system on that waterway also to serve vessels. The Watercom applications and proposal have been placed on public notice and are available for public inspection in the Commission's Aviation and Marine Division licensng room at the Commission's office located at 2025 M St., NW., Washington, D.C.

4. By Memorandum Opinion and Orders released January 15, 1974, and February 14, and December 24, 1975, we have authorized Lorain to operate its proposed system on a prototype basis for three years until January 1, 1977. On March 10, 1976, Lorain furnished us a detailed report on its prototype system and stated that the system is operating successfully. The Lorain proposal for regular operation of the system, essentially, calls for the use of some existing public coast stations and some new stations. All stations would operate on Channel 86 (161.925 MHz), and on either Channel 84 (161.825 MHz) or on Channel 87 (161.975 MHz) at the following locations:

Duluth, Minn.
Ontonagan, Mich.
Copper Harbor, Mich.
Grand Marais, Mich.
Pickford, Mich.
Sturgeon Bay, Wis.
Port Washington, Ill.
Benton Harbor, Mich.
Alpena, Mich.
Harbor Beach, Mich.
Algonac, Mich.
Oregon, Ohio
Cleveland, Ohio
Westfield, N.Y.
Olcott, N.Y.
Oswego, N.Y.

5. The Lorain system stations are to meet what Lorain terms "the unique operating requirements' for radiotelephone communication on the Great Lakes. Lorain's proposed system would provide automated and manual communication as well as other new radio [1] services, and would cover the entire navigational area of the Great Lakes in the United States, and much of the navigational areas of Canada. Lorain states it intends to use channel 86 at all its system stations primarily for radiotelegraph signals and also either channel 84 or 87 at each of its system stations as a primary radiotelephony working channel.

6. In general, the advantages of the Lorain system, as explained in its petition and as we analyze it, are as follows:

a. New automated calling, weather, and position reports will be offered;

b. Expanded, if not complete, coverage of the U.S. navigated waters of the Great Lakes than that now existing, would be achieved;

c. All VHF stations in the Lorain system would be integrated and interconnected and controlled from one station; and

d. Facsimile and teleprinter service would be available.

7. The Lorain system differs from existing VHF public coast station service, mainly, in the following particulars. At present, coast stations providing VHF public correspondence ordinarily operate as separated and independent units. They are not linked together into any kind of an integrated or centrally controlled system, either by land wirelines or by radio frequencies. Communications are exchanged with vessel stations only when a vessel is within a geographical area in which the propagated radio signals of the coast and ship stations can be heard by each station. Calls are usually initiated on the distress, safety and calling frequency 156.8 MHz (Channel 16) by the coast station since vessels do not often maintain listening watches on the working frequencies of the public coast stations. Vessels, however, can usually contact the coast station by monitoring the coast station channel and calling when the channel is unused. Only radiotelephony (voice) messages are exchanged since neither coast nor ship stations are equipped with radiotelegraphy facilities.

8. Lorain's proposed system would consist of about 16 coast stations spread throughout the Greak Lakes area, linked together by a land wireline and all using a "common" channel for teleprinter and facsimile operations. Most of the stations would be unmanned and would be controlled from a central location in Lorain, Ohio. In addition to the "common" frequency, each station would be assigned either channel 84 or 87 on an alternating arrangement so that no destructive electrical interference would occur. A vessel desiring to initiate an exchange of voice communications could do so by calling, by voice or by automated means, the nearest coast station

[1] In is petition Lorain uses the term "non-voice" in reference to certain services other than radiotelephony; e.g. dial calling, radioteleprinter and facsimile emissions.

in the system on the working channel assigned to that station, or the call could be made on channel 16 by voice and then, when instructed by the coast station, the communications could be switched to the working channel. Calls from land phones through a coast station could be made automatically to suitably equipped vessels on a working channel, thus freeing the calling and distress channel for more urgent uses. Messages to or from vessels not specially equipped for automatic calling could continue to be initiated as in the present manner by voice calling on a working channel or on channel 16. An interchange of data such as weather reporting or ship position information would be conducted on channel 86. Facsimile weather broadcasts by a coast station, such as weather, wind or ice information, would also be conducted on channel 86. An interchange of facsimile information, however, between a ship station and a point on shore through a coast station could also be effected on a main working channel; i.e. channel 84 or 87. The Lorain system would also provide the means for better determining the location of vessels since a vessel could be called from any of the stations in the system.

9. The system proposed by Lorain would be inconsistent with our existing rules concerning the operation of coast stations in the Maritime Mobile Services, and would therefore require modification of the rules, in the following respects:

a. The rule provisions concerning limitations on coverage area overlap by public coast stations must be relaxed for a system as proposed by Lorain. At present, § 81.303 provides, essentially, that the coverage areas of stations of this class shall not overlap by more than 20%. Our objectives, generally, have been to establish stations about 30 miles apart so that there would not be an excessive overlap of coverage areas and so that a vessel could usually contact by VHF radio at least one, and preferably two, coast stations. Lorain's proposal would require that these limitations be disregarded and that greater overlap be permitted for stations operating in or near a system of interconnected public coast stations.

b. The permissible emission provisions in §§ 81.132, and 83.132 would require amendment to provide for and allow the transmission by system stations, and ship stations communicating with other ship stations, of F2 (teleprinter) and F4 (facsimile), as well as F3 telephony emissions on one channel to be used as a "common" channel and F4 on the prime working channel.

c. Certain changes will be needed in our conditions of use criteria in Parts 81 and 83, for the frequencies involved and to allow the assignment of a second channel for radiotelegraphy communications without the traffic showing required by § 81.304(b)(22).

d. Some minor changes will be needed in § 81.106 concerning station equipment required for automatic operations, and in § 81.314 concerning station log entries when made automatically.

10. AT&T commented on behalf of Bell System Telephone Companies now operating VHF public coast stations on the Great Lakes. In its comment, it asserted that it would be unwise and potentially damaging to the interests of existing coast stations and vessels on the Great Lakes to assign four frequencies [2] to a system as proposed by Lorain. AT&T argues that this would preclude the future assignment of additional frequencies to existing stations to handle increased traffic as the service grows. AT&T also asserts that an unrestricted overlap in coverage areas could cause a severe economic burden to existing stations. In this regard, AT&T reminds us that in a cited 1972 Report and Order, we said the public interest requires the growth of this service "provided the establishment of additional stations does not have unreasonable adverse economic impact on existing stations". AT&T states, inferentially, that any adverse economic impact on existing stations on the Great Lakes by the establishment of new stations and the advent of new service as proposed by Lorain herein, would be unreasonable.

11. In its comment, Watercom generally supports the Lorain proposal but disagrees that the radiocommunication requirements for the Great Lakes are unique. Watercom asserts that the same general principles and requirements for a new class of VHF service consisting of a system of VHF stations should be extended to include the inland waterways.

12. We believe the establishment of new VHF radiotelephone services through a system of interconnected public coast stations as proposed by Lorain herein, may be in the public interest and advantageous to the maritime community. Lorain has selected channel 86 as the "common" channel to be available for assignment to all its system stations for radiotelegraphy as well as radiotelephony communications. In proposing the use of Channel 86 for other than radio-telephony communications in the manner desired by Lorain, we do not want it assumed that the channel can be used indefinitely in that way. The channel is one of the limited number of public correspondence channels in the maritime mobile VHF band available for radio telephony public correspondence purposes and the need for the channel for that use is expected to grow. We believe, however, that the temporary use of the channel for radiotelegraphy use during an interim period until another solution can be found, will not significantly conflict with the public interest. We are, therefore, proposing the changes in the rules requested by Lorain, as set forth in the attached Appendix. We will further consider the comments of AT&T and Watercom, together with any other comments received in response to our notice of these proposed rule changes, before we reach a final decision in this matter.

13. The proposed amendments to the Commission's rules as set forth below are issued pursuant to authority contained in section 4(i) and 303(a), (b), (c), (d), (e), (f), (g), (h) and (r) of the Communications Act of 1934, as amended.

14. Pursuant to application procedures set forth in § 1.415 of the Commission's rules, interested parties may file comments on or before September 20, 1976, and reply comments on or before September 30, 1976. All relevant and timely comments and reply comments will be considered by the Commission before final action is taken in this proceeding. In reaching its decision in this proceeding, the Commission may also take into account other relevant information before it, in addition to the specific comments invited by this Notice.

15. In accordance with the provisions of § 1.419 of the Commission's rules, an original and 11 copies of all statements, briefs or comments shall be furnished the Commission. Responses will be available for public inspection during business hours in the Commission's Public Reference Room at its headquarters in Washington, D.C.

Adopted: August 5, 1976.

Released: August 12, 1976.

FEDERAL COMMUNICATIONS COMMISSION,[3]

VINCENT J. MULLINS,
Secretary.

Parts 81 and 83 of Chapter I of Title 47 of the Code of Federal Regulations are amended as follows:

PART 81—STATIONS ON LAND IN THE MARITIME SERVICES AND ALASKA-PUBLIC FIXED STATIONS

1. In § 81.106, paragraph (e)(2) is amended by adding a sentence to read as follows:

§ 81.106 Operating controls.

* * * * *

(e) * * *

(2) Discontinuing all emission within 5 seconds after emission is no longer required or after the necessity arises for emission to cease. The equipment of an unattended station in an automated multi-station system, as defined in Section 81.303(d), at which restoration to standby is automatic on conclusion of a call, shall be designed so that all emission will be discontinued within 3 seconds of the disconnect signal or, if disconnect signal is not received, within 20 seconds following reception of the final carrier transmission from a ship station.

* * * * *

2. Section 81.132(a)(2)(iii) is amended as follows:

[2] Lorain reduced their total channel requirements to three, subsequent to AT&T's comments.

[3] Commissioner Wiley concurring in the result; Commissioner Quello absent.

§ 81.132 Authorized classes of emission.

(a) * * *

(2) * * *

(iii) For frequencies in the band 156 to 162 MHz:

161.925 MHz___	F3, and when assigned to stations in an automated multi-station system, F2 and F4. The authorized bandwidth for F2 and F4 emissions will be the same as for F3 as specified in § 81.133.
161.825, 161.975	F3, and when assigned to stations in an automated multi - station system, F4. The authorized bandwidth for F4 emissions will be the same as for F3 as specified in § 81.133.
All other frequencies.	F3.

* * * * *

30. In § 81.303 a new paragraph (d) is added as follows:

§ 81.303 Duplication of service.

* * * * *

(d) The restrictions concerning impermissible overlap of coverage areas contained in paragraph (b) of this section, do not apply to stations operated as part of an automated multi-station Great Lakes System. The term automated multi-station system, as used in this part, refers to a system of contiguous-service-area, automated, coast stations, manually or automatically operated, capable of directly-dialed connection between ship station and land telephones, the operations of which are coordinated to provide the same services and service procedures to ships throughout the entire service area of the system's component stations, with assistance or other functions requiring human action provided by operators at a central location.

4. In § 81.304(a) a new condition of use designator 62 is added for the frequency 161.975 MHz, and in paragraph (b) a new subparagraph (62) is added as follows:

§ 81.304 Frequencies available.

* * * * *

(b) * * *

* * * * *

(62) When this frequency is assigned to stations in an automated multi-station system, the emissions F2 and F4 may be used as provided in § 81.132(a)(2)(iii). The provisions of paragraph (22) of this paragraph concerning a showing of channel occupancy do not apply for the assignment of a second channel to be used primarily for F2 and F4 emissions.

5. In § 81.314 a new paragraph (a)(14) is added to read as follows:

§ 81.314 Station records.

(a) * * *

* * * * *

(14) The required entries in the logs of an unattended public coast station in an automated multi-station system, as defined in § 81.303(d), may be made automatically, or manually by an operator at a central control point, in addition to or in lieu of entries recorded in the manner herein prescribed: *Provided*, The entries are readily available for inspection upon reasonable request by Commission representatives.

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

Section 83.132(a)(2)(iii) is amended to read as follows:

§ 83.132 Authorized classes of emission.

(a) * * *

* * * * *

(2) * * *

(iii) For the frequencies in the band 156 to 162 MHz:

157.325 MHz___	F3, and when exchanging communications with coast stations in an automated multi-station system operating on 161.925 MHz for other than voice communications, F2 and F4. The authorized bandwidth for F2 and F4 emissions will be the same as for F3 emissions as specified in § 83.133.
157.225, 157.375 MHz.	F3, and when exchanging communications with coast stations in an automated multi-station system operating on 161.825 or 161.975 MHz for other than voice communications, F4. The authorized bandwidth for F4 emissions will be the same as for F3 emissions as specified in § 83.133.
All other frequencies.	F3.

* * * * *

[FR Doc.76-24030 Filed 8-16-76;8:45 am]

POSTAL RATE COMMISSION

[39 CFR Part 3003]

[Docket No. RM76-7]

PRIVACY ACT RULES

Notice of Proposed Rulemaking

AUGUST 11, 1976.

Notice is hereby given that the Postal Rate Commission has under consideration rulemaking action to amend 39 CFR Part 3003 in order to improve its implementation of the Privacy Act of 1974 (5 U.S.C. 552a).

The proposed amendments would: (1) Modify the requirements for identification of individuals who make written requests concerning their individual records under 39 CFR § 3003.3; and (2) clarify 39 CFR § 3003.14, which relates to specific exemptions from the disclosure provisions of §§ 3003.3, 3003.4, 3003.5, 3003.6, 3003.7, 3003.8, 3003.9, and 3003.11. The Office of Management and Budget has recommended that the Commission consider the adoption of such changes in our rules.

The first change would be accomplished by replacing the current requirement of § 3003.4(b) that the individual making the request include his or her Social Security number as proof of identity with a more general requirement that the individual include suitable proof of identity, such as a facsimile of the sort of identifying document which the individual would be required to present under § 3003.4(a)(2) should he or she make the request in person. The specific exemption provisions of § 3003.14 would be amended to state that the Commission has not established any systems of records to be exempted.

The proposed amendments to Part 3003 are set forth in full at the conclusion of this notice. The Commission will entertain comments with respect to these proposed changes which are received on or before September 16, 1976. Comments should be filed with the Commission's Secretary, at the offices of the Postal Rate Commission, 2000 L Street, N.W., Washington, D.C. 20268.

Authority for the proposed rulemaking is contained in 39 U.S.C. 3603 and 5 U.S.C. § 552a.

Section 3003.4(b) is proposed to read as follows:

(b) An individual who files a request through the mails pursuant to paragraph (c) of § 3003.3 of this Part shall include his or her date of birth and other suitable proof of identity, such as facsimile of a driver's license, employee identification card, or Medicare card.

Section 3003.14 is proposed to read as follows:

§ 3003.14 Specific exemptions.

The Postal Rate Commission has not established any system of records to be exempted from the provisions of §§ 3003.3, 3003.4, 3003.5, 3003.6, 3003.7, 3003.8, 3003.9, and 3003.11 of this Part.

By the Commission.

[SEAL] JAMES R. LINDSAY, *Secretary.*

[FR Doc.76-24038 Filed 8-16-76;8:45 am]

DEPARTMENT OF LABOR

Employment Standards Administration

[20 CFR Part 725]

BLACK LUNG DISEASE

Claims for Disability or Death Benefits

Pursuant to authority contained in Title IV of the Federal Coal Mine Health and Safety Act of 1969, 83 Stat. 742, 30 U.S.C. 901 et seq., as amended by Pub. L. 92-303, 86 Stat. 156, entitled the Black Lung Benefits Act of 1972 (hereinafter the Act), notice is hereby given that it is proposed to amend Part 725 of Chapter VI of Title 20, Code of Federal Regulations, as set forth below.

20 CFR Part 725 contains the rules of the Department of Labor governing the filing, processing and adjudication of claims for black lung benefits under Part C of Title IV of the Act. Primarily, these amendments are intended to clairify certain interpretations and procedural rules applicable in respect of claims. Special

attention is appropriately given to the following proposed amendments:

1. Under current procedures a coal mine operator notified of his potential liability for the payment of benefits to a miner who alleges total disability due to pneumoconiosis may have that miner examined by one or more physicians selected by such operator (38 FR 26048, 26049). This privilege is afforded on the basis of language contained in sections 7 (e) and (f) of the Longshoremen's and Harbor Workers' Compensation Act, as amended, (LHWCA) 33 U.S.C. 907 (e), (f), as made applicable by section 422(a) of the Act. Sections 7 (e) and (f) of the LHWCA do not afford an employer the unqualified right to have a claimant examined by a physician selected by such employer, and in fact, extends such right to an employer under specified circumstances. It is, therefore, proposed to amend 20 CFR 725.153 to bring that section more in keeping with the meaning and intent of the statutory provision from which it was derived. It is not the intention of those proposed rules to eliminate the employer's right to a medical examination entirely, or to adopt the language of section 7 of the LHWCA verbatim. It is the intention of this proposed rule to more specifically describe the nature and extent of an employer's right to have a claimant examined by a physician selected by such employer.

2. Section 422(i), of the Act, 30 U.S.C. 932(i) provides that a coal mine operator who purchases a mine or substantially all the assets thereof subsequent to December 30, 1969, may be found liable for the payment of black lung benefits in respect of a claim arising out of employment with the seller of the mine or mine assets. 20 CFR 725.304 of the Secretary's regulations simply repeats the language of section 422(i) of the Act. It is, therefore, proposed to amend that section to describe more fully the operation of section 422(i).

3. 20 CFR 725.311 entitled "criteria for identifying a responsible operator" provides generally that the coal mine operator with whom the miner on whose total disability or death a claim is predicated, had the most recent cumulative periods of employment of not less than one year, shall, if such miner is found entitled to benefits pursuant to the Act, be responsible for the payment of those benefits. It is the intent of hese proposed rules to clarify the meaning of the term "one year." The definition of "one year" for the purposes of this part is derived from data provided by the Department of Interior which establishes the average number of days worked by a coal miner in any given year from 1920 to 1973.

4. In addition to the foregoing, these proposed amendments to Part 725 contain other technical and clarifying provisions.

Except as is otherwise provided, these proposed amendments shall be applicable in respect of all claims filed or processed after December 31, 1973. Interested persons are invited to submit written data, views, and comments concerning these proposed rules to the Office of Workers' Compensation Programs, United States Department of Labor, Washington, D.C. 20210, on or before August 30, 1976.

PART 725—CLAIMS FOR BLACK LUNG BENEFITS PAYABLE UNDER PART C OF TITLE IV OF THE FEDERAL COAL MINE HEALTH AND SAFETY ACT, AS AMENDED

1. It is proposed to revoke paragraphs (c) and (d) of § 725.132 as follows:

§ 725.132 Development of evidence—general.

* * * * *

(c) [Revoked]

(d) [Revoked]

* * * * *

2. It is proposed to revise § 725.133 as follows:

§ 725.133 Initial medical examination—miner.

(a) Upon the receipt of the appropriate claims forms, the OWCP, in appropriate cases, will arrange for each miner-claimant to be examined and tested by a physician or medical testing facility approved and authorized by the OWCP to conduct examinations in connection with the black lung benefits program.

(b) A miner who does not wish to be examined by a physician selected for him by the OWCP may, upon request, be afforded the opportunity to select a physician of his own choosing to conduct such examination.

(c) The OWCP shall arrange for a medical examination to be conducted, at a time and place convenient to both the miner and the approved physician or facility, and as soon as is practicable.

(d) The designated physician or facility will complete an examination of the miner to determine the nature and extent of the miner's impairment, enter his findings on the appropriate form pursuant to the instructions contained in such form, and transmit the form together with a bill for medical services rendered to the OWCP within 20 days from the date of the examination (see § 725.130(a)).

(e) The deputy commissioner responsible for initially adjudicating the claim shall have the power, in his discretion, to charge the cost of medical examinations conducted under this section to a notified operator, or to an operator's insurance carrier, or if there is no responsible operator, to the OWCP.

(f) Proceedings and all evidentiary development shall be suspended and no benefits shall be payable for any period during which a claimant-miner may unreasonably refuse to submit to a medical examination under this section. In the event of a suspension pursuant to this paragraph the procedures pertaining to the abandonment of a claim (see § 725.425) shall be followed by the OWCP.

(g) Paragraphs (b), (c), and (d) of § 725.134 shall apply with respect to examinations conducted pursuant to the provisions of this section, as is appropriate.

3. It is proposed to revise paragraph (c) of § 725.137 as follows:

§ 725.137 Action to be taken by the Office—miner's claim.

* * * * *

(c) In cases where the evidence received by the Office in respect to any claim does not support a claim for benefits, the claimant will be advised of the deficiency in his claim and directed by the Office to obtain such additional evidence as is necessary. Medical evidence obtained at the direction of the Office shall be paid for by the Office or notified operator, as appropriate.

* * * * *

4. It is proposed to revise § 725.153 as follows:

§ 725.153 Operator's medical evidence.

(a) Any operator or carrier who is dissatisfied with the evaluation of medical tests submitted to the Office in support of a claim shall, upon written request made to the appropriate deputy commisisoner, be permitted to submit the mechanically recorded results of such tests to one or more physicians selected by such operator or carrier, for re-evaluation. Such request shall contain the name and mailing address of the physician selected by the operator or carrier. Upon receipt of a request made pursuant to this paragraph, the deputy commissioner shall promptly forward such x-ray films, ventilatory test tracings, EKG results, and/or blood gas test results, if any, and/or any other mechanically recorded medical test results as are in his possession, directly to the physician designated by the operator or carrier to re-evaluate the results of such tests. Upon completion of any re-evaluation of test results submitted to a physician selected by an operator or carrier, such test results shall be promptly returned to the deputy commissioner.

(b) Any operator or carrier shall be entitled to have a miner who has filed a claim for benefits under the Act personally examined by one or more physicians selected by such operator or carrier: *Provided*, That:

(1) Such operator or carrier has been notified pursuant to this part or Part 720 of this chapter of its potential liability for the payment of benefits to such miner; and

(2) The miner is not required to travel more than 100 miles from his place of residence to submit to such examination unless the miner consents to travel a greater distance or unless a trip of a greater distance is warranted and will not be injurious to the health of the miner; and

(3) The miner shall, if he so chooses, be permitted to bring any person with him to the examination. Any person accompanying the miner to an examination conducted pursuant to this paragraph shall be permitted to observe the examination and testing of the miner conducted by the physician selected by an operator or carrier; and

(4) Any examination conducted pursuant to this paragraph shall not entail surgical procedures, or any testing or procedures which may be injurious to the health of the miner; and

(5) The physician selected to conduct an examination pursuant to this paragraph shall not be a regular employee of the operator or carrier unless the miner consents to be examined by such physician; and

(6) In the event that two or more operators and/or carriers request that the miner submit to examination(s) pursuant to this section, such examination(s) shall if practicable be conducted at approximately the same time and place. No miner shall be required to submit to multiple examinations at the request of two or more operators and/or carriers unless so ordered for good cause shown.

(c) The findings of any physician selected by an operator or carrier pursuant to paragraphs (a) and (b) of this section shall, unless circumstances justify a different procedure, be mailed to the appropriate adjudication officer and the claimant's duly authorized representative within twenty days after the date of the examination of the miner or review of previously submitted medical evidence. A copy of such findings may be sent to the claimant upon request unless the physician making such findings indicates that such disclosure may adversely affect the claimant.

(d) The findings of any physician selected by an operator or carrier pursuant to paragraphs (a) and (b) of this section, which are predicated upon the results of a roentgenographic examination or re-reading of an x-ray film previously taken, shall be made on Department of Labor Form CM–933 or shall be made pursuant to:

(1) The ILO–U/C International Classification of Radiographs of Pneumoconioses, 1971; or

(2) The International Classification of Radiographs of the Pneumoconioses of the International Labor Office, Extended Classification (1968); or

(3) The Classification of the Pneumoconioses of the Union International Contra Cancer/Cincinnati (1968).

A roentgenographic interpretation not made in accordance with the requirements of this paragraph shall not constitute evidence of the presence or absence of pneumoconiosis.

(e) All reasonable expenses including travel expenses incurred in connection with an examination or review of medical test results conducted pursuant to this section shall be paid by the operator or carrier requesting such review or examination. Reasonable travel expenses and fees, if appropriate, incurred or charged by a person selected by a miner to accompany him or her to such examination pursuant to paragraph (b)(3) of this section, shall be paid by the operator or carrier requesting such examination.

(f) If the miner unreasonably refuses to submit to an examination by a physician selected by the operator, the appropriate adjudication officer may, by order suspend the payment of benefits and further development of the claim during such time as such refusal continues.

5. It is proposed to revise § 725.302 as follows:

§ 725.302 Operator defined.

Section 3(d) of the Act defines "operator" for purposes of the Act to mean "any owner, lessee, or other person who operates, controls, or supervises a coal mine." In keeping with the congressional mandate that operators assume liability for pneumoconiosis benefits to the fullest extent possible the above cited definition of operator shall be liberally construed. In each case an effort shall be made to attribute liability to that individual or business entity most directly responsible for the operation and control of any particular coal mine. However, in appropriate cases where, for instance, the individual or business entity most directly connected with the mine site has not obtained insurance or been authorized to self-insure and is insolvent or is no longer in existence, or does not have sufficient assets to guarantee the payment of future benefits and such individual or business entity is a subsidiary corporation, or a part of a joint venture or partnership, or is or was substantially controlled or owned by another business entity, such other corporation, partnership, joint venture or other business entity, regardless of the primary or diverse nature of its business activity, may be considered an "operator for purposes of sections 415, 422, and 423 of Title IV of the Act. In addition, any other business entity, whose employees may be considered miners as defined in section 402(d) of Title IV of the Act by virtue of the fact that such employees are employed in a coal mine as defined in section 3(h) of the Act, may be considered an operator for purposes of sections 415, 422, and 423 of Title IV of the Act with respect to such employees. Standard workers' compensation tests may be applied to determine the real identity of the employer of any particular employee.

6. It is proposed to amend § 725.304 as follows:

§ 725.304 Prior operator, successor operator.

(a) Section 422(i)(1) of the Act provides that any coal mine operator who on or after December 30, 1969, acquired his mine or substantially all the assets of his mine from a prior operator who was an operator of that mine on or after December 30, 1969, shall be liable for and shall, in accordance with section 423 of the Act and Part 726 of this subchapter, secure the payment of all benefits which would have been payable by the prior operator with respect to miners previously employed in that mine if the acquisition had not occurred and the prior operator had continued to operate the mine.

(b) Section 422(i)(2) of the Act further provides that nothing contained in section 422(i)(1) shall relieve any prior operator of any liability which such prior operator may have incurred under the Act. The stated congressional objective supporting the enactment of section 422(i) is to prevent a coal operator from circumventing the coal operator liability provisions of Part C of the Title IV of the Act by entering into corporate or other business transactions which make the assessment of liability against such coal operator a financial or legal impossibility. Accordingly, a coal operator (prior operator) who sells a mine or mines or substantially all the assets thereof shall remain primarily liable for the payment of benefits under this part predicated upon employment in such mine or mines unless such prior operator either (1) was not a coal mine operator as defined in this chapter after June 30, 1973 or (2) is not financially responsible (see § 725.321). The sale of a mine or mines or the assets of such mine or mines by an ongoing coal mine operator whose coal mining or preparation business continues beyond the date of such sale or transfer shall not be sufficient grounds in and of itself upon which to invoke the exception contained in section 422(i) of the Act. However, if an operator after December 30, 1969, has sold one or all of such operator's mines or substantially all the assets thereof to a successor operator and such prior operator is no longer in existence, or no longer in the coal business, and was never required to secure insurance or qualify as a self-insurer with respect to potential liability under this part, or is not otherwise financially responsible (see § 725.321), such successor operator shall, if appropriate, be responsible for the payment of benefits as required by this part with respect to liability arising out of employment with such prior operator in the mine or mines sold to such successor operator.

(c) Nothing in the section shall be construed to preclude the assessment of liability against a coal mine operator under circumstances not addressed in this section.

7. It is proposed to amend paragraphs (a) and (c)(2) of § 725.311 as follows:

§ 725.311 Criteria for identifying a responsible operator.

* * * * *

(a) *Periods of employment.*—(1) *Cumulative employment.* From the evidence presented of the miner's employment history, the identity of the coal mine operator or operators with whom the miner had the most recent periods of cumulative employment of not less than one year and the beginning and ending dates of such periods shall be ascertained. However, no period of employment terminating more than 15 years prior to the miner's last date of coal mine employment shall be accumulated for the purposes of establishing the one year period described in this paragraph. Continuous periods of employment shall not be split for the purposes of this paragraph. If a miner was

regularly and continuously employed by an operator both before and after a date 15 years prior to such miner's last date of coal mine employment, such miner's entire period of employment with such operator may be accumulated for the purpose of establishing the one year period described in this paragraph.

(2) *One cumulative year defined.* For the purposes of this section, there shall be a rebuttal presumption that a miner has worked for a particular coal operator for a period of one cumulative year if such miner was employed by such operator for a cumulative total of four calendar quarters. This presumption may be rebutted if evidence demonstrates that such miner was not employed for a cumulative period of at least 200 working days during the four or more calendar quarters upon which the determination that a miner was employed by a particular operator for one cumulative year is based.

(3) *Working day defined.* For the purpose of this section the term "working day" shall mean any day or any part of a day during which a miner performed services for pay in the furtherance of the business of the coal mine operator identified as the responsible operator pursuant to the provisions of this section. Periods of excused absence from work such as sick or vacation days, whether with or without pay, shall be considered working days for the purposes of this part.

* * * * *

(c) *Determination of responsible operator.* (1) * * *

(2) If the operator described in paragraph (c) (1) of this section is a prior operator as described in § 725.304 who, on or after December 30, 1969, transferred his coal mining business or substantially all the assets thereof to a successor operator, or if such business or assets was subsequently transferred to a successor to such successor operator as described in § 725.304, such successor operator who has most recently acquired the coal mining operations in question or substantially all of the assets thereof shall if financially responsible be deemed the responsible operator. If such successor operator is not financially responsible any prior operator or any operator in the chain of succession, beginning with the most recent operator, who acquired the coal mining business in question or substantially all of the assets thereof on or after December 30, 1969, and who is financially responsible may be determined to be the responsible operator. Any successor operator may be determined to be the responsible operator with respect to a claim whether or not the miner on whose total disability or death the claim is predicated was employed by such successor operator for any period of time.

* * * * *

8. It is proposed to revise § 725.461 as follows:

§ 725.461 Evidence.

In making an investigation or inquiry or conducting a hearing the administrative law judge shall not be bound by common law or statutory rules of evidence or by technical or formal rules of procedure, except as provided by 5 U.S.C. 554 and this part. He may conduct such investigation or inquiry as to best ascertain the rights of the parties.

§ 725.472 [Reserved]

9. It is proposed to revoke § 725.472.

Signed at Washington, D.C., this 11th day of August 1976.

JOHN C. READ,
Assistant Secretary for Employment Standards.

[FR Doc.76-24080 Filed 8-16-76;8:45 am]

notices

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

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

DEPARTMENT OF STATE

Agency for International Development

[Redelegation of Authority No. 99.1.79]

AID REPRESENTATIVE, BRAZILIA, BRAZIL

Redelegation of Authority Regarding Contracting Functions

Pursuant to the authority delegated to me as Director, Office of Contract Management, under Redelegation of Authority No. 99.1 (38 FR 12836), as amended, from the Assistant Administrator for Program and Management Services of the Agency for International Development, I hereby redelegate to the AID Representative, Brazilia, Brazil, the authority to sign or approve:

1. U.S. Government contracts, and amendments thereto, and AID grant-financed host country contracts for technical assistance, provided that the aggregate amount of each individual contract does not exceed $100,000 or local currency equivalent.

2. Contracts with individuals for the services of the individual alone without monetary limitations.

3. Grants (other than grants to foreign governments or agencies thereof), and amendments thereto, for technical assistance, provided that the aggregate amount of each individual grant does not exceed $100,000 or local currency equivalent.

The authority herein delegated may be redelegated in writing in whole or in part, by said AID Representative at his discretion to the person or persons designated by the AID Representative as Contracting Officer. Such redelegation shall remain in effect until such designated person or persons cease to hold the office of Contracting Officer for AID programs, or until the redelegation is revoked by the AID Representative, whichever shall first occur. The authority so redelegated by the AID Representative may not be further redelegated.

The authority delegated herein is to be exercised in accordance with regulations, procedures, and policies now or hereafter established or modified and promulgated within AID and is not in derogation of the authority of the Director of the Office of Contract Management to exercise any of the functions herein redelegated.

The authority herein redelegated to the AID Representative may be exercised by duly authorized persons who are performing the functions of the AID Representative in an acting capacity.

Redelegations of Authority 99.1.36 (38 FR 29498), dated September 28, 1973, as amended (41 FR 12720), dated March 9, 1976, is hereby revoked.

Any official actions taken prior to the effective date hereof by officers duly authorized pursuant to delegations revoked hereunder are hereby continued in effect, according to their terms until modified, revoked, or superseded by actions of the officer to whom I have delegated relevant authority in this delegation.

Actions within the scope of this delegation and any redelegation hereunder heretofore taken by officials designated in such delegation or redelegation are hereby ratified and confirmed.

This redelegation of authority shall be effective immediately.

Date: August 9, 1976.

RUSSELL DILTS,
Acting Director,
Office of Contract Management.

[FR Doc.76-23994 Filed 8-16-76;8:45 am]

[No. 99.1.71]

GLENWOOD P. ROANE

Cancellation of Redelegation of Authority

Pursuant to the authority delegated to me by Redelegation of Authority No. 99.1 (38 FR 12836), dated May 1, 1973, from the Assistant Administrator for Program and Management Services, I hereby revoke Redelegation of Authority No. 99.1.-71 to Glenwood P. Roane (40 FR 21744). This revocation is effective immediately.

Dated: August 2, 1976.

HUGH L. DWELLEY,
Director Office of
Contract Management.

[FR Doc.76-23993 Filed 8-16-76;8:45 am]

Agency for International Development

RESEARCH ADVISORY COMMITTEE

Meeting

Pursuant to Executive Order 11769 and the provisions of Section 10(a)(2), P.L. 92-463, Federal Advisory Committee Act, notice is hereby given of the A.I.D. Research Advisory Committee meeting on October 12 and 13, 1976, at the Pan American Health Organization Building, 23rd Street and Virginia Avenue, N.W., Conference Room "C", to review, appraise and make recommendations to the Administrator, Agency for International Development, concerning projects proposed for A.I.D. central research funding in the fields of food and nutrition, and health and population. The meeting will begin at 9:00 a.m. and adjourn at 5:30 p.m. each day. The meeting is open to the public. Dr. Erven J. Long, Associate Assistant Administrator is designated as the A.I.D. representative at the meeting. It is suggested that those desiring more specific information contact Dr. Erven J. Long, 21st and Virginia Avenue, N.W., Washington, D.C., 20523, or call area code 202-632-3800.

Dated: August 10, 1976.

ERVEN J. LONG,
A.I.D. Representative,
Research Advisory Committee.

[FR Doc.76-24035 Filed 8-16-76;8:45 am]

Office of the Secretary

[Public Notice 494]

PRESIDIO COUNTY, TEXAS

International Bridge Permits

Notice is hereby given that on July 2, 1976, the Deputy Secretary of State determined that issuance of a permit authorizing Presidio County, Texas, to construct, operate and maintain an international bridge in the vicinity of Presidio County, Texas, would serve the national interest. The Deputy Secretary accordingly signed a permit authorizing Presidio County to do so, subject to stated conditions, in accordance with the International Bridge Act of 1972 and Executive Order 11423.

Thereafter, as required by section 1(f) of E.O. 11423, the Department of State gave written notice to concerned agencies of the Deputy Secretary's determination and of the proposed issuance of the permit. No agency has requested that the matter be referred to the President for decision in accordance with section 1(f) of E.O. 11423.

The fifteen day notification period under section 1(f) of E.O. 11423 having expired, the Department of State has issued and transmitted to Presidio County, Texas, a permit authorizing the County to construct, operate and maintain an international bridge in the vicinity of Presidio, Texas.

For the Secretary of State.

Dated: August 4, 1976.

GERALD A. ROSEN,
Acting, Assistant Legal Adviser
for Economic and Business
Affairs.

[FR Doc.76-23917 Filed 8-16-76;8:45 am]

DEPARTMENT OF DEFENSE

Department of the Air Force

McGHEE-TYSON AIRPORT, TENNESSEE

Environmental Determination Regarding Transfer of KC-135 Tankers

AUGUST 3, 1976.

On April 9, 1976 the Department of the Air Force announced in the FEDERAL

REGISTER (page 15038) its intent to prepare Environmental Impact Statements on certain proposed management actions announced by Secretary of the Air Force Thomas C. Reed on March 11, 1976.

Among the actions for which an Environmental Impact Statement was to be prepared was the transfer of KC–135 tankers to the Air Reserve Forces unit at McGhee-Tyson Airport, Tennessee.

After careful review of a thorough and complete Environmental Impact Assessment it has been concluded on July 30, 1976 that the proposed replacement of the KC–97L aircraft, now at McGhee-Tyson Airport, with the KC–135 aircraft does not constitute a major Federal action significantly affecting the quality of the human environment nor is it likely to be highly controversial with regard to its environmental impacts. This conclusion was based on the following:

(a) The primary environmental impact would be an increase in the ambient noise levels. This would result in an increase in the area delineated by the Day-Night Average Sound Level system in which it is recommended that certain activities be restricted. Programmed installations of sound suppressors on the engine test cell, maximum feasible scheduling of ground runups for periods when they will be less noticed (usually daylight hours) and a variety of operational procedures will minimize the impact from the increased noise levels.

(b) The changes in air pollutants emissions will be a very slight increase in the emissions of particulates, sulfur oxides and nitrogen oxides and a decrease in the carbon monoxide and hydrocarbon emissions. Air quality at McGhee Tyson Airport is now excellent and would continue to be so if this proposal is implemented. When operating with water thrust augmentation, the KC–135 emits a visible plume which is mostly water vapor, dissipates rapidly and contributes virtually nothing in the way of real pollutants.

(c) The proposed action has been widely publicized in the local area. There is substantial local support for the proposed conversion and no known significant controversy.

For the reasons outlined above, the United States Air Force has decided not to file a Draft Environmental Statement with the Council on Environmental Quality but has prepared an Environmental Determination.

Copies of the Environmental Determination and the supporting documentation are available upon request to HQ USAF/PREV, Pentagon, Washington, D.C. 20330.

JAMES L. ELMER, Major,
USAF, Executive Directorate of Administration.

[FR Doc.76–23903 Filed 8–16–76;8:45 am]

Department of the Navy

UNDERWATER SOUND ADVISORY COMMITTEE

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. I), notice is given that the Underwater Sound Advisory Committee (USAC) will meet on September 20, 1976, at the Navy Underwater Systems Center, New London Laboratory, New London, Connecticut. The meeting will commence at 1:00 p.m. The purpose of the meeting is to discuss the following topics: status of 31st Biannual Symposium on Underwater Acoustics; recent approval of USAC as a formally recognized Navy advisory committee; proposed joint sponsorship of USAC by Chief of Naval Research and Chief of Naval Development; recently completed USAC report on 6.1 (budget appropriations for research) sponsored research in acoustics; future mini-symposia/workshops; USAC sub-committees; towed array symposium; and scheduling of next USAC meeting.

Dated: August 10, 1976.

JOHN S. JENKINS,
Captain, JAGC, U.S. Navy, Assistant Judge Advocate General (Civil Law).

[FR Doc.76–24032 Filed 8–16–7;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM 28415, 28418 and 28419]

NEW MEXICO

Applications

AUGUST 4, 1976.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Company has aplied for three 4½-inch natural gas pipeline rights-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 30 N., R. 9 W.,
Sec. 9, S½NW¼;
Sec. 15, SW¼SE¼;
Sec. 27, NW¼NW¼.

These pipelines will convey natural gas across .257 of a mile of national resource land in San Juan County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the applications should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, New Mexico 87107.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc.76–24034 Filed 8–16–76;8:45 am]

[S–52(0]

CALIFORNIA

Designation of Negit Island Natural Area; Correction

AUGUST 10, 1976.

In FR Doc. 72–15242, appearing on pages 18224 and 18225 of the issue of Friday, September 8, 1972, the following correction should be made:

T. 2 N., R. 26 E.,
Secs. 13 and 14 should be
T. 2 N., R. 26 E.,
Secs. 13 and 24.

ED HASTEY,
State Director.

[FR Doc.76–24033 Filed 8–16–76;8:45 am]

BURNS DISTRICT ADVISORY BOARD

Meeting

Notice is hereby given that the Burns District Advisory Board will meet on September 16 and 17, 1976, commencing at 8:30 a.m. on September 16 in the Burns District Office at 74 S. Alvord St., Burns, Oregon. The agenda will include a tour of the Drewsey Resource Area on September 16 and on September 17 a discussion of the Drewsey Environmental Statement and a slide presentation of wilderness proposals will be held in the district office and a tour of the horse holding facility will be held in the afternoon.

The meetings will be open to the public. Transportation on the tour of Drewsey Area will be furnished for board members only, the public will be required to provide their own transportation and meals. In addition to discussion of agenda topics by board members, there will be time for brief statements by nonmembers. Persons wishing to make oral statements should so advise the chairman or co-chairman prior to the meeting, to aid in scheduling the time available. Any interested person may file a written statement for consideration by the board by sending it to the chairman, in care of the co-chairman: Burns District Manager, 74 S. Alvord, Burns, Oregon, 97720.

JEROME M. HEINZ,
Acting District Manager.

AUGUST 6, 1976.

[FR Doc.76–23905 Filed 8–16–76;8:45 am]

MONTROSE DISTRICT MULTIPLE USE ADVISORY BOARD

Meeting

AUGUST 10, 1976.

Notice is hereby given that the Montrose District, Bureau of Land Management Multiple Use Advisory Board will meet September 28 & 29, 1976.

The meeting will begin at 8 a.m., September 28, 1976, in the Montrose District Office, Highway 550 South, Montrose, Colorado.

The agenda for the meeting will include a field trip to view mineral development and associated activities in the Montrose District on the first day. The second day's agenda will include a review of progress and plans for completion of the Uncompahgre Basin Livestock Grazing Environmental Statement and coal development plans in the North Fork of the Gunnison region for the purpose of receiving Advisory Board recommendations.

The meeting is open to the public. Interested persons may make brief oral presentations to the Board on September 29, 1976, at the Montrose District Office, or present written statements. Persons who wish to make oral statements should notify the Montrose District Manager, P.O. Box 1269, Montrose, Colorado 81401 (Phone No. 403/249-7791) prior to the meeting.

AUGUST 10, 1976.

MARLYN V. JONES,
District Manager.

[FR Doc.76-24035 Filed 8-16-76;8:45 am]

PRINEVILLE DISTRICT ADVISORY BOARD

Meeting

Notice is hereby given that the Prineville District, Bureau of Land Management Multiple Use Advisory Board will meet September 30, 1976, at 9:00 AM in the conference room of the Prineville District office at 185 E. Fourth Street, Prineville, Oregon 97754.

Subjects to be discussed at the meeting include: the district's oil and gas leasing program, the geothermal leasing program, allotment management plans and the high desert grazing Environmental Impact Statement, management framework planning for the Prineville and vicinity planning unit, the Bear Creek watershed program, proposed regulations for grazing and off-road vehicle use, the fiscal year 1977 annual work plan, and formulation of an agenda for the next meeting.

The meeting is open to the public; any person or group wishing to make a presentation will be limited to a 15 minute presentation and must notify the District Manager prior to September 25.

Further information concerning the meeting may be obtained from Paul Arrasmith, District Manager of the Prineville District, phone number 503-447-4115.

REINARD B. OKESON,
Acting District Manager.

AUGUST 9, 1976.

[FR Doc.76-23907 Filed 8-16-76;8:45 am]

SALT LAKE DISTRICT MULTIPLE USE ADVISORY BOARD

Meeting

Notice is hereby given in accordance with P.L. 92-463 that a meeting of the Salt Lake District Multiple Use Advisory Board will be held September 15 and 16, 1976, commencing at 8:00 a.m. at the Salt Lake District Office at 2370 South 2300 West in Salt Lake City, Utah. The subject Advisory Board was established to advise the District Manager on matters pertaining to multiple use management in the Salt Lake District.

The first day will consist of a field trip of the Randolph Planning Unit including the Crawford Mountain phosphate mining area, the Big Creek fisheries and enclosure, the Woodruff Pastures Allotment and the on-going oil and gas activity.

The second day will commence with a formal meeting at the Ramada Inn at Evanston, Wyoming at 8:00 a.m. The meeting will continue until approximately 12:00 noon and will consist of brief presentations and discussion on the following topics:

1. Discussion and feed-back from the previous Advisory Board meeting, May 25, 26 and 27, 1976.
2. Phosphate mining program and prospecting permits in Rich County.
3. The range management program in Rich County.
4. Randolph Planning efforts.
5. Oil and gas activity in Rich County.

The second day will continue with the tour from 1:00 p.m. until arrival back in Salt Lake at approximately 6:00 p.m.

The meeting is open to the public. Members of the public must provide their own transportation, meals and accommodations. Time will be made available at 11:00 a.m. for oral statements from the public; however, requests for oral presentations before this Board should be made to the official listed below at least two days prior to the meeting. Topics must be those included in the agenda. The Chairman or Authorized Federal Official may limit public attendance to the extent that available facilities and time require limitation.

Further information concerning this meeting may be obtained from Rulon McRae, Acting District Manager, Bureau of Land Management, 2370 South 2300 West, Salt Lake City, Utah 84119, telephone number (801) 524-5348. Minutes of the meeting will be available for public inspection and copy thirty days after the meeting at the Salt Lake District Office.

Dated: August 9, 1976.

RULON G. MCRAE,
Acting District Manager.

[FR Doc.76-23988 Filed 8-16-76;8:45 am]

[Serial Number A 9613]

ARIZONA

Proposed Withdrawal and Reservation of Lands

The Department of the Army, United States Army Engineer District, Los Angeles, Post Office Box 2711, Los Angeles, California 90053, has filed an application Serial Number A 9613, for the withdrawal of public lands and mineral estates from entry and appropriation under the public land laws and the general mining laws, including the mineral leasing laws, subject to valid existing rights.

It is proposed to withdraw the following described lands from all forms of appropriation under the public land laws and from location and entry under the general mining laws, including the mineral leasing laws:

GILA AND SALT RIVER MERIDIAN, ARIZONA

T. 4 N., R. 3 E.,
Sec. 3, lots 3 and 4, SW¼NW¼, N½SW¼, and SE¼SW¼;
Sec. 4, lots 1, 2, 5, 6, 7, 8, 9, and 10, S½SE¼ and E½SW¼.

The areas described aggregate 534.19 acres in Maricopa County.

The surface of the following described lands has been transferred out of Federal ownership with minerals reserved to the United States; it is proposed to withdraw the mineral estate from location and entry under the mining laws, including the mineral leasing laws:

GILA AND SALT RIVER MERIDIAN, ARIZONA

T. 4 N., R. 3 E.,
Sec. 3, N½SE¼NE¼.
T. 5 N., R. 3 E.,
Sec. 27, S½S½NW¼;
Sec. 33, lots 1, 2, 3, and 4, NE¼, W½SE¼, SE¼SE¼NW¼, and NE¼SW¼;
Sec. 34, lot 1, N½, NE¼SW¼, and S½SW¼.

The areas described aggregate 834.97 acres in Maricopa County.

The lands are needed for the construction, operation, and maintenance of a congressionally authorized flood control project and proposed recreational development. The lands are required either for the location of the dam and appurtenances or are within the reservoir area. Recreational development is proposed as a concurrent use. The intended using agency is the Flood Control District of Maricopa County, a political subdivision of the State of Arizona, 3325 West Durango Street, Phoenix, Arizona 85009.

On or before September 16, 1976, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may pre-

sent their views in writing to the undersigned officer of the Bureau of Land Management, Department of the Interior, 2400 Valley Bank Center, Phoenix, Arizona 85073.

The Department's regulations provide that the authorized officer of the Bureau of Land Management will undertake such investigations as are necessary to determine the existing and potential demands for the lands and their resources. He will also undertake negotiations with the applicant agency with the view of adjusting the application to reduce the area to the minimum essential to meet the applicant's needs, to provide for the maximum concurrent utilization of the lands for purposes other than the applicant's, to eliminate lands needed for purposes more essential than the applicant's, and to reach agreement on the concurrent management of the lands and their resources.

The authorized officer will also prepare a report for consideration by the Secretary of the Interior who will determine whether or not the lands will be withdrawn as requested by the applicant agency.

The determination of the Secretary on the application will be published in the FEDERAL REGISTER. A separate notice will be sent to each interested party of record.

If circumstances warrant, a public hearing will be held at a convenient time and place, which will be announced.

Dated: August 6, 1976.

GLENDON E. COLLINS,
Acting State Director.

[FR Doc.76-23906 Filed 8-16-76;8:45 am]

National Park Service

[Order No. 1, Amdt. 3]

SUPERINTENDENTS, ET AL., ROCKY MOUNTAIN REGION

Delegation of Authority

Order No. 1, approved February 27, 1974, and published in the FEDERAL REGISTER of April 5, 1974 (39 FR 12369); Amendment No. 1, approved January 29, 1975, and published in the FEDERAL REGISTER of March 31, 1975 (40 FR 14346); and Amendment No. 2, approved April 12, 1976, and published in the FEDERAL REGISTER of May 14, 1976 (41 FR 19994), set forth in Section 2 the limitations on delegations of authority. Section 2, paragraphs (e) and (g) are hereby amended to read as follows:

SEC. 2, *Delegation.* * * * (e) *Regional Purchasing Agents.* The Regional Purchasing Agents may execute and approve purchase orders not in excess of $10,000 for equipment, supplies, and services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds. This authority may be executed by the Regional Purchasing Agents in behalf of any office or area for which the Rocky Mountain Regional Office serves as the field finance office.

(g) *Field Land Acquisition Officers.* The Field Land Acquisition Officers, Glacier National Park, Grand Teton National Park and Utah Lands Office are authorized to execute their land acquisition program including contracting for acquisition of lands and related property and acceptance of offers to sell to or exchange with the United States, land or interest in lands, and to execute all necessary agreements and conveyances incidental thereto when the amount does not exceed $150,000. Said authority will be exercised in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

(National Park Service Order No. 77 (38 FR 7478) as amended)

Dated: June 1, 1976.

LYNN H. THOMPSON,
Regional Director,
Rocky Mountain Region.

[FR Doc.76-24027 Filed 8-16-76;8:45 am]

CAPE LOOKOUT NATIONAL SEASHORE, NORTH CAROLINA; STATEMENT FOR MANAGEMENT

Public Meetings

The National Park Service of the Department of the Interior will hold two pre-planning public meetings in North Carolina during September 1976. The purpose of these meetings is to obtain the public's suggestions and information on suggested alternatives for management protection and development of Cape Lookout National Seashore.

The meetings will be held September 14, 1976, at 7 p.m. at Jane S. McKimmon Extension Education Center, North Carolina State University, P.O. Box 5125, Raleigh, North Carolina 27607, located off Western Boulevard and Gorman Street; and September 16, 1976, at 7 p.m. at North Carolina Marine Resources Center/Bogue Banks, Route 1, Bridge Road, Pine Knoll Shores, Morehead City, North Carolina 28557, located 6 miles west of Atlantic Beach off Salter Path Road in Pine Knoll Shores. Comments and suggestions for incorporation in an Environmental Assessment will be received until October 18, 1976.

Anyone needing more information on the public meetings, National Park Service Planning Process, or wishing to submit comments or suggestions on Cape Lookout National Seashore may write to the Superintendent, Cape Lookout National Seashore, P.O. Box 690, Beaufort, North Carolina 28516.

Dated: July 30, 1976.

DAVID G. WRIGHT,
Acting Regional Director,
Southeast Region.

[FR Doc.76-24023 Filed 8-16-76;8:45 am]

ROCKY MOUNTAIN REGIONAL ADVISORY COMMITTEE

Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Rocky Mountain Regional Advisory Committee will be held on September 22-23, 1976, at Grand Teton National Park, Moose, Wyoming; September 23-24, 1976, at Yellowstone National Park, Wyoming; and on September 25, 1976, at Bighorn Canyon National Recreation Area, Lovell, Wyoming.

The purpose of the Rocky Mountain Regional Advisory Committee is to provide for the free exchange of ideas between the National Park Service and the public and to facilitate the solicitation of advice or other counsel from members of the public on problems and programs pertinent to the Rocky Mountain Region of the National Park Service.

The members of the Advisory Committee are as follows:

Dr. John D. Hunt, Logan, Utah (Chairman); Mr. Ralph M. Clark, Denver, Colorado; Mr. Hoadley Dean, Rapid City, South Dakota; Mr. William W. Robinson, Denver, Colorado; Mrs. Alice Fryslie, Bozeman, Montana; Mr. Sanmuel J. Taylor, Moab, Utah; Mr. D. C. "Del" Shipman, Watford City, North Dakota; and Mr. Vince R. Lee, Wilson, Wyoming.

The meetings and onsite inspections will be conducted in different locations as follows:

September 22—
9 a.m.: Tour Grand Teton National Park.
1 p.m.: Public meeting at the Brinkerhoff House, Grand Teton National Park to discuss the following topics: (1) Grand Teton National Park Boundary Study; (2) Regional Transportation Study; (3) Proposed 115 kV transmission line from Jackson to Grand Teton National Park.

September 23—
9 a.m.: Additional onsite tours.
1 p.m.: Depart via bus for Yellowstone National Park.

September 24—
9 a.m.: Tour Yellowstone National Park.
1 p.m.: Public meeting at Old Faithful Inn, Yellowstone National Park to discuss the following topics: (1) Concessions management including Grant Village; (2) Fire Management; (3) Bear management; (4) The Yellowstone Institute.
3 p.m.: Depart for Lovell, Wyoming.

September 25—
11 a.m.: Dedication of Lovell Visitor Center, Bighorn Canyon National Recreation Area, Lovell, Wyoming.

Persons wishing information concerning this meeting or who wish to submit written statements may contact the Superintendents of Grand Teton and Yellowstone National Parks or Committee Manager Forrest Benson, Rocky Mountain Regional Office, National Park Service, Denver, Colorado 80225. Telephone: (303) 234-4943.

Minutes of the meeting will be available for public inspection approximately 4 weeks after the meeting at the Rocky Mountain Regional Office, 655 Parfet Street, Denver, Colorado.

Dated: August 6, 1976.

LYNN H. THOMPSON,
Regional Director,
Rocky Mountain Region.

[FR Doc.76-24025 Filed 8-16-76;8:45 am]

NATIONAL REGISTER OF HISTORIC PLACES

Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before August 6, 1976. Pursuant to § 60.13(a) of 36 CFR Part 60, published in final form on January 9, 1976, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the Keeper of the National Register, National Park Service, U.S. Department of the Interior, Washington, D.C. 20240. Written comments or a request for additional time to prepare comments should be submitted by August 27, 1976.

JERRY L. ROGERS,
Acting Director, Office of Archeology and Historic Preservation.

ALABAMA

Lee County

Opelika, *U.S. Post Office*, 701 Avenue A.

ALASKA

Anchorage Division

Anchorage, *Bieri, Sam, House*, 136 W. 7th Ave.

Kuskokwim Division

Shageluk vicinity, *Iditarod, SE of Shageluk.*

ARIZONA

Maricopa County

Phoenix, *Evans House*, 1108 W. Washington St.

CALIFORNIA

Los Angeles County

Walnut, *Rowland, W. R. Ranch House*, 130 Avenida Alipaz.

Santa Clara County

San Jose, *Roberto-Sunol Abode*, 770 Lincoln Ave.

Yolo County

Davis, *Dresbach-Hunt-Boyer House*, 604 2nd St.

DELAWARE

New Castle County

Newark vicinity, *Eastburn-Jeanes Lime Kilns Historic District*, N of Newark on Limestone Rd. (DE 72).

New Castle County

Wilmington, *Friends Meetinghouse*, 4th and West Sts.
Wilmington, *Old Asbury Methodist Church*, Walnut and 3rd Sts.

GEORGIA

Fulton County

Atlanta, *Peachtree Southern Railway Station*, 1688 Peachtree St., NW.

KENTUCKY

Jefferson County

Louisville, *Louisville City Hall Complex*, 601, 603, 617 W. Jefferson St.

MAINE

Androscoggin County

Auburn, *Foss, Horatio G., House*, 19 Elm St.

Cumberland County

Brunswick, *Lincoln Street Historic District*, Lincoln St. between Main and Union Sts.
Falmouth, *Falmouth House*, 340 Gray Rd.
North Falmouth vicinity, *Falmouth House*, 340 Gray Rd.

Hancock County

Sunset vicinity, *Olmsted, Frederick Law, Summer Home*, SSW of Sunset on Deer Isle.

Kennebec County

Waterville, *First Baptist Church*, Park and Elm Sts.

Lincoln County

Walpole vicinity, *Walpole Meetinghouse*, N of Walpole on Meeting House Rd.

Penobscot County

Dixmont, *Bussey, Louis I., School*, U.S. 202.
North Brewer vicinity, *Penobscot Salmon Club and Pool*, N. Main St.

Piscataquis County

Dover-Foxcroft, *Wiley, James Sullivan, House*, Main St.

Waldo County

Belfast, *First Church of Belfast*, Church St.

Washington County

Machias, *The Lion* (locomotive), University of Maine at Machias.
Machias, *Washington County Courthouse*, Court St.

York County

Saco, *Thacher-Goodale House*, 121 North St.
York Corner vicinity, *Barrell Homestead*, W of York Corner on Beech Ridge Rd.

MARYLAND

Somerset County

Princess Anne, *Manokin Presbyterian Church*, N. Somerset Ave.

MASSACHUSETTS

Berkshire County

Lee, *Hyde House*, 114 W. Park St.

Bristol County

Fall River, *U.S.S. Joseph P. Kennedy Jr.* Battleship Cove.
Fall River, *U.S.S. Lionfish*, Battleship Cove.
Fall River, *U.S.S. Massachusetts*, Battleship Cove.

Worcester County

Royalston, *Royalston Common Historic* District, Main St., Frye Hill Rd., and Athol Rd.

MONTANA

Cascade County

Great Falls, *Great Falls Central High School*, 1400 1st Ave. N.

Missoula County

Missoula, *Missoula County Courthouse*, 220 W. Broadway.

Silver Bow County

Butte, *Clark, Charles W., Mansion*, 108 N. Washington St.

NEW JERSEY

Passaic County

North Haledon vicinity, *Van Duyne House*, NW of North Haledon on Berdan Ave.

NEW YORK

Delaware County

Delhi vicinity, *Frisbee, Judge Gideon, House*, NE of Delhi on NY 10.

Nassau County

Lawrence, *Rock Hall*, 199 Broadway.

Oyster Bay, *First Presbyterian Church of Oyster Bay*, E. Main St.
Westbury vicinity, *Phipps, John S., Estate*, 71 Old Westbury Rd.

Otsego County

Oneonta, *Oneonta State Normal School*, State St.

OHIO

Columbiana County

East Liverpool, *East Liverpool Post Office*, 5th and Broadway Sts.

Crawford County

Galion, *Central Hotel, Hackedorn and Zimmerman, Buildings*, Harding Way E. and Market St.

Cuyahoga County

Cleveland, *Rockefeller Park Bridges*, Rockefeller Park.
Lakewood, *Honam, John, House*, 14710 Lake Ave.

Fairfield County

Amanda vicinity, *Allen, Lyman, House*, NW of Amanda on OH 188.

Franklin County

Columbus, *Trinity Episcopal Church*, 125 E. Broad St.

Hamilton County

Cincinnati, *Mecklenburg's Garden*, 302 E. University Ave.
Sharonville, *Twelve Mile House*, 11006 Reading Rd.

Knox County

Mt. Vernon, *East Gambier Street District*, 100–519 E. Gambier St.

Lucas County

Toledo, *Toledo Yacht Club*, Bay View Park.

Miami County

Casstown vicinity, *Saunders, Elizabeth Sheets, Farm*, 4525 McCandless Rd.

Montgomery County

Dayton, *Reynolds, John R., House*, 24 Klee St.

Tuscarawas County

Dennison, *Pennsylvania Railroad Depot and Baggage Room*, Center St.

OKLAHOMA

Bryan County

Durant, *Oklahoma Presbyterian College*, 601 N. 16th St.

Comanche County

Lawton vicinity, *Meers Mining Camp*, about 20 mi. NW of Lawton.

Delaware County

Jay vicinity, *Polson Cemetery*, NE of Jay.

LeFlore County

Cameron vicinity, *Reynolds, James E., House*, E of Cameron off OK 112.

Oklahoma County

Oklahoma City, *Central High School*, 700 N. Robinson.
Oklahoma City, *Goldbug Building*, NW 25th and Florida Sts.
Oklahoma City, *Oklahoma City Discovery Well*, SE 57th St. and ITIO Blvd.
Oklahoma City, *St. Paul's Cathedral*, 127 NW 7th St.

PENNSYLVANIA

Centre County

Bellefonte, *Centre County Courthouse*, High St.

Bellefonte, *Miles-Humes House*, 203 N. Allegheny St.
Bellefonte, *Thomas Homestead*, 266 N. Thomas St.
Rebersburg vincity, *Centre Mills*, SW of Rebersburg off PA 445.

Montgomery County

For Washington, *Quaker Manor House*, 1165 Pinetown Rd.
Montgomeryville vicinity, *Knapp Farm*, S of Montgomeryville off PA 309.

Philadelphia County

Philadelphia, *Eyre, Wilson, House*, 1003 Spruce St.
Philadelphia, *Roberts-Quay House*, 1035–1037 Spruce St.
Philadelphia, *St. James Hotel*, 1226–1232 Walnut St.

RHODE ISLAND

Bristol County

Barrington, *Barrington Civic Center*, County Rd. (RI 103/114).

TENNESSEE

Hardin County

Savannah, *Cherry Mansion*, 101 Main St.

VIRGINIA

Accomack County

Accomac, *Debtors' Prison*, VA 764.

Albemarle County

Charlottesville vicinity, *Shack Mountain*, 2 mi. NNW of Charlottesville off jct. of VA 657 and 743.
Covesville vicinity, *Sunny Bank*, NE of Covesville, 1.3 mi. W of jct. of VA 712 and 631.

Chesterfield County

Chester, *Chester Presbyterian Church*, Osborne Rd. and VA 10.
Chesterfield, *Castlewood (Poindexter House)*, VA 10.

Hanover County

Studley vicinity, *Totomoi*, W of Studley on VA 643.

Middlesex County

Urbanna, *Middlesex County Courthouse*, off VA 602.

Waynesboro (independent city)

Coiner-Quesenbery House, 332 W. Main St.

[FR Doc.76-23672 Filed 8-16-76;8:45 am]

POTOMAC RIVER WITHIN ORIGINAL BOUNDARIES OF THE DISTRICT OF COLUMBIA

Permit Requirement

Notice is hereby given that the Secretary of the Interior, acting through the Director, National Park Service, requires that any persons undertaking activities which may impact on the proprietary interests of the United States in the existing bed of the Potomac River within the original boundaries of the District of Columbia (except for that portion of the bed lying within the pierhead line on the District of Columbia side of the river) must have a permit from the National Park Service authorizing such activities. Such permit requirement is in addition to requirements of other governmental agencies, including the United States Army Corps of Engineers, and will be administered according to the following policies and procedures.

1. TYPE OF ACTIVITY REQUIRING PERMIT

Dredging, trenching, boring, tunneling, laying of pipes, cables or utility lines, installation of piling, posts, piers, or mooring structures, construction of footings, foundations or permanent anchors or holding tanks, the setting of fencing, walls or riprap, filling, or other activities which may impact on the proprietary interests of the United States in the bed of the Potomac.

2. APPLICATION FOR PERMIT

Applications for permit to undertake such activities and the submission of required supporting documentation shall be submitted to:

Director, National Capital Parks, 1100 Ohio Drive, SW., Washington, D.C. 20242.

3. SUPPORTING DOCUMENTATION

The following materials, and other information if deemed necessary by the National Park Service, are to be submitted with permit applications:

(i) Construction plans (if any);

(ii) Narrative description of the proposed activity, including;

(a) Nature of the activity;

(a) Description of physical area involved;

(c) Anticipated impact on the natural environment and the bed of the river;

(d) Projected duration of the activity.

(iii) Letters or permit or approval from other jurisdictions concerned with the activity.

4. STANDARDS AND CONDITIONS

Permits will be issued in the discretion of the Secretary where the proposed activity is consistent with the protection of the United States' interests in the bed of the river, including environmental, health and safety considerations.

NATHANIEL P. REED,
Assistant Secretary,
Fish, Wildlife and Parks.

AUGUST 3, 1976.

[FR Doc.76-24026 Filed 8-16-76;8:45 am]

Office of Hearings and Appeals

[Docket No. M 76-370]

BETHLEHEM MINES CORP.

Petition for Modification of Application of Mandatory Safety Standard

Notice is hereby given that in accordance with the provisions of section 301 (c) of the Federal Coal Mine Health and Safety Act of 1969, 30 U.S.C. 861(c) (1970), Bethlehem Mines Corporation has filed a petition to modify the application of 30 CFR 77.803 to its No. 111 Mine, Kayford-Boone Division.

30 CFR 77.803 provides:

On and after September 30, 1971, all high-voltage, resistance grounded systems shall include a fail safe ground check circuit or other no less effective device approved by the Secretary to monitor continuously the grounding circuit to assure continuity. The fail safe ground check circuit shall cause the circuit breaker to open when either the ground or ground check wire is broken.

The substance of Petitioner's statement is as follows:

1. On April 21, 1975, a letter was sent from Mr. J. M. Krese, District Manager, to District 4 personnel. This letter set forth requirements relative to § 77.803. Those additional requirements set forth in the letter are as follows:

1. A grounding circuit, in compliance with § 77.701-3, shall originate at the grounded side of the grounding resistor and shall extend along with the power conductors and shall serve as a grounding conductor for the frames of all equipment receiving power from that circuit.

2. A secondary grounding circuit shall connect the frames of the stationary equipment to a low resistance ground field located near the utilization location.

3. The ohmic value of the grounding resistor and the impedance of the low resistance ground field shall be maintained in such manner that not more than 100 volts will appear between the equipment frame and earth under fault conditions in the event that the grounding conductor shall be severed.

2. On view of the language contained in § 77.803 and as a result of the language contained in Item No. 3 of a letter, dated April 21, 1975, sent from Mr. J. M. Krese, District Manager, to District 4 personnel, local MESA representatives have recently advised Kayford-Boone Division supervisors that certain pole-mounted load transformers supplying power to high-voltage surface installations must be grounded in such a manner that no more than 100 volts difference in potential can exist between the equipment and earth at these locations in the event of a ground fault in the circuit.

3. The Kayford maintenance personnel are presently taking steps to install secondary ground fields at each of the 10 high-voltage stationary pole mounted installations in service. At all but two of these installations the grounded frames of the high voltage equipment are either elevated 18 feet from the ground or fenced by a grounded fence 6 feet high. The remaining two installations will be elevated 18 feet in the near future.

After the aforementioned measures have been completed, the Mine No. 111 ground circuit will afford no less than the same measure of protection afforded the miners by the provisions of § 77.803.

A. For example, the existing ground connection from the pole-mounted load transformer is attached to a triad of rods embedded in the earth. This system has been tested repeatedly and has performed effectively under ground fault conditions. The system conducted sufficient ground fault current during the tests to trip the circuit breaker located at the source transformer.

B. Even though the voltage in the connection between the pole-mounted load transformer and the triad of ground rods under fault conditions might exceed the

maximum amount specified in Item No. 3 of Mr. Krese's letter, the fact remains that the connection wire itself is well insulated and protected. However, Kayford-Boone Division supervision is currently taking additional steps to assure the safety of the system under fault conditions. The connection wire to the triad of rods which itself is already well insulated and protected will be encased in compartments to supplement the protection already afforded by the insulation.

C. The vertical clearance between the pole-mounted load transformer and the ground meets the requirements of the National Electrical Safety Code, and the vertical clearance is similar to that commonly utilized by major utility companies. This clearance itself offers protection to the miners even under ground fault conditions. Even if the vertical clearance is diminished or eliminated entirely by an employee's climbing the pole to perform certain maintenance work, established safety procedures require that the power to the pole-mounted load transformers be turned off before such maintenance is instituted.

4. Petitioner submits that the strict application of the terms of Item No. 3 of Mr. Krese's letter will actually result in a diminution of safety to the miners. It is virtually impossible to meet the voltage limit described in Item No. 3 of Mr. Krese's letter, but even if that limit were achieved, it would create additional parallel electrical paths which would tend to interfere with the primary function of the ground check system between the source transformer and the circuit breaker located at the mine entrance.

Wherefore, Petitioner requests that the existing ground check circuit at Mine No. 111 be approved because it guarantees no less than the same measure of protection afforded the miners by the provisions of section 77.803, and also because the strict application of the terms of Item No. 3 of Mr. Krese's letter will actually tend to result in a diminution of safety to the miners.

REQUEST FOR HEARING OR COMMENTS

Persons interested in this petition may request a hearing on the petition or furnish comments on or before September 16, 1976. Such requests or comments must be filed with the Office of Hearings and Appeals, Hearings Division, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

JAMES R. RICHARDS,
Director, Office of Hearings and Appeals.

AUGUST 6, 1976.

[FR Doc.76-23912 Filed 8-16-76;8:45 am]

[Docket No. M 76-366]

L AND M COAL COMPANY, INC.

Petition for Modification of Application of Mandatory Safety Standard

Notice is hereby given that in accordance with the provisions of section 301(c) of the Federal Coal Mine Health and Safety Act of 1969, 30 U.S.C. 861(c) (1970), L and M Coal Company, Inc. has filed a petition to modify the application of 30 CFR 75.1710 to its No. 2 Mine located at Pennington Gap, Virginia.

30 CFR 75.1710 provides:

An authorized representative of the Secretary may require in any coal mine where the height of the coalbed permits that electric face equipment, including shuttle cars, be provided with substantially constructed canopies, or cabs, to protect the miners operating such equipment from roof falls and from rib and face rolls.

To be read in conjunction with § 75.-1710 is 30 CFR 75.1710-1 which in pertinent part provides:

* * * Except as provided in paragraph (f) of this section, all self-propelled electric face equipment, including shuttle cars, which is employed in the active workings of each underground coal mine on and after January 1, 1973, shall, in accordance with the schedule of time specified in subparagraphs (1), (2), (3), (4), (5), and (6) of this paragraph (a), be equipped with substantially constructed canopies or cabs, located and installed in such a manner that when the operator is at the operating controls of such equipment he shall be protected from falls of roof, face, or rib, or from rib and face rolls. The requirements of this paragraph (a) shall be met as follows:

(1) On and after January 1, 1974, in coal mines having mining heights of 72 inches or more;

(2) On and after July 1, 1974, in coal mines having mining heights of 60 inches or more, but less than 72 inches;

(3) On and after January 1, 1975, in coal mines having mining heights of 48 inches or more, but less than 60 inches;

(4) On and after July 1, 1975, in coal mines having mining heights of 36 inches or more, but less than 48 inches;

(5) On and after January 1, 1976, in coal mines having mining heights of 24 inches or more, but less than 36 inches; and

(6) On and after July 1, 1976, in coal mines having mining heights of less than 24 inches. * * *

The substance of Petitioner's statement is as follows:

1. The equipment being used is not designed for canopies and until such time as the corporation can acquire new equipment, installation of canopies on present equipment is impracticable.

(a) *Scoop.* If a canopy is installed on the scoop, the operator would be forced into a reclining position and his body would protrude over the side of the scoop, creating more hazard than if used in its present state.

(b) *Roof Bolting Machine.* This is an older Wilcox bolting machine and is not big enough to allow for installation of a canopy.

(c) *Continuous Miner.* The coal seam is 48 inches and the height of the miner is 41 inches. Installation of a canopy on this machine would obstruct the view of the operator, creating a hazard.

2. The roof is being supported by roof bolts as per roof control plans at the mine and, to date, no roof falls have occurred in any area of the mine where bolts have been installed. By applying the present roof control plan, whether solid roof or fragile roof, the plan covers any roof condition Petitioner may encounter.

REQUEST FOR HEARING OR COMMENTS

Persons interested in this petition may request a hearing on the petition or furnish comments on or before September 16, 1976. Such requests or comments must be filed with the Office of Hearings and Appeals, Hearings Division, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

JAMES R. RICHARDS,
Director, Office of Hearings and Appeals.

AUGUST 6, 1976.

[FR Doc.76-23913 Filed 8-16-76;8:45 am]

Office of the Secretary

REDWOOD NATIONAL PARK

Boundary Modification

Notice is hereby given that the boundaries of Redwood National Park are modified pursuant to the authority contained in Section 2 of the Redwood National Park Act, P.L. 90-545, 82 Stat. 931 (16 U.S.C. 79b(a)), which provides in pertinent part:

The Secretary of the Interior (hereinafter referred to as the "Secretary") may from time to time, with a view to carrying out the purpose of this Act and with particular attention to minimizing siltation of the streams, damage to the timber, and assuring the preservation of the scenery within the boundaries of the national park as depicted on said maps, modify said boundaries, giving notice of any change involved therein by publication of a revised drawing or boundary description in the FEDERAL REGISTER and by filing said revision with the officers with whom the original maps were filed, but the acreage within said park shall at no time exceed fifty-eight thousand acres, exclusive of submerged lands.

The preservation of the scenery and enjoyability of the park, and the purpose of the Act will be better carried out by the inclusion within the park boundaries of the parcel described below. The parcel is adjacent to the present boundary as shown by plats of survey, notice of filing of which was published in the FEDERAL REGISTER October 7, 1971 (36 F.R. 19518). This addition of approximately thirty-three acres does not cause the acreage limitation to be exceeded.

In compliance with the National Environmental Policy Act the National Park Service has prepared an environmental assessment covering this boundary adjustment. The assessment process did not indicate a significant environmental impact from the proposed action and a negative statement is on file in the Western Region, National Park Service, which summarizes the planning considerations of the proposed boundary change.

Effective upon the publication of this notice, the boundary of Redwood National Park is extended to embrace a Portion of Section 35, Township 16 North, Range 1 West, Humboldt Meridian, described as follows: Parcel "1" and "2" as shown on the Parcel Map filed

August 10, 1973 in Book 1 of Parcel Maps, page 104, Del Norte County Records and all that portion of Section 35, Township 16 North, Range 1 West, Humboldt Meridian, situated in Del Norte County, California, bounded and described as follows: Beginning at a point in the north line of Section 2, Township 15 North, Range 1 West, Humboldt Meridian, 20 feet east of the quarter corner in said north line of Section 2; thence North 80 feet; thence East 480 feet; thence South 80 feet; thence West 480 feet to the point of beginning.

This boundary modification will be reflected in a revised plat to be filed with the Bureau of Land Management, State Land Office, Sacramento, California, and with the Del Norte County, California Recorder's Office. In addition, copies of the plats of survey will be made available for inspection in the offices of the National Park Service, Department of the Interior.

Done at Washington, D.C., this 10th day of August 1976.

THOMAS S KLEPPE,
Secretary of the Interior.

[FR Doc.76-23989 Filed 8-16-76;8:45 am]

SOUTHWESTERN POWER ADMINISTRATION

Legal Review of Procurement Actions

Pursuant to Department of the Interior Procurement Regulations, 41 CFR 14-1.352, the Southwestern Power Administration has issued procedures regarding the legal review of procurement actions.

In each instance involving the procurement of supplies, services, or construction estimated to cost in excess of $10,000, and in other instances when the Contracting Officer considers review desirable, each Contracting Officer shall request, not less than five working days before proposed procurement action, that the Office of the Regional Solicitor, Tulsa, review for legal sufficiency procurement documents prior to taking the following actions:

1. Issuance of solicitations (Invitations for Bids and Requests for Proposals);
2. Award or modification of contracts;
3. Acceptance of pre-contract documents such as bids, proposals, or bonds;
4. Acceptance of a novation, change of name agreement, notice of assignment, assignment, or release of assignment, pursuant to the Assignment of Claims Act of 1940, as amended;
5. Release of any Contracting Officer's report of communication relative to a protest, alleged mistake in bid, determination of bidder nonresponsibility or determination of bid nonresponsiveness;
6. Execution of findings of fact and final decisions made pursuant to the Disputes Clause, notices of termination, cure notices, show cause letters, suspension orders, and other documents which may have legal effect.

The procedures described herein may be modified by written agreement between the Administrator and the Regional Solicitor, Tulsa.

Any communications regarding this notice should be addressed to the Chief, Branch of General Services, Southwestern Power Administration, Tulsa, Oklahoma 74101.

WILLIAM L. FISHER,
Assistant Secretary of the Interior.

Dated: August 10, 1976.

[FR Doc.76-23989 Filed 8-16-76;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

AGRICULTURAL CONSERVATION PROGRAM

Availability of Draft Environmental Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Agricultural Stabilization and Conservation Service, Department of Agriculture, has prepared a draft environmental statement on the Agricultural Conservation Program (ACP) USDA-ASCS-ES (Leg.) 76-2.

The draft statement reflects proposed changes in the ACP as contained in S. 3299, a bill to amend the Soil Conservation and Domestic Allotment Act published in the Congressional Record on April 13, 1976.

The proposed bill will update the national direction relating to the condition under which the Federal government will provide financial assistance to agricultural producers for needed soil, water, woodland and wildlife conservation on agricultural lands. The principal purpose of the proposed amendment to the Soil Conservation and Domestic Allotment Act is to direct the ACP towards an emphasis on enduring conservation and environmental enhancement practices which otherwise might not be undertaken by farmers without cost-share assistance from the Federal government.

The impact of this program on the environment will generally be beneficial. Major adverse environmental effects are not anticipated in implementing this program. Some minor impacts may occur principally during the implementation of some of the practices such as noise, dust and fumes from machinery operation, soil open for potential erosion, some wildlife habitat disturbed, etc.

This draft statement was filed with the Council on Environmental Quality on July 8, 1976. Copies of the statement have been forwarded to all State clearinghouses, various conservation and environmental organizations and Federal agencies as outlined in the CEQ guidelines. To assist in implementing this program, we wish to receive any comments on the draft statement by September 20, 1976.

Copies of the statement are available for inspection during regular working hours at USDA, Agricultural Stabilization and Conservation Service, Room 4702 South Building, 14th and Independence Avenue, SW., Washington, D.C. 20250, and at all State offices for the Agricultural Stabilization and Conservation Service. A limited number of single copies are available upon request at the Washington, D.C. office.

Comments concerning the draft statement should be addressed to the Director, Environmental Quality and Land Use Division, Agricultural Stabilization and Conservation Service, Room 4091 South Building, 14th and Independence Avenue, SW., Washington, D.C. 20250.

All comments must be received on or before September 20, 1976, in order to be sure of consideration in the preparation of the final environmental impact statement.

Signed at Washington, D.C., on August 11, 1976.

SEELEY G. LODWICK,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc.76-23946 Filed 8-16-76;8:45 am]

Forest Service

CALIFORNIA ADVISORY COMMITTEE TO THE U.S. FOREST SERVICE

Meeting

The California Advisory Committee to the U.S. Forest Service will hold a meeting at 1:30 p.m., September 20, 1976, at Bishop, California and a joint meeting with the California Bureau of Land Management Advisory Committee, September 21 and 22 at Bishop, California and various field locations on the Inyo National Forest. The groups will convene initially at the Forest headquarters, 873 North Main Street, Bishop, California.

The agenda for the Forest Service Advisory Committee will include reports on Regional atttainments in the tree improvement program, wetland projects, land-use planning and wilderness studies, FIRESCOPE and the Resources Planning Act.

The joint committee meeting agenda will include reports and discussions on mining and geo-thermal proposals and land-use planning and management activities where Public Lands and National Forest lands are intermingled.

Public participation is invited, and written statements are welcome, before or after the meeting, by contacting the Regional Forester, U.S. Forest Service, 630 Sansome Street, San Francisco, California 94111—Telephone (415) 556-4310. Oral statements can be made by making arrangements with the chairman in advance.

DOUGLAS R. LEISZ,
Regional Forester.

AUGUST 9, 1976.

[FR Doc.76-23902 Filed 8-16-76;8:45 am]

Rural Electrification Administration

BRAZOS ELECTRIC POWER COOPERATIVE, INC. AND SOUTH TEXAS ELECTRIC COOPERATIVE, INC.

Final Environmental Impact Statement

Notice is hereby given that the Rural Electrification Administration has pre-

pared a Final Environmental Impact Statement in accordance with section 102 (2)(C) of the National Envirnomental Policy Act of 1969, in connection with proposed loan applications from Brazos Electric Power Cooperative, Inc., P.O. Box 6296, Waco, Texas 76706, and South Texas Electric Cooperative, Inc., P.O. Box 2485, Victoria, Texas 77901. These proposed loan applications, together with funds from other sources, include financing for a 447 MW (gross) lignite generating plant, associated mine, approximately 254 miles of 345 kV transmission line and related substation facilities, 195 miles of 138 kV transmission line and related substation facilities, and 25 miles of 69 kV transmission line and related substation facilities.

Additional information may be secured on request, submitted to Mr. Richard F. Richter, Assistant Administrator-Electric, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250. The Final Environmental Impact Statement may be examined during regular business hours at the offices of REA in the South Agriculture Building, 12th Street and Independence Avenue, S.W., Washington, D.C., Room 4322, or at Brazos Electric Power Cooperative, Inc., P.O. Box 6296, Waco, Texas 76706 and South Texas Electric Cooperative, Inc., P.O. Box 2485, Victoria, Texas 77901.

Final REA action may be taken with respect to this matter after thirty (30) days.

Any loan which may be made pursuant to these applications will be subject to, and release of funds thereunder will be contingent upon, REA's reaching satisfactory conclusions with respect to environmental effects and final REA action will be taken only after compliance with Environmental Statement procedures required by the National Environmental Policy Act of 1969.

Dated at Washington, D.C., this 11th day of August 1976.

DAVID H. ASKEGAARD,
Acting Administrator, Rural Electrification Administration.

[FR Doc.76-23948 Filed 8-16-76;8:45 am]

CHUGACH ELECTRIC ASSOCIATION, INC.

Final Environmental Impact Statement

Notice is hereby given that the Rural Electrification Administration has prepared a Final Environmental Impact Statement in accordance with section 102 (2)(C) of the National Environmental Policy Act of 1969, in connection with a request for insured loan commitments from the Rural Electricfication Administration for Chugach Electric Association, Inc. of Anchorage, Alaska. These requests for insured loan funds will provide this organization financing to construct and operate approximately 20 miles of 230 kV transmission line from the existing Teeland Substation to the Reed Substation of the Alaska Power Administration. Included in the proposed project will be minor expansions to the existing Teeland and Reed Substations.

Additional information may be secured on request, submitted to Mr. Richard F. Richter, Assistant Administrator-Electric, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250. The Final Environmental Impact Statement may be examined during regular business hours at the Office of REA in the South Agriculture Building, 12th Street and Independence Avenue, SW., Washington, D.C., Room 4053, or at the borrowers address indicated above.

Final REA action with respect to this matter (including any release of funds) may be taken after thirty (30) days, but only after REA has reached satisfactory conclusions with respect to its environmental effects and after procedural requirements set forth in the National Environmental Policy Act of 1969 have been met.

Dated at Washington, D.C., this 11th day of August 1976.

DAVID H. ASKEGAARD,
Acting Administrator, Rural Electrification Administration.

[FR Doc.76-23947 Filed 8-16-76;8:45 am]

TRI-STATE GENERATION AND TRANSMISSION ASSOCIATION, INC.

Notice is hereby given that the Rural Electrification Administration has prepared a Draft Environmental Impact Statement in accordance with Section 102(2)(C) of the National Environmental Policy Act of 1969 in connection with a loan application from Tri-State Generation and Transmission Association, Inc., 10520 Melody Drive, Northglenn, Colorado (Mailing Address: P.O. Box 29198, Denver, Colorado 80229). The Statement covers two 50 MW combustion turbine generating units to be installed at a 43 acre site in Kit Carson County, Colorado and accessory facilities which include bus work for interconnection with the Burlington Substation presently under construction, fuel supply and fuel storage facilities, water storage reservoir, evaporative cooler blowdown storage reservoir and site peripheral irrigation system with associated pumps, and an office and parts warehouse building.

Additional information may be secured on request, submitted to Mr. Richard F. Richter, Assistant Administrator—Electric, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250. Comments are particularly invited 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 from which comments have not been requested specifically.

Copies of the REA Draft Environmental Impact Statement have been sent to various Federal, State and local agencies, as outlined in the Council on Environmental Quality Guidelines. The Draft Environmental Impact Statement may be examined during regular business hours at the offices of REA in the South Agriculture Building, 12th Street and Independence Avenue SW., Washington, D.C., Room 4310, or at Tri-State's address indicated above.

Comments concerning the environmental impact of the construction proposed should be addressed to Mr. Richter at the address given above. Comments must be received on or before October 18, 1976 to be considered in connection with the proposed action.

Final REA action with respect to this matter (including any release of funds) will be taken only after REA has reached satisfactory conclusions with respect to its environmental effects and after procedural requirements set forth in the National Environmental Policy Act of 1969 have been met.

Dated at Washington, D.C., this 10th day of August 1976.

DAVID H. ASKEGAARD,
Acting Administrator, Rural Electrification Administration.

[FR Doc.76-23825 Filed 8-16-76;8:45 am]

DEPARTMENT OF COMMERCE

Economic Development Administration

ROUND STAINLESS STEEL WIRE INDUSTRY

Study of Producing Firms

SUMMARY

The Department of Commerce has conducted a study of the firms producing round stainless steel wire in accordance with Section 264 of the Trade Act of 1974. Such a study by the Department is required whenever the U.S. International Trade Commission ("USITC") makes an import relief investigation under Section 201 of the Trade Act.

In its report to the President on June 14, 1976, the USITC determined by a four to one vote (one abstention) that round stainless steel wire is *not* being imported into the U.S. in such increased quantities as to be a substantial cause of serious injury, or the threat therof, to the domestic industry producing an article like or directly competitive with the imported article.

Stainless steel wire is used in a wide range of products such as nails and other fasteners, springs, rope, welding wire, and woven or knitted products. Stainless steel wire is also produced as flat wire, but round wire is by the far the principal type of stainless steel wire produced.

Domestic output of stainless steel wire rose from 130 million pounds in 1968 to 199 million pounds in 1974 and then fell to 100 million pounds in 1975. Employment of production workers engaged in producing stainless steel wire increased from an average of 2,212 in 1971 to 2,819 in 1974, and then declined to 1,619 in 1975. Imports of stainless steel wire in-

creased at an average annual rate of nine percent during the 1968–1975 period, from 23 million pounds in 1968 to a peak of 54 million pounds in 1974 and then declined to 37 million pounds in 1975. The principal foreign supplying countries are Japan, Sweden and France.

To be certified eligible to apply for trade adjustment assistance, a firm must demonstrate that increased imports of articles like or directly competitive with those produced by the firm contributed importantly to declines in sales or production, or both, and separation, or threat of separation, of the firm's workers. Following certification, a firm may apply for technical and financial assistance to aid its economic recovery.

It is possible for a petitioning firm to be certified eligible for Trade Act benefits even though the industry of which it is a member receives a negative determination on a Section 201 investigation by the USITC. In determining whether imports "contributed importantly" among possible causes for worker separation and decreases in sales or production for a petitioning firm, the influence of imports as a cause would be considered by the Department on the basis of the totality and inter-relationship of all possible causes affecting the operations of the individual firm. The "contributed importantly" criterion which must be met for the firm to be certified is somewhat less stringent than the "substantial cause" criterion which is required for a positive determination in a USITC industry investigation.

As of the date of this report, the Department of Commerce has not accepted a petition for certification of eligibility to apply for trade adjustment assistance from any firm in the wire industry. The USITC identified 58 U.S. firms producing stainless steel wire, including 9 integrated steel mills, 30 wire end-product producers and 19 independent wire drawers. It is possible that a few of the independent were drawers could meet the qualifying criteria for certification, depending on a number of unknown factors which could vary considerably in individual cases. The Department of Commerce is unable to determine with any degree of accuracy the number of firms in the domestic industry which might petition and be qualified for certification, but probably not more than half a dozen firms are likely to submit certifiable petitions.

Under the porgram of trade adjustment assistance for firms authorized by the Trade Act, financial assistance to certified firms may take the form of direct loans and loan guarantees, and technical assistance, to enable a firm to establish a competitive position in the same or a different industry. Financial assistance may be used for the acquisition, construction, installation, modernization, expansion or conversion of fixed assets, or for working capital necessary for a firm to implement its adjustment plan. Technical assistance may be used for management and operational assistance, feasibility studies and related research to aid in developing and implementing a firm's recovery plan.

Firms may also benefit indirectly from financial assistance available to trade-impacted communities under provisions of the Trade Act in a manner similar to the public works, business development and Title IX programs administered by the Department's Economic Development Administration ("EDA") pursuant to the Public Works and Economic Development Act of 1965, as amended. These other programs of EDA provide business development loans to assist firms in certain designated places identified on the basis of economic distress such as unemployment; loans and grants to states, redevelopment areas and other nonprofit local entities for public works projects and development facilities and for a comprehensive program of adjustment to an actual or threatened economic dislocation or adjustment problem.

Another Federal program which might be of some interest is the program administered by the Farmers Home Administration, Department of Agriculture, of direct and guaranteed loans to firms which may be located in areas other than cities having a population of more than 50,000 persons.

The Small Business Administration ("SBA") administers three programs of potential assistance to small producers: a management assistance program for small business; a loan program for local development companies; and a business loan program of direct, participating, and guaranteed loans. Eligibility is limited to independently owned and operated firms that are not dominant in their field and do not have over 1,000 average employment. The amount of the guaranteed loan, however, cannot exceed $350,000, and participating and direct loans have even lower limits.

JACK W. OSBURN, Jr.,
Chief, Trade Act Certification Division, Office of Planning and Program Support.

[FR Doc.76-23980 Filed 8-16-76;8:45 am]

Office of the Secretary

PRIVACY ACT OF 1974

Adoption of New General Routine Use and Additional System of Records

On June 10, 1976, the Department of Commerce gave notice (41 FR 23446) that it proposed to adopt a new use No. 12 to the Prefatory Statement of General Routine Uses for the Systems of Records of the Department (40 FR 45635, October 2, 1975). Interested persons were invited to submit written data, views, or arguments on or before July 12, 1976.

On June 18, 1976, the Department of Commerce gave notice (41 FR 24744–45) that it proposed to adopt an additional System of Records, entitled COMMERCE/DIBA–8, Foreign Service Officer Evaluations, to the previously noticed Systems of Records (40 FR 45634–74, October 2, 1975 and 40 FR 52074, November 7, 1975). Interested persons were invited to submit written data, views, or arguments on or before July 19, 1976.

No comments were received in response to either notice.

Therefore, the Department hereby adopts General Routine Use No. 12 and the System of Records entitled COMMERCIAL/DIBA–8, Foreign Service Officer Evaluations.

Inasmuch as the texts of the new general routine use and the additional System of Records were published in their entirety as described above, and they are adopted without change, there is no need to republish at this time.

Dated: August 8, 1976.

JOSEPH E. KASPUTYS,
Assistant Secretary for Administration.

[FR Doc.76-24039 Filed 8-16-76;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

ADVISORY COUNCIL ON ENVIRONMENTAL EDUCATION'S WORK GROUP ON EVALUATION AND CONTRIBUTIONS

Public Meeting

Notice is hereby given, pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), that a meeting of the Advisory Council on Environmental Education will be held on Tuesday, August 31, from 9:00 a.m. to 5:00 p.m., at the U.S. Office of Education, Room 2004, 400 Maryland Avenue, S.W., Federal Office Building No. 6, Washington, D.C. 20202.

The Advisory Council on Environmental Education is established under (20 U.S.C. 1532) Environmental Education Act, P.L. 91–516, Section 3 (84 Stat. 1312), as amended by P.O. 93–278 (88 Stat. 121).

The Council shall:

(A) advise the Commissioner and the Office concerning the administration of, preparation of general regulations for, and operation of preparation of general regulations for, and operation of programs assisted under the Environmental Education Act;

(B) make recommendations to the Office with respect to the allocation of funds appropriated pursuant to Section 7 among the purposes set forth in paragraph (2) of subsection (b) of the Environmental Education Act and the criteria to be used in approving applications, which criteria shall insure an appropriate geographical distribution of approved programs and projects throughout the Nation;

(C) develop criteria for the review of applications and their disposition; and

(D) evaluate programs and projects assisted under the Environmental Education Act and disseminate the results thereof.

The meeting of the Council shall be open to the public.

The proposed agenda shall consist of preparing a working paper for presentation to the Council.

Records shall be kept of all Council proceedings and shall be available for

public inspection at the Office of the Advisory Council on Environmental Education located in Room 2025, Federal Office Building No. 6, 400 Maryland Avenue, S.W., Washington, D.C.

Signed at Washington, D.C., on August 13, 1976.

WALTER J. BOGAN, Jr.,
Director,
Office of Environmental Education.

[FR Doc.76-24206 Filed 8-16-76;8:45 am]

Food and Drug Administration

[Docket No. 76N-0154]

ORAL RESERPINE DOSAGE FORMS OF GREATER THAN 1 MILLIGRAM STRENGTH

Opportunity for Hearing on Proposal To Withdraw Approval of Pertinent Parts of New Drug Applications

This notice proposes to withdraw approval of the oral reserpine drug products listed below. All of them contain more than 1 milligram of reserpine per dosage unit. Reserpine is used primarily in the treatment of high blood pressure. Persons wishing to request a hearing may do so on or before September 16, 1976.

In the FEDERAL REGISTER of April 28, 1971 (36 FR 7984) (DESI 8867) reserpine in conventional oral dosage form was classified as effective for use in hypertension and for psychiatric disorders. The recommended dosage for use in hypertension had a range of from 0.1 milligram to 0.5 milligram, and the dosage for psychiatric disorders had a range of from 0.1 milligram to 1 milligram. The notice of April 28, 1971 did not discuss dosage form potencies. Clinical experience has shown that when oral doses of more than 1 milligram of reserpine are administered, there is greater frequency and severity of adverse effects, without compensating therapeutic benefits, than occur with doses of 1 milligram or less. The following references support this concept:

1. Nickerson, M., "Antihypertensive Agents and the Drug Therapy of Hypertension," The Phamacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, Macmillan, New York, 1970, p. 739.

2. Jarvik, M. E., "Drugs Used in the Treatment of Psychiatric Disorders," ibid. pp. 172–173.

3. Silber, E. N. and L. N. Katz, "The Treatment of Hypertensive Diseases," Heart Disease, Macmillan, New York, 1975, p. 1270.

4. Vidt, D. G., "Choice of Antihypertensive Drugs for the Treatment of Hypertension, Including Hypertensive Emergencies," Cardiovascular Drug Therapy, Edited by Melmon, K. L., F. A. Davis Co., Philadelphia, 1974, p. 207.

5. Orgain, E. S. and J. C. Gunnells, "Treatment of Systemic Hypertension," The Heart, Edited by Hurst, J. W., McGraw-Hill, New York, 1974, p. 1234.

In view of this, and the availability of reserpine products in potencies of 0.1 milligram to 1 milligram as well as other products used for the same indications and which have a wider margin of safety, the Director of the Bureau of Drugs concludes that the benefit-to-risk considerations associated with oral dosage forms containing more than 1 milligram of reserpine do not justify their continued marketing.

NDA No.	Name of drug	Potency	Applicant's name and address
9-115	Serpasil tablets	2 and 4 mg	Ciba Pharmaceutical Co., Division of Ciba-Geigy Corp., 556 Morris Ave., Summit, N.J. 07901.
9-347	Reserpoid tablets	4 mg	The Upjohn Co., 7171 Portage Rd., Kalamazoo, Mich. 49002.
9-357	Ran-Sed tablets	2 and 4 mg	E. R. Squibb, & Sons, Inc., P.O. Box 4000, Princeton, N.J. 08540.
9-376	Sandril tablets	5 mg	Eli Lilly & Co., Box 618, Indianapolis, Ind. 46206.
9-391	Serpanray tablets	2, 3, 4, and 5 mg	Panray, Division of Ormont Drugs & Chemicals, Inc., P.O. Box 150, Englewood, N.J. 07631.
9-572	Reserpine tablets	2, 3, 4 mg	Keith-Victor Pharmacal Co., 2503 S. Hanley Rd., St. Louis, Mo. 63114.
9-573	do	2, 3, 4, and 5 mg	U.S.V. Pharmaceutical Corp., 1 Scarsdale Rd., Tuckahoe, N.Y. 10707.
9-591	Reserpine tablets, Reserpine capsules.	2, 3, 4, and 5 mg	Pfizer Laboratories, Division of Charles Pfizer & Co., Inc., 235 E. 42d St., New York, N.Y. 10017.
9-596	Raulen tablets	2 and 4 mg	Lemmon Pharmacal Co., Sellersville, Pa. 18960.
9-623	Reserpine tablets	4 mg	American Pharmaceutical Co., P.O. Box 448, Passaic, N.J. 07055.
9-627	do	2, 3, 4, and 5 mg	Richlyn Laboratories, 3725 Cantor Ave., Philadelphia, Pa. 19124.
9-629	do	3, 4, and 5 mg	Ketchum Laboratories, Inc., 26 Edison St., Amityville, N.Y. 11701.
9-771	Reserpine Alkaloid tablets.	2 mg	Invenex Pharmaceuticals, 2303 Schuetz Rd., St. Louis, Mo. 63141.
9-826	Anquil tablets	4 and 5 mg	Dumex-Wilson Co., Division Mallinckrodt Inc., 2d and Mallinckrodt Sts., St. Louis, Mo. 63147.
9-882	R-E-S tablets	2 mg	Cole Pharmacal Co., Inc., P.O. Box 14404, St. Louis, Mo. 63178.
10-045	Vio-Serpine tablets	2 and 4 mg	Rowell Laboratories, Inc., Baudette, Minn. 56623.

Therefore, notice is given to the holders of the new drug applications and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (2 U.S.C. 55(e)), withdrawing approval of those parts of the new drug applications providing for the drug products listed above and all amendments and supplements thereto on the ground that new evidence of clinical experience, not contained in the applications or not available to him until after the applications were approved, evaluated together with the evidence available when the applications were approved, reveals that the drug products are not shown to be safe for use under the conditions of use upon the basis of which the applications were approved.

In addition to the holders of the new drug applications specifically named above, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling, Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6) e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicants and all other persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the new drug applications should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and of all identical, related, or similar drug products.

If an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before September 16, 1976, a written notice of appearance and request for hearing, and (2) on or before October 18, 1976, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the persons(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

All submissions pursuant to this notice, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk during working hours, Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–1053, as amended (21 U.S.C. 355)), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 2.121).

Dated: August 9, 1976.

CARL M. LEVENTHAL,
Acting Director, Bureau of Drugs.

[FR Doc.76-23781 Filed 8-16-76;8:45 am]

Office of the Secretary

OFFICE OF HUMAN DEVELOPMENT, REHABILITATION SERVICES ADMINISTRATION

Statement of Organization, Functions and Delegations of Authority

Part 1 of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health, Education, and Welfare is hereby amended by revising Subchapter 1R94, as amended, Rehabilitation Services Administration (RSA), Office of Human Development, by the reorganization of activities in RSA to fully attain the purposes mandated by the Rehabilitation Act Amendments of 1974 and, the deletion of program activities from RSA concerning Developmental Disabilities which is now newly established in OHD as a separate office, the Developmental Disabilities Office. Therefore, the statement published in the FEDERAL REGISTER on February 7, 1975, at 40 FR 5807, is hereby deleted in its entirety and a new statement is added to read as follows:

1R94.00 *Mission.* Provides leadership in the planning, development, administration and coordination of RSA/OHD programs which provide services for the handicapped and severely handicapped, including disabled social security applicants and beneficiaries, the blind, and welfare recipients who are handicapped or disabled. Establishes program goals and objectives, develops standards, program policies, criteria, guidelines, and professional direction and consultation to RSA staff in the administration of RSA programs. Directs RSA regional office staff in their responsibilities to provide guidance and leadership to State, local, and voluntary organizations; conducts research and demonstration and related activities for the purpose of developing methods, procedures, and devices which could promote and advance employment for handicapped individuals; directs and promotes a training program to improve the national manpower capability to work with handicapped or severely disabled individuals; maintains relationships with Federal, State, and local organizations which serve or have an impact upon the handicapped; evaluates progress in meeting the needs of the handicapped and takes affirmative action to promote improvement. Reviews and prepares legislative proposals to enhance overall program operations, develops and directs implementation of administrative and management actions affecting agency programs and services, and coordinates its activities and programs with other OHD organizations and operating components.

1R94.10 *Organization.* The Rehabilitation Services Administration is under the direction of a Commissioner who reports to the Assistant Secretary for Human Development. RSA consists of the following organizational components which report to the Commissioner:

A. Executive Office of the Commissioner
B. Office of the Assistant Commissioner for Planning, Budget, and Information Systems
C. Office of the Assistant Commissioner for the Blind and Visually Handicapped
D. Office of the Assistant Commissioner for Research and Evaluation
E. Office of the Assistant Commissioner for Training and Facility Improvement
F. Office of the Assistant Commissioner for Special and Cooperative Programs
G. Office of the Assistant Commissioner for State Programs.

A. *Executive Office of the Commissioner (EOC).* The EOC is under the supervision and direction of The Executive Assistant Commissioner (EAC) of RSA who reports to the RSA Commissioner. Supervises and directs the staffs responsible for the following activities: Regional office operations; public affairs; administrative services; executive correspondence; programs for the deaf and communicatively disabled populations; medical consultation support services; and, committee management.

The EOC serves as the principal staff arm to the Commissioner in exercising leadership and direction for the Commissioner on matters relating to the overall administration and management of RSA. Resolves critical issues and problems concerning executive management cross-cutting RSA programs. Coordinates the activities of appropriate RSA offices in all areas of responsibility. When necessary, coordinates these responsibilities with the Office of Human Development, the Department and other organizations inside and outside Government. Provides consultation and assistance to the RSA regional offices in those areas of responsibility affecting regional office operations, which are of interest to the regions, or which require their involvement or participation.

B. *Office of Assistant Commissioner for Planning, Budget, and Information Systems (PBIS).* Provides leadership and direction, under the Commissioner, in overall program and operational planning, programs and administrative budgeting and financial services, provision of information needs, data analysis, project grants and contracts policy and technical assistance, legislation and policy development, and coordination of these activities as they interlock with other offices. Provides consultation and technical assistance to the RSA regional office staff as it relates to these activities. The Office consists of: Division of Planning and Budgeting, Division of Information Systems and Data Analysis, Legislation and Policy Development Staff, and Grants and Contracts Policy and Technical Assistance Staff.

1. *Division of Planning and Budgeting.* This Division is composed of two branches, one for planning and one for budgeting. In the area of planning, the Division provides direction and guidance to RSA in the development of plans and operational objectives to implement plans and programs for the handicapped and to be responsive to DHEW and OHD goals. Provides leadership and direction in the establishment of priority forward and short-range objectives and determines staff and other resources and responsibilities for their achievement. Works closely with Research and Evaluation, other program offices and Regional Offices to develop measurable goals and to recommend alternative plans as conditions change or goals are readjusted. Identifies trends and problems in planning and program redirection. Recommends program improvement, technical assistance and strategies to evolve new methodologies and approaches to improve the administrative management of programs for handicapped individuals. In terms of S&E and program budget matters, the Division serves as principal support arm to the Commissioner in the area of budgetary services and assistance, and maintains formal liaison with the OHD Budget Office. With technical

assistance and guidance from OHD, formulates, justifies, and monitors the RSA administrative and program budgets. Reviews budget submissions prepared by RSA components to assure conformity with legislatively mandated formulae. Provides technical assistance to RSA operating units in the implementation of budgetary directives and the preparation of financial reports and summaries. Aids in the identification and execution of improved internal financial analysis procedures and methods. Provides guidance to other program units in the formulation of short- and long-term financial planning methods.

2. *Division of Information Systems and Data Analysis.* Provides coordination, direction and control for all activities and functions of RSA related to statistical analysis, systems analysis, systems design, data reporting and reporting requirements, and the development, design, implementation and continued use of management information systems. Provides advice, consultation and assistance to the States on data automation, systems analysis, information systems, statistical analysis and the utilization of these tools for more effective management. Supports RSA program planning and evaluation activities by developing and analyzing statistical measures of the impact of the RSA program; of needs for and gaps in service provided by the programs; of the effectiveness of State agency programs and operations. Determines the statistical needs of RSA; upgrades and improves the RSA data base and information systems; develops the necessary information systems in conformance with emerging priorities. Collects and compiles all statistical data reported to RSA. Publishes statistical data. Provides coordination, direction, and advice for all statistical activities of RSA. Monitors and evaluates State methods of information, collection and utilization through the Director, Office of Rehabilitation Services, Regions I–X.

C. *Office of the Assistant Commissioner for the Blind and Visually Handicapped.* Administers the national program for the rehabilitation of the blind and severely visually handicapped mandated by the Randolph-Sheppard and Rehabilitation Acts, as amended. Expands and develops employment opportunities and new careers for the blind and severely visually impaired through consultation and guidance to State agencies. In cooperation with the Office of State Programs, provides technical assistance and consultation to States to obtain maximum benefits from SSDI and SSI funds spent under special provisions for the blind. In collaboration with the RSA regions, provides leadership and consultation in the initiation and development of special projects, including the older blind. Provides technical assistance to the Office of Research and Evaluation regarding the development and evaluation of special research projects for the blind and severely visually impaired, including international projects. Provides technical guidance in the development of course materials designed to improve the skill and increase the number of persons specialized in the provision of services for the blind and severely visually handicapped. Provides consultation and technical assistance to the National Center for Deaf-Blind Youth and Adults in the administration of their service, training and research programs. This Office consists of: Division for the Administration of the Randolph-Sheppard Act and the Division of Rehabilitation Services for the Blind and Visually Handicapped.

1. *Division for the Administration of the Randolph-Sheppard Act.* Provides technical assistance to State agencies, instrumentalities of the Federal Government and blind licensees regarding operations of the national Vending Stand Program with particular emphasis on developing guidelines for the operations of the program by State licensing agencies and on stronger administrative and oversight functions by the RSA. Ensures the uniformity of treatment of blind-venders by all Federal instrumentalities, ensures that blind vendors are given priority for vending facilities on Federal property, and establishes administrative and judicial procedures under which fair treatment of blind vendors is assured. Provides direct technical assistance to State agencies concerning critical issues with respect to vending stand operations based on studies and program review. Prepares and issues regulations to assure that affirmative action is taken to employ and advance in employment qualified blind individuals. In collaboration with RSA program units, compiles and disseminates all pertinent data regarding the Randolph-Sheppard program, including evaluative material required by Congress.

2. *Division of Rehabilitation Services to the Blind and Visually Handicapped.* Provides leadership and consultation to public and private agencies serving the blind and visually handicapped with particular emphasis on carrying out the vocational goals of the Rehabilitation Act. In conjunction with the Office of State Programs and regional staff, conducts program reviews of State agencies serving the blind and visually handicapped. At the national level, expands and develops employment opportunities and new careers for blind and the severely visually impaired. Prepares guidelines and provides technical assistance to States regarding the administration of the SSDI and SSI programs for the blind. In collaboration with the regions, provides leadership and technical assistance in the initiation and development of special projects, including projects for the older blind. Provides technical assistance to the Office of Research and Evaluation regarding special research projects for the blind and severely visually impaired, including international projects. Works with consumer groups at the national level to improve the delivery of RSA services to the blind. Provides consultation and collaborates with the National Eye Institute, Office of Education, Administration on Aging, the National Institute of Neurological Diseases and Stroke, and other public agencies serving the blind.

D. *Office of the Assistant Commissioner for Research and Evaluation.* Directs and manages the overall research and evaluation program of the Rehabilitation Services Administration based on stated goals, objectives, and strategies of programs and emerging needs of the handicapped population. Administers research grants or contracts awarded for the purpose of planning and conducting research and related activities which bear directly on the development of new methods, procedures, and devices to assist in the provision of vocational rehabilitation services to handicapped individuals. Such projects may include medical and other scientific, technical, methodological, and other investigations into the nature of disability, methods of analyzing it, and restorative techniques. Conduct studies and evaluations of industrial, vocational, social psychological, economic, and other factors affecting rehabilitation of handicapped individuals; analyzes special problems of homebound and institutionalized handicapped individuals; conducts studies of the programmatic impact of architectural and engineering design adapted to meet the special needs of the handicapped; examines related activities concerning the handicapped which hold promise of increasing knowledge and improving methods in the rehabilitation of handicapped individuals and individuals with severe handicaps. Responsible for activities of research and demonstration components of RSA in the development of the RSA forward plan. Measures and evaluates the impact of RSA programs in order to determine their effectiveness in achieving stated goals, in general, and in relation to their cost, their impact on related programs, and their structure and mechanisms for the delivery of services for the handicapped. Develops and publishes general standards for evaluation of RSA programs and project effectiveness in achieving the objectives of the Rehabilitation Act. In carrying out these evaluations, considers the views of persons participating in and served by the program. Provides technical assistance to the regional offices and through them the State agencies on the effectiveness and efficiency of State agency operations.

Conducts a program for international rehabilitation research, demonstration, and training for the purpose of developing new knowledge and methods in the rehabilitation of handicapped individuals and sharing this knowledge among the community of nations. Major components of this Office are the Division of Research and the Division of Evaluation and Program Support. Special activities are handled by technical staff in staff-level offices reporting directly to the Assistant Commissioner.

1. *Division of Research.* Directs and manages the overall domestic research and demonstration program, in the areas of medical, psychosocial and vocational rehabilitation which bear directly on the

development of scientific, technical, methodological, and other investigations into the nature of disability, methods of analyzing it and restorative techniques. Conducts studies in cooperation with rehabilitation staffs and concerned organizations to identify program needs and establish priorities, and develops strategies to met the special needs of handicapped individuals and persons with the most severe handicaps. Prepares and implements a forward plan for domestic rehabilitation research consistent with policy and priority guidelines established by the Commissioner and the ASHD. Directs and manages the overall Research and Training Centers program in collaboration with institutions of higher education for the purpose of providing coordinated and advanced programs of research in rehabilitation and training of rehabilitation research and client services personnel. Collaborates with other units of RTC to develop research strategy to insure that RTC research programs are integrated in the RSA research goals and objectives. Interfaces with other RSA units to monitor Special Centers Programs.

Directs and manages a comprehensive research and demonstration program to develop devices and service delivery programs and innovative methods of applying advanced medical technology, scientific achievement, and psychological and social knowledge to solve rehabilitation problems through planning and conducting research designed to produce new knowledge, equipment and devices suitable for solving problems in the rehabilitation of handicapped individuals. In cooperation with the Facility Improvement Staff, supports and stimulates the development and utilization, including production and distribution of new and existing devices, having direct applicability to the rehabilitation of handicapped individuals and manage training activities related to Rehabilitation Engineering. Cooperates with domestic and international organizations to develop systems of information exchange and promotes the prompt dissemination and utilization of engineering and other scientific research information to assist in solving problems in the rehabilitation of handicapped individuals.

2. *Division of Evaluation and Program Support.* Directs and impliments RSA responsibilities related to studies and evaluation of State-Federal agency programs in vocational rehabilitation and develops and implements an evaluation strategy and evaluation standards consistent with policy and priority guidelines set by the Commissioner and the ASHD. Provides technical assistance to Regional staff and State agencies in carrying out the provisions of evaluation functions of the Rehabilitation Act. In cooperation with RSA units, OHD and other agencies, recommends to the Commissioner appropriate and necessary areas for evaluation, and provides the evaluation focal point for all of RSA. Directs the exchange of information to promote the prompt utilization of engineering and scientific research to assist in solving problems in the rehabilitation of handicapped individuals. Manages research information systems and monitors research information system projects. Works with planning, evaluation, and legislative staffs to promote cross utilization of results of research into new program initiatives. Coordinates and prepares mandated reports and special studies. Supports the Office for Handicapped Individuals in its clearinghouse functions. Provides technical assistance to regional staff on research utilization techniques.

E. *Office of the Assistant Commissioner for Training and Facility Improvement.* Ensures that special RSA-negotiated training and technical assistance support resources available from Federal, public and private sectors except research are focused on strengthening and improving the vocational rehabilitation delivery system. Has related responsibility for assuring that all project grants, particularly those serving the most severe disabilities, are directed to improve the delivery of services to the disabled and are fully supportive of RSA's short and long-range objectives. Provides means by which promising new approaches are integrated into the on-going vocational rehabilitation system. Provides programmatic assistance related to the expansion of manpower and the improvement of rehabilitation facilities for the effective implementation of the vocational rehabilitation delivery system. Coordinates the development and production of project guidelines, instructions and other training materials. Assures that effective linkages are established and maintained with voluntary organizations and associations representing professional rehabilitation workers and consumers in the fields of rehabilitation facilities and training. Provides the focal point in RSA for assuring that requests for technical consultation in these areas are appropriately met. Coordinates the activities of regional offices and central office facility improvement staff relating to rehabilitation facilities, manpower development, training, projects with industry, innovation, and expansion. Provides for the utilization and direction of appropriate resources for the support of rehabilitation objectives. This Office consists of: The Division of Training and Manpower Development and the Division of Facility Improvement.

1. *Division of Training and Manpower Development.* Provides and expands training opportunities and materials for professional, technical, and subprofessional persons to meet the manpower requirements of State and other agencies responsible for providing rehabilitation services. Reviews project grant applications, develops evaluative criteria, and provides guidance on the review of grant applications in the regional offices. Provides guidance for the achievement of agency goals in accordance with guidance from the Commissioner. Develops guidelines and analytic procedures to measure the need for, progress and achievement of all manpower training programs financed under agency appropriations. Works with State agencies to assess requirements and develop plans and programs for training professional and paraprofessional staff to meet manpower needs in agency supported programs. Promotes and encourages grant applications from institutions of higher education and other organizations. Prepares and disseminates guidance materials for volunteers to serve in agency sponsored programs. Encourages the development of innovative instructional materials and methods. Plans and conducts short-term training courses for the purpose of generating new knowledge in program areas of high priority to the Department and the agency. Works with the Office of State Programs in the analysis of State agency manpower training needs and in the processing of grant applications and the awarding of grants. Consults with other RSA units in the development of strategies for the training of personnel to service special disability groups in the review of applications for training grant support. Participates with the Office of Planning, Budget and Information Systems and based on guidance issued by the Commissioner and the Assistant Secretary for Human Development, in the development of forward and short-range plans for rehabilitation manpower development and training.

2. *Division of Facility Improvement.* Develops and supports the introduction of techniques and methods leading to the establishment and improvement of rehabilitation facilities which are responsive to agency client needs. Reviews project grant application as assigned to the Division, in accordance with OHD guidelines, appropriate evaluative criteria, and central-regional office responsibilities. Assumes leadership for the achievement of agency missions assigned by the Commissioner on the basis of the Division's particular expertise. Develops agency programs and models. Prepares manual chapters and standards to improve client services and to coordinate public and private programs. Assists in developing a program of technical consultation and assistance to other Federal and State agencies and other grantees to accomplish the Division mission. Collaborates in development of demonstration programs to test concepts in community facilities and special purpose centers. Provides programmatic assistance in the achitectural aspects and design of public and nonprofit facilities provided for the diagnosis, treatment, education, vocational training care, and provision of maintenance services for the disabled. Within assigned areas of responsibility, collaborates in the development of guidelines, manual issuances and other directives for existing and new programs for the support of rehabilitation facilities. Collaborates with voluntary organizations and associations representing rehabilitation facilities, sheltered workshops, and professional groups in areas of specialized rehabilitation practice. Cooperates with State agencies to assess requirements and develops plans and

programs for the establishment and utilization of rehabilitation facilities by State agencies. Coordinates program activities relating to the improvement of rehabilitation facilities with regional offices. Provides leadership under the legislative mandate for the development of jointly financed cooperative arrangements with employers and organizations for the establishment of projects designed to prepare handicapped individuals for gainful employment in the competitive labor market through training. Initiates discussion and dialogue between labor, industry and rehabilitation at the local and community level. Provides the liaison for utilizing the Governmental resources that have been identified through interagency agreements by the Office of Special and Cooperative Program.

F. *Office of the Assistant Commissioner for Special and Cooperative Programs.* Directs the development of a wide range of cooperative agreements with Federal, public and private agencies and organizations having nationwide responsibilities for services related to the rehabilitation of handicapped individuals. Develops agreements, plans, policies and procedures for effective operational relationships between RSA and these agencies and organizations. Monitors the implementation of all such cooperative agreements and keeps the Commissioner advised on issues related to RSA performance in carrying out the agreements. Provides national leadership in the development of vocational rehabilitation programs for special disability populations, and for other groups of disabled individuals offering special programs in their rehabilitation, including the aging. Within assigned area of responsibility, collaborates with other appropriate agency staff in the development of guidelines, manual issuances and other directives for existing programs serving various disability groups and for those programs mandated by legislation, including disabled veterans. Coordinates activities related to these special projects and cooperative programs with other appropriate organizational elements of RSA and with the Office of Human Development to effectively utilize inter-agency linkages for the achievement of program goals and objectives. This office consists of: Division of Special Projects and the Division of Cooperative Programs.

1. *Division of Special Projects.* Provides national leadership in the development of vocational rehabilitation programs for severely handicapped persons, except for the aurally and visually impaired; provides developmental technical assistance, and collaborates in the administration and monitoring of special projects, except for research and training activities, including special projects for the severely handicapped and migratory worker projects; collaborates in the dissemination of special project findings including those of research-demonstration projects, to rehabilitation resources in order to improve and expand services for the severely handicapped; and collaborates in the formulation of agency policy, legislative proposals, planning and budgetary activities in those specialized program areas for which the Division is responsible. Provides staff functions in special population areas and stimulates changes related to research efforts. Maintains continuing coordination and liaison with other RSA units, including the regional staffs, and with other public and voluntary agencies, in order to: Stimulate and develop special projects for the severely handicapped; publicize the favorable outcomes of such projects, and foster their integration within the rehabilitation system; and provide technical consultation in vocational rehabilitation of the special populations within the Division's area of concern.

2. *Division of Cooperative Programs.* In collaboration with other RSA units, plans and develops nationwide cooperative agreements with public and private agencies and organizations as provided by Titles I, IV, and V of the Rehabilitation Act, as amended, including Federal agencies providing services for the rehabilitation of handicapped individuals. Develops policies, standards and procedures for effective operational relationships involving these agencies and organizations, including regional staff, and the State vocational rehabilitation agencies. Monitors and evaluates the implementation of these agreements, recommending as indicated any revision or modification to the existing agreement or arrangement. Coordinates with all other appropriate elments of RSA and OHD in maintaining effective inter-agency cooperative activities to assure achievement of program goals and objectives. Maintains continuous liaison activities with these agencies and organizations, the State vocational rehabilitation agencies, and RSA regional offices either directly or through close collaboration with other appropriate elements of RSA.

G. *Office of the Assistant Commissioner for State Programs.* Provides leadership, coordination, and policy direction for the development and review of the annual State plans for vocational rehabilitation programs and financial plans. Directs the planning, development, and coordination of social security related programs involving vocational rehabilitation services for social security disability insurance beneficiaries and for the severely disabled and the blind under Titles II and XVI of the Social Security Act, as amended. Coordinates State programs and financial matters with appropriate offices of RSA and, when necessary with OHD, the Department and other government agencies. Directs the provision of consultation and technical assistance to RSA Federal staff and to State agencies. This Office consists of: Division of State Plans and Program Administration, Division of State Program Financial Operations, and Division of Social Security Rehabilitation Programs.

1. *Division of State Program Financial Operations.* Provides financial management services for RSA formula grant programs in accordance with established policies and regulations of the Department. Develops and interprets administrative and fiscal policies and procedures governing the use of formula grant funds. Prepares standards, policies, and procedures for formula grants and fiscal management. Develops and coordinates formula grants and procedures with OHD, the Department, other Federal instrumentalities and State agencies. Provides guidance and technical assistance to regional office staff on financial provisions of the Rehabilitation Act and for the Disability Insurance and Supplemental Security Income Programs as they relate to the formula grant program; participates in studies related to overall management and performance of State agencies with particular emphasis on financial accountability, cost-effectiveness, and cost benefit analysis; participates with regional offices in performing follow-ups and special analyses to determine priority of action taken by States on findings and recommendations covered in national studies and State program reviews. Analyzes and coordinates audit findings relating to formula grant programs; negotiates audit exceptions for RSA and serves as focal point on all audits on State Plan programs. Develops basic guidelines and assumptions for use by the States in developing their short and long range goals and resource requirements with technical assistance from OHD, develops tables and narrative statements for use by the Division of Budget in the formulation and justification of the RSA budget. Applies statutory formulae for allotment of funds for the State plan programs and develops plans for the issuance and accountability of all funds. Formulates programs, policies, and procedures to provide for the accounting requirements of the agency for all formula grant funds. Develops and issues financial reports on formula grants for RSA. Develops and conducts financial management workshop conferences for regional and State agency staff.

2. *Division of State Plans and Program Administration.* Provides instructions and guidelines concerning the preparation and submission of the State plan. Acts as the focal point in RSA for the Commissioner and assists the Director, Office of Rehabilitation Services, Regions I–X to identify, negotiate, and otherwise resolve conformity/compliance issues regarding the State plan and operations under such plans; interprets State plan requirements; and based on these requirements, develops guidelines, standards and procedures for the effective and efficient administration of the program, e.g., eligibility, ineligibility, confidentiality, administrative review and fair hearing, and provision of services. Initiates and participates with Director, Office of Rehabilitation Services, Regions I–X in the planning and directing of special or periodic reviews of State agency administration of the State plan to assure: Conformity with the Rehabilitation Act, regulations and State plan and to assure quality services under the State plan.

Provides central RSA leadership in effecting the development of program materials, technical assistance, and short-term training in the solution of critical management problems or improvement in State programs and to achieve State program utilization of selected research and special project results. Initiates policy statements on issues concerning State plans and practices, proposes legislation or regulation changes. Provides program input in the development of data requirements and appropriate RSA reports dealing with VR clients and their progress to successful closure. Provides program input in evaluation, research, statistics, long-range planning, budget, and OPS.

3. *Division of Social Security Rehabilitation Programs.* Collaborates and coordinates with the Social Security Administration (SSA) in developing nationwide policies, standards and procedures for the guidance of State vocational rehabilitation agencies in providing services to severely disabled applicants for disability insurance benefits (DIB) and supplemental security income (SSI). Translates policy statements, legislation and directives into regulations, guidelines and manuals. Provides technical consultation, interpretation of policy matters and advice to State agency and regional staff. Participates in planning, organizing, and conducting lines and manuals. Provides technical consultation, interpretation of policy matters and advice to State agency and regional staff. Participates in planning, organizing and conducting orientation and in-service training programs for State agency and regional office professional staff. In conjunction with RSA units and SSA, develops reporting systems essential to effective administration and monitoring of the trust fund programs. Similarly participates in developing research and evaluation studies for improving methodology, procedural systems, management techniques and other aspects to the end of furthering services to disabled clients. Analyzes research findings and incorporates results into standards, regulations and manuals for use by State VR agencies. Maintains continuous liaison activities with SSA, RSA regional staff, Council of State Administrators of Vocational Rehabilitation (CSAVR) and State VR agencies with respect to program objectives and the conduct of the program.

MARJORIE LYNCH,
Acting Secretary.

AUGUST 4, 1976.

[FR Doc.76-24041 Filed 8-16-76;8:45 am]

Office of the Secretary

REGULATORY POLICIES

The Secretary of Health, Education, and Welfare isued the following memorandum on July 25, 1976. In keeping with his expressed desire to provide more opportunity for public involvement in the operation of the Department, the Secretary has directed that the above-referenced document be published in the FEDERAL REGISTER. Comments may be directed to the Director, Office of Regulatory Review, Room 310 G, South Portal Building, 200 Independence Avenue, SW., Washington, D.C. 20201; Telephone: 202 245-3161.

Dated: August 11, 1976.

JOHN R. OTTINA,
Assistant Secretary for Administration.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

To: The Under Secretary
Assistant Secretaries
Principal Operating Components
OS Staff Offices
From: The Secretary
Subject: Regulatory Policies

July 25, 1976.

On the basis of recommendations from the Regulations Advisory Group (RAG), comments on thosee recommendations by the various units of the Department, advice from a discussion of the RAG recommendations at a Departmental meeting and further comments on my "preliminary rulings" memorandum, a comprehensive body of new policies and procedures for the issuance of regulations has been developed. These policies, together with certain additional directions to the staff of the Department and the outline of my future plans in this area are set forth in this memorandum.

These policies and procedures apply to the development and issuance of regulations, whether of Department-wide effect or limited to a particular program administered by a single component within the Department, except where authority to issue a category of regulations has been specifically delegated by the Secretary.

Although existing delegations remain in effect, such delegations will continue only to the extent that it is demonstrated that policy review and direction by the Secretary's Office is unnecessary.

Even in those cases where authority is delegated, the policy set forth in this memorandum should be followed to the extent feasible by officials to whom the delegations have been made.

The procedures set forth in this memorandum will not be applied to regulaitions for which a Notice of Proposed Rule Making (NPRM) was transmitted to the Office of the Secretary prior to the date of this memorandum.

1. DEPARTMENTAL REGULATIONS POLICY

a. The development of specific program regulations is the responsibility of the Assistant Secretary or Principal Operating Component (POC) head who is responsible for the administration of that program. The development of crosscutting or Department-wide regulations will be the responsibility of the appropriate Departmental officials.

b. Except where authority to issue regulations without prior approval of the Secretary has been specifically delegated, no Notices of Intent (NOIs), NPRMs or final rules may be issued or published without the signed approval of the Secretary.

c. Any proposed regulation which the appropriate Assistant Secretary, POC head or the Secretary has determined to be of major program significance may not be executed or published even as an NOI or NPRM until a regulation implementation plan has been submitted to the Secretary by the appropriate Assistant Secretary or POC head and the plan has been approved by the Secretary or the Under Secretary.

The regulation implementation plan instructions concerning form and content will also provide for the use of a modified or abbreviated plan for regulations not having a major program significance.

In approving a regulation implementation plan, the Secretary or the Under Secretary may authorize the Assistant Secretary or the POC head to proceed with the development and issuance of an NOI, NPRM or a final rule without obtaining further specific authorization from the Secretary for that regulation or set thereof.

d. An NOI should be published, and the implementation plan should so provide, whenever the Department's consideration of important policy issues will be aided by public comment prior to publication of an NPRM. The NOI mechanism should be liberally used to permit interested outside groups and other members of the public to have an impact on the decisionmaking process at an early stage. Therefore, implementation plans that fail to provide for an NOI will be critically reviewed.

e. In addition to publication in the FEDERAL REGISTER, other channels of communication with the public will be liberally used in order to reach as many interested individuals and organizations as possible.

f. Public hearings to permit the Department to receive information and views on proposed regulations should be held either before or after the publication of NPRMs if it appears that such hearings will aid the Department in developing its position on any of the issues involved. Advance notice of any such hearings will be published either as part of an NOI or separately.

g. Each NOI and NPRM shall set forth the major issues to be addressed in the development of the regulation and the major alternatives that the Department is considering to resolve those issues. If there is more than one Assistant Secretary or POC head having a direct jurisdictional interest in a particular regulation and if any of them have submitted to the Secretary different views concerning the major issues, these views should be stated in the NOI or NPRM along with the source of the views.

h. In the spirit of openness, a draft regulation may be disclosed upon request prior to its publication in proposed form. If, however, the availability of the draft has not already been stated in a public notice, such a notice will be published before the disclosure is made. In addition to publication, steps should be taken to make copies of the draft directly available to interested groups and individuals, including the appropriate committees and Members of Congress.

i. Each NOI and NPRM will give the name, position, address and telephone number of a contact person within the Department who will be available to answer inquiries and receive information concerning the proposed regulation.

j. Except as otherwise authorized or required by the Administrative Procedure Act and the rules and regulations of the Department, the comment period provided for in NPRMs will be at least 45 days unless the regulation implementation plan has justified the lesser period of 30 days and the plan has been approved by the Secretary or the Under Secretary.[1]

k. Each NOI and the preamble to each NPRM and final regulation will be written

[1] The comment period for the NPRM also applies to the NOI.

in common everyday English understandable to the general public.

1. Whenever, as a result of public comment or for any other reason, it appears to the appropriate Assistant Secretary or POC head that a major provision in a proposed regulation should be significantly changed before being published as a final rule, the regulation should be carefully reviewed to determine whether the NPRM fairly permitted public comment on the issue embodied in the change. If it further appears that the public did not have a fair opportunity to comment on the matter which is the subject of the change, a new NPRM should be published inviting such comment.

2. INTERNAL PROCEDURES FOR THE REGULATION PROCESS

a. The Secretary's Office will develop requirements for the form and content of regulation implementation plans. These requirements will be distributed to the Assistant Secretaries and POC heads for their use in preparing such plans. At a minimum, each plan will be required to include a concise but complete statement of significant issues relating to the proposed regulation and the particular steps and timetable that will be followed.

b. All documents routed to the Secretary on any proposed regulation (including regulation implementation plans, NOIs, NPRMs and final regulations) should be sent through the Executive Secretariat (ES). ES will track the processing of each proposed regulation from the transmittal to the Secretary's Office of a proposed implementation plan until the publication of the final regulation. Each Assistant Secretary and POC head will be responsible for providing current information to ES of each step in the development and processing of the proposed regulation. Further instructions in this regard will be developed and provided by the Secretary's Office.

c. Each Assistant Secretary and POC head should develop a pool of professionally competent and trained regulation draftsmen who will be assigned responsibility to draft NOIs, NPRMs and final regulations on the basis of specifications developed by program staff.

The pool should have sufficient members to meet the regulation drafting needs of the component in an expeditious manner. The membership of the pool should not be restricted to those of any particular professional discipline.

Training and evaluation programs for regulation draftsmen will be developed and implemented by both the Department and the POCs. Training will emphasize writing skills, including clarity of language and organization.

d. In transmitting an NOI, NPRM or final regulation to ES, the Assistant Secretary or POC head making the transmittal should include under separate cover the name of each draftsman who participated in the preparation of the document.

e. Each final regulation sent to the Secretary for approval should be accompanied by a separate written plan for monitoring and reviewing the effect of the regulation after its publication. This plan should state the dates by which the results of the regulation will be reviewed. If the Assistant Secretary or POC head believes that this plan should be made available to the public, by publication in the FEDERAL REGISTER or otherwise, it should be so recomended.

f. Internal clearance procedures will be developed by the Secretary's Office to minimize clearance disputes and to elimiante any redundant processes. Deadlines will be established by which nonconcurrence disputes will be resolved.

g. In those instances where the Secretary or Under Secretary relies upon an informal group of staff members for a briefing on an NOI, NPRM or final regulation that has been submitted for Secretarial approval, the appropriate Assistant Secretaries or POC heads should be included.

h. A long-range plan for reviewing regulations will be developed by P in consultation with RAG. The plan should include:

Categories or criteria for selecting regulations for reconsideration.

Means for comparing results with intent.

Plans for an automatic review system for regulations.

i. A small group of regulations will be selected by the Secretary's Office for review as a pilot project. These regulations will then be assigned to the appropriate Assistant Secretary or POC head for review and, as appropriate, rewrite by specified due dates.

j. If there is inadequate qualified staff within the Office of any Assistant Secretary or POC to accomplish the necessary review of regulations published by that Office, an appropriate detail of personnel from other parts of the Department, or the hiring of, or contracting for, the services of qualified consultants will be arranged.

As indicated in this statement, the development and review of regulations are the primary responsibility of the Assistant Secretaries and POC heads. It is not intended that a central agency be estbalished to add another layer of control on top of an already complicated process. However, both the Secretary and the Under Secretary, in order to discharge their duties described in this document, need staff assistance which will be provided through a Special Assistant to the Secretary for Regulatory Reform. The Special Assistant will also be the presiding officer of the Regulatory Advisory Group.

A review of these policies and procedures is planned within the next year. At that time changes will be made if desirable.

[FR Doc.76-24042 Filed 8-16-76;8:45 am]

CIVIL AERONAUTICS BOARD

CERTIFICATE OF PUBLIC CONVENIENCE AND NECESSITY

Application for Amendment

AUGUST 11, 1976.

Notice is hereby given that the Civil Aeronautics Board on August 11, 1976, received an application, Docket 29632, from Frontier Airlines, Inc. for amendment of its certificate of public convenience and necessity for route 73 to authorize nonstop service between Albuquerque, New Mexico and Phoenix, Arizona.

The applicant requests that its application be processed under the expedited procedures set forth in Subpart M of Part 302 (14 CFR 302).

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.76-24050 Filed 8-16-76;8:45 am]

CIVIL RIGHTS COMMISSION

CONNECTICUT ADVISORY COMMITTEE

Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Connecticut Advisory Committee (SAC) to this Commission will convene at 7:00 p.m. and end at 10:00 p.m. on September 27, 1976, at 5 Long Lane, Middleton, Connecticut 06457.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Northeastern Regional Office of the Commission, 26 Federal Plaza, Room 1639, New York, New York.

The purpose of this open meeting is to discuss SAC projects for the coming year.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 10, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23932 Filed 8-16-76;8:45 am]

DELAWARE ADVISORY COMMITTEE

Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Delaware Advisory Committee (SAC) to this Commission will convene at 12:00 noon and end at 2:00 p.m. on September 8, 1976, at the YMCA, 11th and Washington Sts., Wilmington, Delaware.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Mid-Atlantic Regional Office of the Commission, 2120 L Street, NW., Room 510, Washington, D.C. 20037.

The purpose of the meeting is to plan projects for remainder of year.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 10, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23933 Filed 8-16-76;8:45 am]

DISTRICT OF COLUMBIA ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the District of Columbia Advisory Committee (SAC) to this Commission will convene at 2:00 p.m. and end at 9:00 p.m. on September 9, 1976, at the Martin Luther King Memorial Library, 901 G Street, NW., Washington, D.C.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Mid-Atlantic Regional Office of the Commission, 2120 L Street, NW., Room 510, Washington, D.C.

The purpose of this open meeting is to hear presentations made to the Advisory Committee by group representatives and knowledgeable individuals on civil rights

issues as input into the Advisory Committee's program planning process.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 11, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23981 Filed 8-16-76;8:45 am]

GEORGIA ADVISORY COMMITTEE

Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Georgia Advisory Committee (SAC) to this Commission will convene at 11:00 a.m. and end at 5:30 p.m. on September 10, 1976, at the Executive House Augusta, 640 Broad Street, Apple Room, Augusta, Georgia.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Southern Regional Office of the Commission, Citizens Trust Bank Building, Room 362, 75 Piedmont Avenue, NE., Atlanta, Georgia 30303.

The purpose of this open meeting is to review proposal and plan for a study on the post effect of school desegregation on minority students and teachers and the impact of the private school on the educational process in selected urban and rural areas in the state of Georgia.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 10, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23934 Filed 8-16-76;8:45 am]

IOWA ADVISORY COMMITTEE

Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a conference of the Iowa Advisory Committee (SAC) to this Commission will convene at 9:30 a.m. and end at 4:00 p.m. on September 8, 1976, at Fort Des Moines Hotel, 10th & Walnut Streets, Des Moines Iowa.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Central States Regional Office of the Commission, Old Federal Office Building, Room 3103, 911 Walnut Street, Kansas City, Missouri 64106.

The purpose of this conference is the Migrant Farm Labor Study followup. This conference will also include Committee assignments, organization feed back and migrant advocacy.

This conference will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 11, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23935 Filed 8-16-76;8:45 am]

MONTANA ADVISORY COMMITTEE

Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Montana Advisory Committee (SAC) to this Commission will convene at 1:00 p.m. and end at 3:00 p.m. on September 25, 1976, at the Federal Building, 316 N. 26th, Room 3033, Billings, Montana.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Mountain States Regional Office of the Commission, Executive Tower Inn, Suite 1700, 1405 Curtis Street, Denver, Colorado 80202.

The purpose of this meeting is to discuss followup to media project and form subcommittees on relevant civil rights concerns in the State.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 10, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23936 Filed 8-16-76;8:45 am]

NEW JERSEY ADVISORY COMMITTEE

Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the New Jersey Advisory Committee (SAC) to this Commission will convene at 7:30 p.m. and end at 11:00 p.m. on September 12, 1976, at the Ramada Inn, New Brunswick, New Jersey.

Persons wishing to attend this meeting should contact the Committee Chairperson, or the Northeastern Regional Office of the Commission, 26 Federal Plaza, Room 1639, New York, New York.

The purpose of this meeting is to discuss programs and receive reports on subcommittees.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., August 10, 1976.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.76-23937 Filed 8-16-76;8:45 am]

CIVIL SERVICE COMMISSION

DEPARTMENT OF THE TREASURY

Title Change in Noncareer Executive Assignment

By notice of April 12, 1973, FR Doc. 73-7079 the Civil Service Commission authorized the Department of Treasury to fill by noncareer executive assignment the position of Deputy Assistant Secretary (Enforcement, Tariff and Trade Affairs and Operations), Office of the Secretary. This is notice that the title of this position is now being changed to Deputy Assistant Secretary (Enforcement, Operations, and Tariff Affairs), Office of the Secretary.

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.76-24040 Filed 8-16-76;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 601-2]

STATE OF CALIFORNIA

Approval of State Implementation Plans; Time Extension

This notice revises the Governor's 60-day time period for submitting a letter of intent to the Regional Administrator identifying the various steps which the State will take to develop the plan revisions in accordance with the requirements set forth in the notices published July 12, 1976 (41 FR 28603) for various Air Quality Control Regions in the State of California.

This time extension is hereby given since the technical support documents referenced in the July 12, 1976, FEDERAL REGISTER were not available at the time of publication. The 60-day period will commence on or before October 18, 1976.

Dated: August 9, 1976.

PAUL DE FALCO, Jr.,
Regional Administrator.

[FR Doc.76-24090 Filed 8-16-76;8:45 am]

[FRL 601-1; OPP-42028]

STATE OF DELAWARE

Submission of State Plan for Certification of Pesticide Applicators

In accordance with the provisions of section 4(a)(2), of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136) and 40 CFR Part 171 (39 FR 36446 (October 9, 1974) and 40 FR 11698 (March 12, 1975)), the Honorable Sherman W. Tribbitt, Governor of the State of Delaware, has submitted a State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides to the Environmental Protection Agency (EPA) for approval on a contingency basis. Contingency approval is being requested pending enactment of all necessary legislation and the promulgation of implementing regulations pursuant thereunder.

Notice is hereby given of the intention of the Regional Administrator, EPA Region III, to approve this plan on a contingency basis.

A summary of the plan follows. The entire plan, together with all attached appendices, may be examined during normal business hours at the following locations:

Room 3323, Curtis Building, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106. Pesticides Branch, U.S. Environmental Protection Agency, Region III, Phone: 215/597-9869.

Delaware Department of Agriculture, Division of Production and Promotion, Room 115, Agriculture Building, Dover, Delaware 19901. Phone: 302/678-4815.

Room 401, East Tower, Waterside Mall, 401 "M" Street, SW., Office of Pesticide Programs, EPA, Federal Register Section, Washington, D.C. 20460. Phone: 202/755-4854.

SUMMARY OF DELAWARE STATE PLAN

The Delaware Department of Agriculture (DDA) has been designated as the State Lead Agency solely responsible for the administration and enforcement of the pesticide applicator certification program.

The Delaware Cooperative Extension Service (CES) will cooperate with the lead agency by being the primary organization for training leading to certification. Also, the Delaware Department of Agriculture will receive support from its Pesticide Advisory Committee.

Legal authority for the program will exist upon enactment of the Delaware Pesticide Act of 1975 by the General Assembly of the State of Delaware and upon promulgation of implementing regulations. The proposed pesticide act is exhibited in the plan.

The plan indicates that the lead agency and cooperating agency will have sufficient qualified personnel and funds necessary to carry out the proposed program. Amendments to section 2 of the Delaware code allows $25,230 for fiscal year 1977 for the purpose of establishing an administrative staff to carry out the provisions of the proposed Act. Furthermore, the plan indicates that additional funds will be requested for FY 1978 if required.

The State estimates that 400 commercial applicators and 1300 private applicators will need to be certified.

Both certified commercial and private applicators will be issued a document indicating the category or limitation of their certification. Pocket size identification cards will also be issued for use in purchasing pesticides classified for restricted use.

The State lead agency will submit an annual report to EPA on the first day of each year. Other reports shall also be submitted to EPA from time to time to meet specific needs.

The commercial applicator categories proposed in the plan are those which are listed in 40 CFR 171.3. No new categories are presented. A subcategory for fumigation is provided, however, under Category 7 "Industrial, Institutional, Structural and Health Related Pest Control."

Commercial applicators who wish to become certified will be required to achieve a passing score of 70% on each of two written examinations. One exam will cover the general standards while the other exam will cover the specific standards for the categories in which certification is desired. The standards are outlined in the plan and are the same as those Federal standards presented in 40 CFR 171.4 (b) and (c) and 171.6.

Training for both commercial and private applicators will be based on training manuals approved and developed by EPA. Training sessions will be conducted and exams administered by qualified personnel from the Delaware CES and/or DDA. Times and locations of such training and examinations, for each of the 3 Delaware counties, will be announced.

Types of certifications available to the private applicator (agricultural commodity producers) are optional. The plan provides for:

(1) General Certification.
(2) Pesticide Class Certification.
(3) Commodity/Crop/Site Certification.
(4) Single Product Certification.
(5) Single Product/Single Use Authorization. (This option is only available as an emergency provision.)

Methods to determine private applicator competency are also optional to the applicator. Options include: A written examination, oral examination, or in the case of Single Product/Single Use Authorization, the applicant may participate in a fact finding interview. Individuals with reading difficulties will be certified after satisfactorily completing an oral and/or demonstration procedure administered by Department of Agriculture personnel. Certification will be limited to the use and handling of those pesticides for which the individual has demonstrated competence.

Regardless of which method or type of certification the private applicator may elect, competency standards for the private applicator will be based on 40 CFR 171.5 and 171.6. These standards are listed in the plan. Sample examination questions are attached to the plan as provided for by 40 CFR 171.7(e)(1)(i)(D) and (ii)(C).

The State plan provides that within 60 days of the approval of the Government Agency Plan (GAP) by EPA, Delaware will submit a statement in accordance with 40 CFR 17.17(e)(4)(i).

At the proper time, Delaware will give favorable consideration to the development of reciprocal agreements with other states. Also, the lead agency will forward copies of reciprocal agreements entered into with other states to EPA for inclusion in its State plan. Other regulatory activities listed in the plan which will supplement Delaware's certification program provide for the stop sale and removal of non-registered pesticides, routine surveillance activities conducted by regulatory field inspectors and the label review of pesticide products to protect against misbranding.

Pesticide field agents assigned full time to pesticide use and application activities will provide adequate assurance that certified applicators comply with standards.

The Delaware State Plan mentions that various short courses, seminars, special training sessions, etc., will be provided by the Delaware CES and by various trade association groups. Assurances are provided in the proposed pesticide law that certified applicators continue to meet requirements of changing technology.

PUBLIC COMMENTS

Interested persons are invited to submit written comments on the proposed plan for the State of Delaware to the Chief, Pesticides Branch, Region III, Environmental Protection Agency, 6th and Walnut Streets, Room 3323, Philadelphia, Pennsylvania 19106. The comments must be received on or before September 19, 1976, and should bear the identifying notation OPP-42028. All written comments filed pursuant to this notice will be available for public inspection at the above mentioned locatons from 8:30 to 3:30 p.m. Monday thru Friday.

Dated: July 19, 1976.

DANIEL J. SNYDER, III,
Regional Administrator,
Region III.

[FR Doc.76-24088 Filed 8-16-76;8:45 am]

[FRL 600-8; OPP-42019A]

NEVADA

Approval of State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides

Section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136), and the implementing regulations of 40 CFR Part 171 require each state desiring to certify applicators to submit a plan for its certification program. Any state certification program under this section shall be maintained in accordance with the state plan approved under this section.

On May 12, 1976, a notice was published in the FEDERAL REGISTER (41 FR 19374-19375) of the intent of the Regional Administrator, EPA, Region IX, to approve, on a contingency basis, the Nevada Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides (Nevada State Plan). Contingency approval was requested by the State of Nevada pending promulgation of additional regulations implementing the legislation. Complete copies of the Nevada plan were made available for public inspection at the Nevada Department of Agriculture, Reno, Nevada; EPA, Region IX Office, San Francisco, California; and the Office of Pesticide Programs, EPA, Washington, D.C.

No comments were received; therefore, the plan as it appeared in the FEDERAL REGISTER, May 12, 1976, will go unchanged.

It has been determined that the Nevada plan will satisfy the requirements of section 4(a)(2) of the amended FIFRA and of 40 CFR Part 171, if the regulations described in the plan are promulgated by the Nevada Department of Agriculture. Accordingly, the Nevada plan is approved contingent upon this.

This contingency approval shall expire 12 months from its effective date, if these terms and conditions are not satisfied by that time. On or before the expiration of the period of contingency approval, a notice shall be published in the FEDERAL REGISTER concerning the extent to which these terms and conditions have been satisfied and the approval status of the Nevada plan as a result thereof.

Effective date. Pursuant to section 4(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), the Agency finds that there is good cause for providing that the 12 months contingency approval granted herein to the Nevada plan shall be effective immediately. Neither the Nevada plan itself nor this Agency's contingency approval of the plan creates any direct or immediate obligations on pesticide applicators or other persons in the State of Nevada. Delays in starting the work necessary to implement the plan, such as may be occasioned by providing some later effective date for this contingency approval, are inconsistent with the public interest. Accordingly, this contingency approval shall become effective immediately.

Dated: July 22, 1976.

PAUL DEFALCO, Jr.,
Regional Administrator,
EPA Region IX.

[FR Doc.76-24089 Filed 8-16-76;8:45 am]

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

PRIVACY ACT OF 1974

Additional Routine Use

Notice is hereby given that, pursuant to 5 U.S.C. §§ 301 and 552a and 42 U.S.C. 2000e-12(a), the Equal Employment Opportunity Commission hereby adopts a new routine use for all of its Privacy Act systems of records except EEOC-3, Charge of Discrimination Case Files.

At 41 FR 27112 (July 1, 1976), the Commission published notice that it proposed to adopt the following routine use:

> Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

In that notice, the Commission stated that comments on it received no later than July 31, 1976, would be considered. The Commission received no comments on said routine use and therefore adopts said use for systems EEOC-1, -2, and 4-13.

Also at 41 FR 27112, the Commission notice a proposed routine use for system EEOC-3, Charge of Discrimination Case Files. The proposed routine use for that system read as follows:

> The Commission has established in Section 83 of its Compliance Manual (Vol. 1), policies with respect to the disclosure to charging parties of information contained in this system of records. Disclosure which is consistent with these policies may be made to a Congressional office from the charge of discrimination case file of a charging party in response to an inquiry from the Congressional office made at the request of that charging party.

As a result of comments received thereon, the Commission is considering an amendment to that proposed routine use. Therefore, the Commission is not at this time adopting said routine use.

Signed at Washington, D.C. this 11th day of August, 1976.

ETHEL BENT WALSH,
Vice-Chairman.

[FR Doc.76-23921 Filed 8-16-76;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

FM BROADCASTING

Applications Ready and Available for Processing

Notice is hereby given, pursuant to section 1.573(d) of the Commission's rules, that on October 4, 1976, the FM broadcast applications listed in the attached Appendix will be considered as ready and available for processing. Pursuant to section 1.227(b)(1) and section 1.591(b) of the Commission's rules, an application, in order to be considered with any application appearing on the attached list or with any other application on file by the close of business on October 1, 1976, which involves a conflict necessitating a hearing with any application on this list, must be substantially complete and tendered for filing at the offices of the Commission in Washington, D.C., by the close of business on October 1, 1976. The attention of prospective applicants is directed to the fact that some contemplated proposals may not be eligible for consideration with an application appearing in the attached Appendix by reason of conflicts between the listed applications and applications appearing in previous notices published pursuant to section 1.573(d) of the Commission's rules.

The attention of any party in interest desiring to file pleadings concerning any pending FM broadcast applications, pursuant to section 309(d)(1) of the Communications Act of 1934, as amended, is directed to section 1.580(i) of the Commission's rules for provisions governing the time for filing and other requirements relating to such pleadings.

Adopted: Aug. 10, 1976.

Released: Aug. 17, 1976.

Federal Communications Commission.

VINCENT J. MULLINS,
Secretary.

Attachment.

APPENDIX

BPE-9720 New, Patterson, N.Y.
Patterson Broadcasting Corp.
Req: 105.5 mHz; Channel No. 288A, ERP: 1.11 kW; HAAT: 460 ft.

BPH-9841 New, Bozeman, Mont.
Northern Sun Corp.
Req: 93.7 mHz; Channel No. 229C, ERP: 100 kW; HAAT: 221 ft.

BPH-9862 WQWK, State College, Pa.
State College Communications Corp. Has: 96.7 mHz; Channel No. 244A, ERP: 3 kW; HAAT: 78 Ft. (Lic).
Req: 96.7 mHz; Channel No. 244A, ERP: .225 kW; HAAT: 919 Ft.

BPH-9900 New, Deming, N. Mex.
Luna County B/cting Co.
Req: 94.3 mHz; Channel No. 232A, ERP: 3 kW; HAAT: 195 Ft.

BPH-9902 New, Hilo, Hawaii.
Christian Broadcasting Association.
Req: 97.1 mHz; Channel No. 246C, ERP: 100 kW; HAAT: —98 Ft.

BPH-9903 New, Palm Springs, Calif.
Gray-Schwartz Broadcasting.
Req: 100.9 mHz; Channel No. 265A, ERP: .575 kW; HAAT: 619 Ft.

BPH-9904 New, Pana, Ill.
Pana Broadcasting Corp.
Req: 100.9 mHz; Channel No. 265A, ERP: 3 kW; HAAT: 292 Ft.

BPH-9907 New, Gilmer, Tex.
Daniels Broadcasting, Inc.
Req: 95.3 mHz; Channel No. 237A, ERP: 1.4 kW; HAAT: 420 Ft.

BPH-9908 WIVY-FM Jacksonville, Fla.
Jacksonville Broadcasting Corp.
Has: 102.9 mHz; Channel No. 275C, ERP: 29 kW; HAAT: 205 Ft. (LIC).
Req: 102.9 mHz; Channel No. 275C ERP: 60 kW; HAAT: 572 Ft.

BPH-9909 New, Eunice, La.
Tri-Parish B/cting Co., Inc.
Req: 105.5 mHz; Channel No. 288A, ERP: .2 kW; HAAT: 105.6 Ft.

BPH-9910 New, Berryville, Va.
Berryville Media Group.
Req: 105.5 mHz; Channel No. 288A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9913 New, Columbia, S.C.
Oasis Media Limited.
Req: 103.1 mHz; Channel No. 276A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9914 New, Jeffersontown, Ky.
Publicast Communications, Inc.
Req: 101.7 mHz; Channel No. 269A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9915 New, Lewisburg, W. Va.
Lewisburg FM Broadcasters.
Req: 105.5 mHz; Channel No. 289A, ERP: 3 kW; HAAT: 300 Ft. (Allocated to Ronceverte, W. Va.)

BPH-9917 New, Frankfort, Mich.
Benzie County Communications, Inc.
Req: 99.3 mHz; Channel No. 275A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9918 New, Lake Village, Ark.
Jack A. Carpenter.
Req: 95.9 mHz; Channel No. 240A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9920 KBRE-FM, Cedar City, Utah.
New Era Broadcasting Co.
Has: 94.9 mHz; Channel No. 235C, Erp: 25.5 kW; Haat: —160 Ft. (LIC).
Req: 94.9 mHz; Channel No. 235C, Erp: 25.3 kW; Haat: 1681 Ft.

BPH-9921 New, Bethlehem, W. Va.
Radio Wheeling, Inc.
Req: 1055 mHz; Channel No. 288A, Erp: 3 kW; Haat: 300 Ft. (Allocated to Moundsville, W. Va.)

BPH-9923 New, Ashland, Oreg.
Faith Tabernacle, Inc.
Req: 101.7 mHz; Channel No. 269A, Erp: 3 kW; Haat: —1298 Ft.

BPH-9924 New, Prentiss. Miss.
Jeff Davis Broadcasting Service.
Req: 98.3 mHz; Channel No. 252A, Erp: 1 kW; Haat: 94 Ft.

BPH-9926 New, Mariposa, Calif.
Mariposa Broadcasting, Inc.
Req: 96.3 mHz; Channel No. 242B, Erp: 1.1 kW; Haat: 2079 Ft.

BPH-9928 WTWE, Manning, S.C.
Clarendon County Broadcasting Co.
Has: 92.1 mHz; Channel No. 221B, Erp: 3 kW; Haat: 160 Ft. (Lic)
Req: 92.1 mHz; Channel No. 221A, Erp: 3 kW; Haat: 300 Ft.

BPH-9929 KDES-FM, Palm Springs, Calif.
Tourtelot Broadcasting Company.
Has: 104.7 mHz; Channel No. 284B, Erp: 20 kW Haat: —600 Ft. (LIC)
Req: 104.7 mHz; Channel No. 284B, Erp: 41.5 kW; Haat: 543 Ft.

BPH-9930 WKPT-FM, Kingsport, Tenn.
Holston Valley Broadcasting Corp.
Has: 98.5 mHz; channel No. 253C, ERP: 45 kW; HAAT: 960 Ft. (LIC)
Req: 98.5 mHz; Channel No. 253C, ERP: 100 kW; HAAT: 1260 Ft.

BPH-9931 New, Price, Utah.
Eastern Utah Broadcasting Co.
Req: 98.3 mHz; Channel No. 252A, Erp: 3 kW; HAAT: —144 Ft.

BPH-9932 New, Livingston, Mont.
Yellowstone B/cting Servces, Inc.
Req: 97.7 mHz; Channel No. 249A, ERP: 3 kW; HAAT: —245 Ft.

BPH-9934 New, Lake Arrowhead, Calif.
Arrowhead Broadcasting Corp.
Req: 103.9 mHz; Channel No. 280A, ERP: .087 kW; HAAT: 1486 Ft.

BPH-9937 New, High Springs, Fla.
Country Broadcasting Co.
Req: 104.9 mHz; Channel No. 285A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9938 KDUX-FM, Aberdeen, Wash.
Aberdeen Broadcasting Co.
Has: 104.7 mHz; Channel No. 284C, ERP: 48 kW; HAAT; 155 Ft. (LIC) (Ocean Shores, Wash.)
Req: 104.7 mHz; Channel No. 284C, ERP: 31.3 kW; HAAT: 361 Ft. (Aberdeen, Wash.)

BPH-9948 New, Gaylord, Mich.
Maumee Valley Broadcasting Association.
Req: 95.3 mHz; Channel No. 237A, ERP: 1.8 kW; HAAT: 371 Ft.

BPH-9949 New, St. Ignace, Mich.
Maumee Valley Broadcasting Asssociation.
Req: 102.3 mHz; Channel No. 272A, ERP: 3 kW; HAAT: 300 Ft.

BPH-9952 WDAS-FM, Philadelphia, Pa.
Max M. Leon, Inc.
Has: 105.3 mHz; Channel No. 2878, ERP: 50 kw; HAAT: 185 Ft. (LIC).
Req: 105.3 mHz; Channel No. 2878, ERP: 3.31 kw; HAAT: 872 Ft.

BPH-9954 New, Bastrop, La. Hagan Broadcasting, Inc.
Req: 100.1 mHz; Channel No. 261A, ERP: 3 kw; HAAT: 182 Ft.

BPH-9955 New, Plymouth, N.C.
Ralph D. Epperson.
Req: 95.9 mHz; Channel No. 240A, ERP: 2.6 kw; HAAT: 326 Ft.

BPH-9956 New, Slaton, Tex.
Faith Broadcasting Service.
Req: 92.7 mHz; Channel No. 224A, ERP: 3 kw; HAAT: 300 Ft.

BPH-9957 KWHO-FM, Salt Lake City, Utah.
Radio Station KWHO.
Has: 93.3 mHz; Channel No. 227C, ERP: 37 kw; HAAT: —93 Ft. (LIC).
Req: 93.3 mHz; Channel No. 227C, ERP: 13 kw; HAAT: 3650 Ft.

BPH-9965 New, Mineola, Texas.
A-C Corp.
Req: 96.7 mHz; Channel No. 244A, ERP: 3 kw; HAAT: 300 Ft.

BPH-9967 New, Aztec, New Mex.
Basin Broadcasting Co.
Req: 94.9 mHz; Channel No. 235C, ERP: 30 kw; HAAT: 429 Ft.

BPH-9971 KSND, Springfield-Eugene, Ore.
Sterling Recreation Organization Co.
Has: 93.1 mHz; Channel No. 226C, ERP: 2.6 kw; HAAT: 81 Ft. (LIC).
Req: 93.1 mHz; Channel No. 226C, ERP: 26.7 kw; HAAT: 814 Ft.

BPH-9972 KSOM-FM, Ontario, Calif.
Media Management Co., Inc.
Has: 93.5 mHz; Channel No. 228A, ERP: 3 kw; HAAT: —400 ft. (LIC).
Req: 93.5 mHz; Channel No. 228A, ERP: 3 kw; HAAT: 89 ft.

BPH-9974 KTYL, Tyler, Tex.
Oil Center Broadcasting Co.
Has: 93.1 mHz; Channel No. 226C, ERP: 4.8 kw; HAAT: 380 Ft. (LIC).
Req: 93.1 mHz; Channel No.

226C, ERP: 100 kw; HAAT: 468.2 Ft.

BPH-9977 New, Alliance, Nebr.
Quiven Q. Fortner and Robert V. Hill.
Req: 92.1 mHz; Channel No. 221A, ERP: 3 kw; HAAT: 300 Ft.

BPH-9980 New, Bethany, Mo.
Jerrell A. Shepherd.
Req: 95.9 mHz; Channel No. 240A, ERP: 3 kw; HAAT: 300 Ft.

BPH-9981 New, Hermiston, Oreg.
Hermiston Broadcasting Co.
Req: 99.3 mHz; Channel No. 257A, ERP: 3 kw; HAAT: 78 Ft.

BPH-9996 KLSN, Brownwood, Tex.
G.B.E., Inc.
Has: 99.3 mHz; Channel No. 257A, ERP: 0.7 kw; HAAT: 115 Ft. (LIC).
Req: 104.1 mHz; Channel No. 281C, ERP: 25 kw; HAAT: 206 Ft.

BPH-10111 New, Healdsburg, Calif.
Carroll E. Brock.
Req: 92.9 mHz; Channel No. 225B, ERP: 18 kw; HAAT: 730 Ft.

BMPH-14866 WBJH, Trenton, N.J.
WBUD, INC.
Has: 101.5 mHz; Channel No. 268B, ERP: 20 kw; HAAT: 130 Ft. (LIC).
Has: 101.5 mHz; Channel No. 268B, ERP: 20 kw; HAAT: 120 Ft. (CP).
Req: 101.5 mHz; Channel No. 268B, ERP: 50 kw; HAAT: 120 Ft.

BMPH-14875 KRKE-FM, Albuquerque, N. Mex.
Gaylord Broadcasting Co., Inc.
Has: 94.1 mHz; Channel No. 231C, ERP: 1.6 kw; HAAT: −150 Ft. (LIC).
Has: 94.1 mHz; Channel No. 231C, ERP: 3.5 kw; HAAT: −155 Ft. (CP).
Req: 94.1 mHz; Channel No. 231C, ERP: 8.14 kw; HAAT: 4104 Ft.

BMPH-14876 KNCY-FM, Nebraska City, Nebr.
The KNCY Radio Corp.
Has: 97.7 mHz; Channel No. 249A, ERP: 3 kw; HAAT: 125 Ft. (CP).
Req: 97.7 mHz; Channel No. 249A, ERP: 3 kw; HAAT: 300 Ft.

BPED-2146 New, Chester, Pa.
Widener College.
Req: 89.5 mHz; Channel No. 208D, TPO: .01 kw.

BPED-2210 New, Bainbridge, Ohio.
Kenston Local School District.
Req: 88.3 mHz; Channel No. 202D, TPO: .01 kw.

BPED-2215 New, Richmond, Va.
University of Richmond.
Req: 90.1 mHz; Channel No. 211D, TPO: .01 kw.

BPED-2239 New, Prairie View, Tex.
Prairie View A & M University.
Req: 88.3 mHz; Channel No. 202C, ERP: 50 kw; HAAT: 402 Ft.

BPED-2245 New, Carolina, Puerto Rico.
Christian Broadcasting Corp.
Req: 90.5 mHz; Channel No. 213B, ERP: 25 kW; HAAT: 1861 Ft.

BPED-2246 New, Elkton, Md.
Maranatha Bible Institute, Inc.
Req: 88.3 mHz; Channel No. 202A, ERP: 3 kW; HAAT: 260.6 Ft.

BPED-2248 New, Elon College, N.C.
Elon College.
Req: 89.3 mHz; Channel No. 207D, TPO: .01 kW.

BPED-2252 WVXU-FM, Cincinnati, Ohio.
Xavier University.
Has: 91.7 mHz; Channel No. 219D, ERP: .065 kW HAAT: 650 Ft. (LIC).
Req: 91.7 mHz; Channel No. 219B, ERP: 6.39 kW; HAAT: 683 Ft.

BPED-2254 New, New Orleans, La.
New Orleans Baptist Theological Sem.
Req: 90.7 mHz; Channel No. 214D, TPO: .01 kW.

BPED-2259 KVTT, Dallas, Tex.
Research Educational Foundation, Inc.
Has: 91.7 mHz; Channel No. 219C, ERP: .78 kW; HAAT: 69 Ft. (LIC).
Req: 91.7 mHz; Channel No. 219C, ERP: 100 kW; HAAT: 786 Ft.

BPED-2260 New, Monroe, Mich.
Monroe Public Schools.
Req: 89.5 mHz; Channel No. 208D, TPO: .01 kW.

BPED-2261 New, Utica, N.Y.
Syracuse Univ. Utica College Branch.
Req: 90.7 mHz; Channel No. 214D, TPO: .01 kW.

BPED-2264 New, Boxford, Mass.
Masconomet Regional School System.
Req: 88.3 mHz; Channel No. 202A, ERP: .710 kW; HAAT: 19 Ft.

BPED-2265 New, Lake Havasu City, Ariz.
Royal Ranger Trailblazer Outpost No. 67.
Req: 88.3 mHz; Channel No. 202D, TPO: .01 kW.

BPED-2267 WKTL, Struthers, Ohio.
Bd. of Educ., Struthers City Sch. Dist.
Has: 90.7 mHz; Channel No. 214A, ERP: .91 kW; HAAT: 26 Ft. (LIC).
Req: 90.7 mHz; Channel No. 214A, ERP: 14.9 kW; HAAT: 23 Ft.

BPED-2272 New, Sodus, N.Y.
Sodus Central School.
Req: 89.5 mHz; Channel No. 208D, TPO: .01 kW.

BPED-2276 New, Lancaster, Pa.
Lancaster Bible College.
Req: 90.3 mHz; Channel No. 212A, ERP: 1.06 kW; HAAT: 87.5 Ft.

BPED-2281 KAVS, Thief River Falls, Minn.
Area Vocational Technical Institute.
Req: 90.1 mHz; Channel No. 211A, ERP: 1.8 kW; HAAT: 82 Ft.

BPED-2359 KDVS, Davis, Calif.
University of California.
Has: 91.5 mHz; Channel No. 218D, TPO: .01 kW. (LIC).
Req: 90.3 mHz; Channel No. 212B, ERP: 5 kW; HAAT: 149 Ft.

BMPED-1291 WEVL, Memphis, Tenn.
Southern Communication Volunteers.
Has: 90.3 mHz; Channel No. 212D, TPO: .01 kW. (CP).
Req: 89.9 mHz; Channel No. 210C, ERP: 6.3 kW; HAAT: 279 Ft.

[FR Doc.76-24031 Filed 8-16-76;8:45 am]

FEDERAL MARITIME COMMISSION

INDEPENDENT OCEAN FREIGHT FORWARDER LICENSE

Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as independent ocean freight forwarders pursuant to Section 44(a) of the Shipping Act, 1916 (Stat. 522 and 46 U.S.C. 841(b)).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to communicate with the Director, Bureau of Certification and Licensing, Federal Maritime Commission, Washington, D.C. 20573.

Forwarding Services, Inc., 6127 Valkeith Street, Houston, Texas 77093. Officers: John M. Revolinski, Secretary/Treasurer; Pauline Rosales, President; Rose G. Bennett, Vice President.

Aspen Forwarders & Custom House Brokers, Inc., 39 Broadway, Suite 3003, New York, NY 10006. Officers: Ralph W. Launer, President; Norman I. Isacoff, Vice President; Edward B. Fitzgerald, Treasurer; Norman C. Schwartz, Secretary.

Panda Freight Forwarders, Inc., P.O. Box 340086, Coral Gables, FL 33134. Officers: Miguel A. Lopez, President/Director; Alberto F. Perdomo, Vice Pres./Director; Concepcion Martinez, Secretary/Treas.

Dated: August 12, 1976.

By the Federal Maritime Commission.

FRANCIS C. HURNEY,
Secretary.

[FR Doc.76-24045 Filed 8-16-76;8:45 am]

FAR EAST CONFERENCE, ET AL.

Agreement Filed

Notice is hereby given that the following agreement, accompanied by a statement of justification, has been filed with the Commission for approval pursuant to Section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement and the statement of justification at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10126; or may inspect the agreement and the statement of justification at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before September 6, 1976. Any person desiring a hearing on the proposed agree-

ment shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of Agreement Filed by:

Edward D. Ransom, Esq.,
Lillick McHose & Charles,
Two Embarcadero Center, 26th Floor,
San Francisco, California 94111.

Agreement No. 10135 is a policy level discussion agreement between the member lines of the Far East Conference (Agreement No. 17) and the Pacific Westbound Conference (Agreement No. 57) which permits the member lines of each to discuss various, enumerated, matters of mutual concern in the trades served by each with the object of drafting appropriate recommendations for referral to either or both Conferences for consideration and, if acceptable, for implementation. This arrangement is scheduled to expire on October 8, 1976 "* * * or sixty (60) days following Commission decision in Docket 74–41 should decision result in disapproval of Agreement 8200 [a rate-making agreement, essentially, between the Far East and Pacific Westbound Conferences] * * * whichever shall occur earlier." No decision in Docket 74–41 has been reached by the Commission.

The effect of Agreement No. 10135–2, here, is to accord the basic agreement an unlimited approval or "* * * until the sixtieth (60th) day after a notice of termination subscribed by three or more parties shall have been mailed to each of the other parties * * *" and to the Commission.

Dated: August 12, 1976.

By Order of the Federal Maritime Commission.

FRANCIS HURNEY,
Secretary.

[FR Doc.76-24044 Filed 8-16-76;8:45 am]

LYKES BROS. STEAMSHIP CO., INC. AND STRACHAN SHIPPING CO.

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 6, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of agreement filed by:

R. J. Finnan, Pricing Analyst, Lykes Bros. Steamship Company, Inc., 300 Poydras Street, New Orleans, Louisiana 70130.

Agreement No. 10257 between Lykes Bros. Steamship Company, Inc. (Lykes) and Strachan Shipping Company (Strachan) is an agency agreement whereby Lykes appoints Strachan as its agent in the ports of Port Canaveral, Port of Palm Beach, and Key West, Florida, on the terms and conditions and to the extent set forth therein.

By Order of the Federal Maritime Commission.

Dated: August 12, 1976.

FRANCIS C. HURNEY,
Secretary.

[FR Doc.76-24047 Filed 8-16-76;8:45 am]

LYKES BROS. STEAMSHIP CO., INC. AND UNITED STATES LINES, INC.

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 6, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of agreement filed by:

R. J. Finnan, Pricing Analyst, Lykes Bros. Steamship Company, Inc., 300 Poydras Street, New Orleans, Louisiana 70130.

Agreement No. 10258 between Lykes Bros. Steamship Company, Inc. (Lykes) and United States Lines, Inc. (USL) is an agency agreement whereby Lykes appoints USL as its husbanding agent for its vessels at the ports of New York, New York; Baltimore, Maryland; and Norfolk, Virginia, on the terms and conditions and to the extent set forth therein.

By Order of the Federal Martime Commission.

Dated: Aug 12, 1976

FRANCIS C. HURNEY,
Secretary.

[FR Doc.76-24046 Filed 8-16-8;8:45 am]

SOUTH AND EAST AFRICA/U.S.A. CONFERENCE

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 6, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of Agreement Filed by:

William L. Hamm, Chairman, South and East Africa/U.S.A. Conference, 25 Broadway, New York, New York 10004.

Agreement No. 8054–13, among the member lines of the South and East Africa Conference, (1) deletes Paragraph 2 of Article 3(h) in its entirety, whereby conference membership automatically ceases when a party fails to have a sailing for six consecutive months for reasons other than war, strikes, boycotts or other force majeure and (2) adds three new paragraphs to Article 3(h) to require a positive unanimous action by the other members to expell a member whereby in the event said carrier truly abandoned the trade but neglected to send a notice of withdrawal, some action could be taken to remove the carriers' name from the agreement.

By Order of the Federal Maritime Commission.

Dated: August 11, 1976.

FRANCIS C. HURNEY,
Secretary.

[FR Doc.76-24048 Filed 8-16-76;8:45 am]

UNITED STATES/SOUTH AND EAST AFRICA CONFERENCE

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 6, 1976. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of Agreement Filed by:

William L. Hamm, Chairman, United States/South and East Africa Conference, 25 Broadway, New York, New York 10004.

Agreement No. 9502–8, among the member lines of the United States/South and East Africa Conference, (1) deletes Article 11 in its entirety, whereby conference membership automatically ceases when a party fails to have a sailing for six consecutive months for reasons other than war, strikes, boycotts or other force majeure and (2) adds a new Article 11 to require a positive unanimous action by the other members to expel a member whereby in the event said carrier truly abandoned the trade but neglected to send a notice of withdrawal some action could be taken to remove the carrier's name from the agreement.

By Order of the Federal Maritime Commission.

Dated: August 11, 1976.

FRANCIS C. HURNEY,
Secretary.

[FR Doc.76-24049 Filed 8-16-76;8:45 am]

FEDERAL POWER COMMISSION

[Docket No. E-9563]

BONNEVILLE POWER ADMINISTRATION

Filing of Transmission Rate Schedules and Provisions

AUGUST 11, 1976.

Take notice that on July 30, 1976, the Secretary of the Interior, upon behalf of Bonneville Power Administration (BPA), pursuant to Section 9 of the Federal Columbia River Transmission System Act (93 Stat. 454) filed with the Federal Power Commission a request for confirmation and approval of proposed transmission rate schedules and General Transmission Rate Schedule Provisions for the transmission (wheeling) of power by BPA.

The BPA submittal, which comprises three rate schedules, includes:

1. *Schedule FPT–1.* Available for the firm transmission of electric power and energy for another entity over Federal electric transmission system facilities. The rate is designed for transmitting power from non-Federal hydro and existing thermal plants to load centers over Federal facilities where the specific facilities used may not be readily determined.

2. *Schedule UFT–1.* Available for the transmission of electric power and energy for another entity over specified Federal transmission system facilities. The basic monthly charge shall be one-twelfth of the sum of the products of the annual cost of each element of the specific facilities per kilowatt of capacity rating and the transmission demand.

3. *Schedule ET–1.* This schedule is available for the incidental transmission of electric energy for another entity using excess capacity of the Federal transmission system.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 10, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24022 Filed 8-16-76;8:45 am]

[Docket No. ER76-832]

CENTRAL HUDSON GAS & ELECTRIC CORP.

Rate Filing

AUGUST 10, 1976.

Take notice the Central Hudson Gas & Electric Corporation (Central Hudson), on August 2, 1976, tendered for filing as a rate schedule an executed agreement dated May 17, 1976 between Central Hudson and New York State Electric & Gas Corporation (NYSEG). The proposed rate schedule provides for the sale of firm capability and associated energy by Central Hudson.

The rate schedule provides for a capability charge of $100 per megawatt per day of operating capability made available by Central Hudson and an energy charge equal to Central Hudson's average system steam electric generation costs, which includes fuel and operation and maintenance costs, plus $.0005 per kilowatt-hour.

Central Hudson requests waiver of the notice requirements of Section 35.3 of the Commission's Regulations so that the proposed rate schedule can be made effective on May 18, 1976 in accordance with the terms thereof. Central Hudson states that it will be uncompensated for costs already incurred pursuant to the terms of the proposed rate schedule, if the waiver is not granted.

Central Hudson states that a copy of its filing was served on NYSEG.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 20, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this

filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24013 Filed 8-16-76;8:45 am]

[Project No. 2284]

CENTRAL MAINE POWER CO.

Application for Easement Over Project Lands

AUGUST 10, 1976.

Public notice is hereby given that an application was filed on July 6, 1976, under the Federal Power Act (16 U.S.C. 791a-825r) by the Central Maine Power Company (correspondence to: Mr. Jon S. Readnour, Counsel, Central Maine Power Company, 9 Green Street, Augusta, Maine 04330) for approval of an easement over lands of Brunswick-Topsham Project No. 2284, located on the Androscoggin River, in Cumberland and Sagadahoc Counties, Maine.

The Company requests Commission approval for the granting of a 25-foot wide permanent easement approximately 640 feet long to the Topsham Sewer District (District), which would accommodate a 10-inch interceptor pipe as part of the District's proposed interceptor sewer system. The pipe would not discharge into project waters.

The District received a Corps of Engineers Permit (ME-BATH-73-290) for a river crossing not on project lands but part of the total sewer project. Also, approvals were received from the Environmental Protection Agency (EPA), Southern Mid Coast Regional Planning Commission, State of Maine—State Planning Office, Maine Department of Transportation and the Maine Department of Environmental Protection.

Public notices have been published in connection with applications for approval with EPA, Maine Department of Environmental Protection, and the Town of Topsham Shoreland Zoning Commission. After public notice and hearings, all approvals were granted by the appropriate agencies.

The Company has requested the earliest possible Commission action and the use of the shortened procedures pursuant to Section 1.32(b) of the Commission Rules.

Any person desiring to be heard or to make any protest with reference to said application should, on or before September 27, 1976, file with the Federal Power Commission, 825 North Capitol Street, N.W., Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 C.F.R. § 1.8 or § 1.10 (1975). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and conferred upon the Federal Power Commission by Sections 308 and 309 of the Federal Power Act, 16 U.S.C. §§ 825g and 825h, and the Commission's Rules of Practice and Procedure, specifically § 1.32(b), a hearing on this application may be held before the Commission without further notice if no issue of substance is raised by any request to be heard, protest, or petition filed subsequent to this notice within the time required herein. If an issue of substance is so raised, further notice of hearing will be given.

Under the shortened procedure herein provided for, unless otherwise advised, it will not be necessary for the Company to appear or be represented at the hearing before the Commission.

The application is on file with the Commission and is available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24014 Filed 8-16-76;8:45 am]

[Docket No. ER76-709]

CINCINNATI GAS & ELECTRIC CO.

Order Denying Requested Relief

AUGUST 3, 1976.

On July 2, 1976, the Village of Georgetown, Ohio, intervenor herein, filed a motion requesting that the Commission order The Cincinnati Gas & Electric Company (CG&E) to commence billing Georgetown on CG&E's presently effective FPC Rate Schedule No. 36. For the reasons hereinafter stated, we shall deny Georgetown's motion.

Docket No. ER76-709 was initiated by CG&E's filing on May 25, 1976, of a proposed rate increase to Georgetown and The Union Light, Heat and Power Company (Union Light), a wholly-owned subsidiary of CG&E. One of the stated purposes of the proposed rate change was to place Georgetown and Union Light under the same rate schedule. By order issued June 23, 1976, the Commission accepted for filing and suspended for two months the proposed tariff changes, established hearing procedures, and granted the petitions of Georgetown and Union Light to intervene.

In the instant pleading, Georgetown contends that pursuant to a settlement agreement dated May 14, 1975, in Docket Nos. E-8885 and E-8546 and approved by Commission order issued September 5, 1975, CG&E granted Georgetown's request for the same rate as Union Light and agreed to file a rate schedule which would be applicable to both Georgetown and Union Light. Georgetown states that to date, it has received no benefit from the lower rate within Rate Schedule No. 36 that is presently applicable to only Union Light, which rate will be superseded on August 25, 1976, by the increased rate filed in Docket No. ER76-709. Georgetown requests that CG&E be ordered to bill Georgetown under Rate Schedule No. 36 so that Georgetown may receive the prospective advantages of such lower rate prior to its August 25 cancellation.

On July 14, 1976, CG&E filed an answer to Georgetown's motion contending that (1) the motion seeks interlocutory relief that cannot be granted, and (2) the terms of the settlement agreement do not entitle Georgetown to the relief requested.

Upon review of the May 14, 1975 settlement agreement we find no support for the relief requested by Georgetown. Article 8 of the settlement agreement provides in pertinent part:

> 8. Since Georgetown requests the same rate as the Union Light, Heat and Power Company, CG&E shall file, pursuant to § 205(d) of the Federal Power Act, at some time subsequent to termination of these consolidated cases a notice of revised rate schedule for wholesale electric service to both Georgetown and The Union Light, Heat and Power Company. Such revised rate schedule shall be designed to contain a single demand step and a single energy step. Such filing will contain two cost of service studies. One will utilize twelve month average coincidental peak for allocation purposes and the other will be premised upon a single annual coincidental peak for such allocation, with testimony in support of the latter allocation approach.

The above language clearly indicates that CG&E would file a rate change applicable to both Georgetown and Union Light so as to place them on the same rate. We find no basis for granting Georgetown's request to be placed on the present rate applicable to Union Light (Rate Schedule No. 36).

The Commission finds: Good cause does not exist to grant the relief requested by Georgetown in its July 2, 1976 motion.

The Commission orders: (A) The relief requested by Georgetown in its July 2, 1976 motion is hereby denied.

(B) The Secretary shall cause the prompt publication of this order in the Federal Register.

By the Commission.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24003 Filed 8-16-76;8:45 am]

[Docket No. CP76-454]

COLUMBIA GAS TRANSMISSION CORP. AND COLUMBIA GULF TRANSMISSION CO.

Application

AUGUST 3, 1976.

Take notice that on July 22, 1976, Columbia Gas Transmission Corporation (Columbia Gas), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, and Columbia Gulf Transmission Company (Columbia Gulf), 3805 West Alabama Avenue, Houston, Texas 77027, filed in Docket No. CP76-454 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing Columbia Gas to construct and operate certain facilities and to transport up to 2,500 Mcf of natural gas per day for the City of Somerset, Kentucky (Somerset), and authorizing a new delivery point from Columbia Gulf to Columbia Gas

and the construction and operation of certain natural gas facilities related thereto, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Columbia Gas proposes to construct and operate a measuring and regulating facility and approximately 0.1 mile of 6-inch pipeline to connect said facility to Columbia Gas' existing Line KA–1, which services the City of Manchester, Clay County, Kentucky. It is said that these facilities are required to receive volumes of gas to be transported for Somerset and would also be used to receive volumes of gas purchased by Columbia Gas from Somerset and Patrick Petroleum Corporation (Patrick). The application shows the estimated cost of Columbia Gas' proposed facilities is $45,600, which cost would be generated from internal sources.

Columbia Gulf proposes to establish an additional point of delivery to Columbia Gas and construct and operate a measuring and regulating facility related thereto. It is said that the proposed point of delivery and related facilities would be used to deliver volumes of gas to Somerset for the account of Columbia Gas and would be located on existing and intersecting rights-of-way of Columbia Gulf and Somerset in Casey County, Kentucky. The application shows the estimated cost of these facilities to be $41,200, which cost would be reimbursed to Columbia Gulf by Somerset.

The application indicates that the transportation and redelivery of gas is pursuant to an effort by Somerset to supplement its supply of natural gas for the benefit of all of the industrial customers of Somerset Gas Service, which is Somerset's gas utility business. It is further incidated that Somerset is in the process of constructing an 8-inch gas pipeline from Hyden, Leslie County, Kentucky, to Manchester to move production volumes from the Hyden field to market and that not less than 50 percent of the volumes dedicated to Somerset would be sold by Somerset to Columbia Gas. It is asserted that Somerset's remaining 50 percent, not to exceed 2,500 Mcf per day, is to be transporated under the requested authorization, for which transportation service Somerset would pay Columbia Gas 20.0 cents per Mcf. It is further asserted that all capacity in the Hyden to Manchester 8-inch line above 5,000 Mcf per day is dedicated and reserved for Columbia Gas' exclusive use without charge for transportation and that Columbia Gas would pay Somerset $300,000 as a contribution in aid of construction after the completion of and the placing in service of the Hyden-to-Manchester line.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 26, 1976, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter find that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76–24004 Filed 8–16–76;8:45 am]

[Docket Nos. E–8769, E–8770, E–9119, ER76–218 and ER76–219]

FLORIDA POWER AND LIGHT CO.

Further Extension of Time

AUGUST 11, 1976.

On July 26, 1976, the Commisison Staff Counsel filed a motion to extend the procedural dates fixed by order issued July 3, 1975, as most recently modified by notice issued July 16, 1976, in the above-designated proceeding. The motion states that Florida Power and Light Company supports the proposed schedule.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Company Testimony, October 15, 1976.
Service of Staff Testimony, October 29, 1976.
Service of Intervenor Testimony, November 12, 1976.
Service of Company Rebuttal, November 29, 1976.
Hearing, December 14, 1976.

By direction of the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76–24021 Filed 8–16–76;8:45 am]

[Docket No. ER76–837]

ILLINOIS POWER CO.

Filing Amendment No. 8 to Interconnection Agreement

AUGUST 10, 1976.

Take notice that Illinois Power Company (Illinois Power) on August 2, 1976, tendered for filing Amendment No. 8 to the Interconnection Agreement dated March 1, 1964 between Commonwealth Edison Company (Commonwealth Edison) and Illinois Power. The Commission has previously designated the March 1, 1964 Agreement as Illinois Power Rate Schedule FPC No. 11 and Commonwealth Edison Rate Schedule FPC No. 5.

The parties state that Amendment No. 8 to the Agreement provides for an increase in the minimum energy charges for Emergency Service from 17.5 mills to 30 mills per kilowatthour, proposed to become effective September 1, 1976. The parties also state that since the use of Emergency Service under the proposed minimum charge cannot be accurately determined or estimated, it is impossible to determine or estimate the increase in revenues resulting from Amendment No. 8.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 or 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 August 2?, 1976. 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.

KENNEETH F. PLUMB,
Secretary.

[FR Doc.76–24015 Filed 8–16–76;8:45 am]

[Docket No. ER76–823]

IOWA SOUTHERN UTILITIES CO.

Proposed Rate Change

AUGUST 10, 1976.

On July 30, 1976, Iowa Southern Utilities Company, ("Iowa Southern" or "Company") submitted for filing proposed changes in its rates under which wholesale electric service for retail is provided to Albia Light and Railway and to the following Iowa cities: Seymour, Afton, Eldon, Orient, Danville, and New London. Presently effective rate schedules 91 and 96 would be withdrawn and a single Rate 92 would be applicable to service to all seven customers. The proposed change set forth in that filing would increase revenues from jurisdictional sales by $202,720, based on the twelve months ended December 31, 1975.

Iowa Southern states that the cost of service study for the test year 1975 as submitted in the filing demonstrates the need for the increase in revenue to provide a reasonable return on the investment dedicated to providing electrical service to these wholesale customers.

Iowa Southern requests that the Commission waive the notice requirements of Section 35.13(b)(4)(i) and 35.13(b)(5)(i) of the regulations and accept the

proposed rate schedule for filing with an effective date of August 31, 1976, or, in lieu thereof, order a suspension period of not more than one day.

Copies of this filing have been served by personal delivery to Albia Light and Railway and to the cities of Seymour, Afton, Eldon, Orient, Danville, and New London. A copy of the filing has also been mailed to the Iowa State Commerce Commission.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 30, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24016 Filed 8-16-76;8:45 am]

[Docket No. ER76-838]

MISSOURI PUBLIC SERVICE CO.

Filing of Notice of Cancellation

AUGUST 10, 1976.

Take notice that on July 14, 1976, Missouri Public Service Company (MPS) filed a Notice of Cancellation of Service Schedule E, Supplement No. 1 to its FPC Rate Schedule No. 18. MPS states that Service Schedule E terminated by its own terms on May 31, 1973.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 24, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24018 Filed 8-16-76;8:45 am]

[Docket No. E-9473]

MISSOURI UTILITIES CO.

Tender of Tariff Sheets

AUGUST 9, 1976.

Take notice that on July 20, 1976, Missouri Utilities Company (MU) tendered for filing the following tariff sheets as part of its FPC Electric Tariff, Original Volume No. 1:

1st Revised Sheet No. 3, superseding Interim, 1st Revised Sheet No. 3.
1st Revised Sheet No. 4, superseding Interim, 1st Revised Sheet No. 4.
1st Revised Sheet No. 5, superseding Interim, 1st Revised Sheet No. 5.
Original Sheet No. 5A, superseding Interim, Original Sheet No. 5A.

MU states that the tariff sheets are tendered pursuant to the Commission's order issued December 5, 1975, in Docket No. E-9473 and represent MU's proposed final settlement of that docket. MU states that the tendered SFR-1 rate schedule reduces the per kW billing demand charge to reflect the settlement in Union Electric Company, Docket No. E-9496. MU states that there are no refunds due to the City of Kennett in Docket No. E-9473 since it incurred no billing demand responsibility, but that it is necessary to lower the per kW billing demand charge in case billing demand responsibility is incurred in the future.

MU requests waiver of the 30-day notice requirement to permit an effective date of August 1, 1976.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 20 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-23995 Filed 8-16-76;8:45 am]

[Docket No. ER76-801]

MISSOURI UTILITIES CO.

Tariff Sheet Correction

AUGUST 10, 1976.

Take notice that on July 16, 1976, Missouri Utilities Company (MU) tendered for filing tariff sheet, Interim Original Sheet No. 5A, superseding Interim Original Sheet No. 6 in its FPC Electric Tariff, Original Volume No. 1. MU states that Interim Original Sheet No. 6 was accepted by Commission order dated December 5, 1975, to become effective November 17, 1975, in Docket No. E-9473, but that the designation was improper because an Original Sheet No. 6 had previously been filed. MU states that the tender herein corrects the tariff sheet numbering. MU requests waiver of the 30 day notice requirement to permit an effective date of July 31, 1976, for the tendered tariff sheet.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 20, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24017 Filed 8-16-76;8:45 am]

[Docket No. ER76-831]

MONONGAHELA POWER CO. AND WEST PENN POWER CO.

Changes in Rates and Charges

AUGUST 10, 1976.

Take notice that Allegheny Power Service Corporation (APSC) on July 30, 1976 tendered for filing on behalf of Monongahela Power Company (Monongahela) and West Penn Power Company (West Penn), two of the electric utilities which make up the integrated Allegheny Power System, Amendment No. 4 dated July 21, 1976 to the Interchange Agreement dated October 17, 1968 between Monongahela, West Penn and the Ohio Edison Company and Pennsylvania Power Company (Ohio Edison) designated Monongahela Rate Schedule FPC No. 29 and West Penn Rate Schedule FPC No. 27.

APSC states that Amendment No. 4 provides for an increase in the demand charge for short-term power from $0.45 to $0.50 per kilowatt week to become effective September 1, 1976. Applicants state that since short-term power transactions are scheduled from time to time as load capacity conditions on the systems of the parties dictate, it is impossible to estimate the increase in revenues which would result from Amendment No. 4.

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, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 20, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this

filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24019 Filed 8-16-76;8:45 am]

[Docket Nos. RI76-132; RI76-133; RI76-135]

NORTHERN MICHIGAN EXPLORATION CO. ET AL.

Order Consolidating Proceedings and Granting Intervention

AUGUST 4, 1976.

On June 14, 24, and 29, 1976, Northern Michigan Exploration Company (NOMECO) Clark Oil Producing Co. (Clark), and Diamond Shamrock Corporation (Diamond Shamrock), respectively, filed petitions for special relief pursuant to Sections 1.7 and 2.56(a)(g)(2) from the rate established in Section 2.56(a)(1) of the Commission's General Policy and Interpretations.[1] On July 8, 1976, the Michigan Public Service Commission filed a Notice of Intervention and on July 15, 1976, Consumers Power Company filed a petition to intervene both in Docket No. RI76-132.

NOMECO requests a base rate of $1.7456 per Mcf with annual escalations of 4 percent per annum for the sale of natural gas from its 12.5 percent working interest in production from West Cameron Block 639, Offshore Louisiana, to Trunkline Gas Company (Trunkline) and Consumers Power Company (Consumers). NOMECO is currently making emergency deliveries to Trunkline from West Cameron Block 639 pursuant to Section 157.29 of the Commission's Rules of Practice and Procedure. However, on July 9, 1976, the Commission approved NOMECO's application for a limited term sale of this gas in Docket No. CI76-524 pending the issuance of a permanent certificate in Michigan Gas Storage Company, Docket No. CP74-322. In the latter proceeding, NOMECO proposes to sell gas to its parent, Consumers Power Company. The July 9 order made clear that any rate relief would apply only to its proposed permanent sales to Consumer and not to the limited term sale.

Additionally, NOMECO requests that, pursuant to Section 1.32(b) of the Commission's Rules, the intermediate decision procedure be omitted inasmuch as NOMECO will begin to incur losses if it does not receive the requested relief of July 6, 1976. Further, NOMECO requests, pursuant to Section 1.20(b) of the Rules of Practice and Procedure, that its petition be consolidated with those petitions for special relief of Sun Oil Company (Sun) and Anadarko Production Company (Anadarko) contained in Docket Nos. RI76-117 and RI76-119 insofar as its petition presents issues of law and fact common to those of Sun and Anadarko.

Clark requests a base rate of $2.0418 per Mcf with annual escalations of 4 percent per annum for the sale of natural gas from its 15 percent working interest in production from West Cameron Block 639, Offshore Louisiana, to Trunkline. Clark is currently making deliveries pursuant to its small producer certificate issued in Docket No. CS71-447.

Diamond Shamrock requests a base rate of $1.8272 per Mcf with annual escalations of 4 percent per annum for the sale of natural gas from its 13.34 percent working interest in production from West Cameron Block 639, Offshore Louisiana, to Trunkline. Diamond Shamrock curently receives 52.5 cents per Mcf plus BTU adjustment for gas deliveries pursuant to FPC Gas Rate Schedule No. 67 excepting 10 percent of its 13.34 percent working interest in such reserves. On April 29, 1976, Diamond Shamrock and Trunkline amended their existing agreement to include the 10 percent portion previously reserved for its own use and to provide for an increased base rate of $1.8272 per Mcf with annual escalations of 4 percent per annum, authority for which in the form of special relief is to be considered herein.[2]

Petitioners together with Sun and Anadarko are owners of 100 percent of the working interest in West Cameron Block 639, Offshore Louisiana. As do Sun and Anadarko, petitioners asert that the total costs associated with West Cameron Block 63. exceed the rate established in Section 2.56a(a)(1) and petition for special relief pursuant to Section 2.56a(g)(2) which refers to relief available in cases where wells are located in water depths greater than 250 feet. As do Sun and Anadarko, petitioners state that these sales will be made from wells located in water depth of 365 feet.

The Commission finds: (1) The public convenience warrants the consolidation of Docket Nos. RI76-132, RI76-133, and RI76-135 with previously consolidated Docket Nos. RI76-117 and RI76-119.

(2) No good cause exists for granting the request for waiver and omission of the intermediate decision.

(3) Good cause exists to grant the petition to intervene of Consumers Power Company.

The Commission orders: (A) The petitions for special relief filed herein in Docket Nos. RI76-132, RI76-133, and RI 76-135 are hereby consolidated with Docket Nos. RI76-117 (Sun) and RI76-119 (Anadarko) which were set for hearing with pre-hearing conference by our order dated July 9, 1976.

(B) Accordingly, pursuant to the authority of the Natural Gas Act, particularly Sections 4, 5, 7, 14, and 16 thereof, the Commission's Rules of Practice and Procedure and the Regulations under the Natural Gas Act (18 CFR Chapter 1), a public hearing shall be held in a hearing room of the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, to determine the lawfulness of Petitioners' proposed rate increases.

(C) Petitioners and any intervenor supporting the foregoing shall file their direct testimony and evidence on or before August 17, 1976, in conformance with our July 9 order. All testimony and evidence shall be served upon the Presiding Administrative Law Judge, the Commission Staff, and all parties to this proceeding.

(D) The Presiding Administrative Law Judge shall preside at a pre-hearing conference to be held on September 9, 1976, at 9:30 A.M. EDT, in a hearing room at the address noted in Ordering Paragraph (B).

(E) The Secretary shall cause prompt publication of this order to made in the FEDERAL REGISTER.

By the Commission.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24010 Filed 8-16-76;8:45 am]

[Docket No. CP76-456]

NORTHERN NATURAL GAS CO.

Application

AUGUST 3, 1976.

Take notice that on July 26, 1976, Northern Natural Gas Company, operating as Peoples Natural Gas Division (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP 76-456 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the operation of facilities and the exchange with and sale to Colorado Interstate Gas Company (CIG) of natural gas in interstate commerce, all as more fully set forth in the application on file with the Commission and open to public inspection.

The application states that Applicant and CIG have executed an agreement dated April 20, 1976, for the sale and exchange of natural gas under control of Applicant in the Kendall Field area of Kearny and Hamilton Counties, Kansas. It is stated in the agreement that it supersedes the agreement between Applicant and CIG dated June 1, 1972, pursuant to which the application states service is authorized in Docket Nos. CP 72-275 and CP72-291. Applicant states that several new wells have been drilled in the Kendall area which are dedicated to Applicant; and, as a result, Applicant is again experiencing underage of its production takes which it cannot make up by utilizing existing facilities or by means of the currently authorized exchange. Accordingly, Applicant proposes to exchange and sell gas under the agreement of April 20, 1976.

Under the agreement of April 20, 1976, Applicant would deliver gas to CIG at

[1] Notice of NOMECO's petition was issued on June 22, 1976, and appeared in the FEDERAL REGISTER on July 28, 1976, at 41 FR 26613. Notices of Clark's and Diamond Shamrock's petitions were issued on July 9, 1976.

[2] Concurrently Diamond Shamrock filed on June 29, 1976, an application to amend its certificate in Docket No. CI75-13 with a copy of the amendatory agreement to be filed as a supplement to its FPC Gas Rate Schedule No. 67 so as to include 10 percent of its 13.34 working interest ownership previously reserved for its own use at a rate of $1.8272 per Mcf with annual escalations of 4 percent as requested in this petition for special relief.

two points of interconnection on CIG's gathering system in Kearny County, Kansas, at aggregate delivery rates of not less than 3,000 Mcf on an average day and not more than 7,500 Mcf on any day. CIG would have a continuing option to purchase 25 percent of the gas delivered by Applicant which might be in excess of 37,500 Mcf per month. Applicant would charge CIG for the sale gas the average price Applicant pays for gas it purchases in the area from wells contracted for and connected on or after January 1, 1973, which rate is said initially to be 63.75 cents per Mcf subject to Btu adjustment. In addition Applicant would charge an amount for gathering and transporting such gas, which rate is said initially to be 6.32 cents per Mcf. The application states that minimum sales would be 161,250 Mcf annually.

CIG would redeliver to Applicant, from April 1 through October 15, thermally equivalent volumes of gas, less volumes purchased from Applicant. For all gas deliveries by Applicant to CIG which would be in excess of 37,500 Mcf per month and not purchased by CIG, Applicant would pay CIG an initial rate of 4.5 cents per Mcf for compression and transportation. Redeliveries would be made at one point in Moore County, Texas, at one point in Bent County, Colorado, and at three points in Baca County, Colorado.

Applicant states that in order to effect delivery of gas to CIG in Section 31, T. 24 S., R. 34 W., Kearny County, Kansas, it requests authorization to operate an existing measuring station located in proximity of the point of interconnection.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 27, 1976, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24005 Filed 8-16-76;8:45 am]

[Docket No. CP76-457]

NORTHERN NATURAL GAS CO.

Application

AUGUST 3, 1976.

Take notice that on July 26, 1976, Northern Natural Gas Company (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP76-457 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas in interstate commerce for Iowa Electric Light and Power Company (Iowa Electric) and the construction and operation of facilities for the delivery of gas to Iowa Electric, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant proposes to deliver from March 27 through October 26 of each year (summer season) up to 2,000 Mcf of summer maximum daily volume of gas to Iowa Power and Light Company (Iowa Power) at Iowa Power's Des Moines Town Border Station No. 1 in Polk County, Iowa, for the account of Iowa Electric for liquefaction. On days not within the summer season gas might be delivered under the same circumstances, the application states.

The application states that each day during the summer season Iowa Electric would designate by individual billing group the specific volume it wishes Applicant to deliver to Iowa Power and that the volume designated for any billing group would not exceed the summer maximum daily volume then currently in effect for such billing group as set forth below. It is stated further that the gas delivered on any day would be that which could otherwise be delivered to Iowa Electric within its authorized entitlement for such day. The proposed summer maximum daily volumes are as follows:

Billing group	Rate zone	Volume (in thousand cubic feet)
B	2	8
	3	409
Total group B		417
C	2	673
	3	430
Total group C		1,103
D	3	428
	B	52
Total group D		480
Total summer		2,000

The gas delivered during the summer season would be considered as sold to Iowa Electric within the billing group from which the gas was diverted and would be billed to such billing group under Rate Schedule CD-1. The deliveries under the instant proposal would be considered to be the first volumes delivered to each designated billing group.

Applicant also proposes to transport by displacement to the various billing groups as designated by Iowa Electric volumes of vaporized LNG at a daily rate of up to 9,000 Mcf from October 27 through March 26 (winter season). It is stated that all volumes would be designated by individual billing group and would not exceed the winter maximum daily volume then in effect for such billing group as set forth below. The proposed winter maximum daily volumes[1] are as follows:

Billing group	Rate zone[1]	Volume (in thousand cubic feet)
B	2	39
	3	1,840
Total group B		1,879
C	2	3,029
	3	1,939
Total group C		4,968
D	3	1,922
	B	231
Total group D		2,153
Total winter		9,000

The application states that the total daily volumes designated for transportation by Iowa Electric would be made available by Applicant's concurrent reduction of authorized deliveries to Iowa Power at Des Moines under Rate Schedule CD-1. Further, it is stated all gas transported for Iowa Electric under the instant proposal would be resold only to firm and small volume consumers.

For the proposed service Applicant would charge seasonal demand charges of $2.465 times the summer maximum daily volume and $5.239 times the winter maximum daily volume. In addition, there would be a commodity charge in the summer season for deliveries to Iowa Power of 0.16 cent per Mcf for Billing Group C and none for Billing Groups B and D. There would be commodity charges in the winter season for deliveries from Iowa Power of 4.204 cents per Mcf for Billing Group B, 0.841 cent per Mcf for Billing Group C, and 3.149 cents per Mcf for Billing Group D.

Applicant states that it has reviewed the capacity of each town border station through which Applicant effects delivery and sale of natural gas on a firm basis to Iowa Electric for distribution and resale in Iowa and that certain of the meter facilities of the town border stations have been found deficient with regard to

[1] The agreement among Applicant, Iowa Electric, and Iowa Power specifies delivery points within each rate zone.

measuring the respective firm gas volumes. Accordingly, Applicant proposes to changeout the measuring equipment at the following town border stations in order to assure accurate measurement:

Town Border Station	*Location on*
Central City No. 1	Linn County, Iowa
Delmar No. 1	Clinton County, Iowa
Huxley No. 1	Story County, Iowa
Kanawha No. 1	Hancock County, Iowa

The facilities are estimated to cost $9,330 which would be financed with cash on hand.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 25, 1976 file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised it will be unnecessary for Applicant to appear or be represented at the hearing.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24006 Filed 8-16-76;8:45 am]

[Project No. 108]

NORTHERN STATES POWER CO.

Issuance of Annual License(s)

AUGUST 9, 1976.

On February 24, 1970, Northern States Power Company, Licensee for Chippewa Reservoir Project No. 108, located in Sawyer County, Wisconsin, filed an application for a new license under the Federal Power Act and Commission regulations thereunder.

The license for Project No. 108 was issued effective August 8, 1921, for a period ending August 7, 1971. Since the original date of expiration, the project has been maintained and operated under annual licenses, the most recent of which will expire August 7, 1976. In order to authorize the continued operation and maintenance of the project pursuant to the Federal Power Act, pending Commission action on Licensee's application, it is appropriate and in the public interest to issue an annual license to the Northern States Power Company.

Take notice that an annual license is issued to Northern States Power Company under the Federal Power Act for the period August 8, 1976, to August 7, 1977, or until Federal takeover, or until the issuance of a new license for the project, whichever comes first, for the continued operation and maintenance of the Project No. 108, subject to the terms and conditions of its present license. Take further notice that if Federal takeover or issuance of a new license does not take place on or before August 7, 1977, a new annual license will be issued each year thereafter, effective August 8 of each year, until such time as a new license is issued, or Federal takeover takes place, without further notice being given by the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-23996 Filed 8-16-76;8:45 am]

[Docket No. CP76-247]

NORTHERN NATURAL GAS CO. AND PANHANDLE EASTERN PIPE LINE CO.

Amendment to Application

AUGUST 9, 1976.

Take notice that on July 26, 1976, Northern Natural Gas Company (Northern), 2223 Dodge Street, Omaha, Nebraska 68102, and Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77001, filed in Docket No. CP76-247 an amendment to their application filed in said docket pursuant to Section 7(c) of the Natural Gas Act requesting authorization to add certain wells to the gas exchange between Applicants proposed in said docket, all as more fully set forth in the amendment which is on file with the Commission and open to public inspection.

Applicants state that their application in the instant docket requests, among other things, authority to receive and deliver gas on a volume-for-volume basis, all in accordance with two Gas Exchange Agreements between Applicants both dated August 11, 1957. Applicants further state that subsequent to the filing of the application in this docket, they entered into an Amended Exhibit "A", dated June 17, 1976, and an Amended Exhibit "B", dated July 7, 1976, to the Gas Exchange Agreement Deep Gas providing for the addition of four deep gas wells as follows:

Well name, county, state	Producer	Docket No.	Interest committed to or owned by—
Lauck-Massey No. 1, Edwards, Kans.	D. R. Lauck	CS71-166	Northern.
Elliott E., No. 1, Stevens, Kans.	Mobil Oil Corp.	G-7642	Do.
Shell, G. W., No. 1, Stevens, Kans.	do.	G-7642	Do.
Calhoon No. 1 (Lower Morrow), Beaver, Okla.	Decalta International Corp.	CS74-8	Panhandle.

It is indicated that Applicants have contracted for the purchase of gas from the wells set forth above and desire that such wells be included in the exchange between them. Applicants state that they have been depleting their dedicated reserves during the past several years at a rate faster than either has been able to acquire new reserves, thereby reducing the total reserves available to their respective systems. It is asserted that as a result, neither Applicant is able to supply the full requirements of its customers and that the addition of the wells to the gas exchange as herein proposed would assist in maintaining adequate and reliable service to Applicants' customers.

Any person desiring to be heard or to make any protest with reference to said amendment should on or before August 30, 1976, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules. Persons who have heretofore filed need not file again.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-23997 Filed 8-16-76;8:45 am]

[Project No. 175]

PACIFIC GAS AND ELECTRIC CO.

Issuance of Annual License(s)

AUGUST 9, 1976.

On June 29, 1970, Pacific Gas and Electric Company, Licensee for Balch Project No. 175, located in Fresno County, near the city of Fresno in Sequoia and Sierra National Forests, filed an application for a new license under the Federal Power Act and Commission regulations thereunder.

The license for Project No. 175 was issued effective July 28, 1922, for a period ending July 27, 1972. Since the original date of expiration, the project has been

maintained and operated under annual licenses, the most recent of which will expire on July 27, 1976. In order to authorize the continued operation and maintenance of the project pursuant to the Federal Power Act, pending Commission action on Licensee's application, it is appropriate and in the public interest to issue an annual license to Pacific Gas and Electric Company.

Take notice that an annual license is issued to Pacific Gas and Electric Company under the Federal Power Act for the period July 28, 1976, to July 27, 1977, or until Federal takeover, or until the issuance of a new license for the project, whichever comes first, for the continued operation and maintenance of the Balch Project No. 175, subject to the terms and conditions of its present license. Take further notice that if Federal takeover or issuance of a new license does not take place on or before July 27, 1977, a new annual license will be issued each year thereafter, effective July 28 of each year, until such time as Federal takeover or a new license is issued, without further notice being given by the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-23998 Filed 8-16-76;8:45 am]

[Docket No. ER76-820]

PUBLIC SERVICE COMPANY OF OKLAHOMA

Tariff Change

AUGUST 10, 1976.

Take notice that the Public Service Company of Oklahoma (the "Company"), on July 30, 1976, tendered for filing proposed changes in its FPC Electrict Service Tariff No. 162. The proposed changes would increase revenues from sales and service to the Grand River Dam Authority ("GRDA") by $9,055,158 based on the 12 month period ending December 31, 1976. The filing is made as a complaint under Section 206(a) of the Federal Power Act.

The Company states that it is filing these proposed changes as a result of the large deficit it is incurring on operations related to serving GRDA. The Company alleges that there is a resulting adverse effect on the public interest in that, in the absence of a rate increase, the existing rate is confiscatory, the Company's ability to provide reliable and safe electric service to its retail and wholesale customers is jeopardized, the cost of financing the Company's construction program is increased such as to threaten the continuation of service to its customers at fair and reasonable rates, GRDA is the recipient of an unduly discriminatory and preferential rate, and waste of energy resources, principally natural gas, is encouraged.

The Company further states that copies of the filing were served upon the following parties:

The Grand River Dam Authority, P.O. Drawer 112, Vinita, Oklahoma 74301.

The Oklahoma Corporation Commission, Jim Thorpe Office Building, Oklahoma City, Oklahoma 73102.

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 Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 17, 1976. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-24020 Filed 8-16-76;8:45 am]

[Opinion No. 742-B; Docket No. R-393]

SMALL PRODUCER REGULATION

Opinion and Order Clarifying Opinion No. 742-A

AUGUST 2, 1976.

On July 27, 1976, the Commission issued Opinion No. 742-A, denying rehearing and reconsideration of Opinion No. 742. In its discussion in Opinion No. 742-A, the Commission, at mimeo p. 17, stated that small producers would receive the same rate as large producers for sales that qualified under Opinion No. 770, Opinion And Order Prescribing Uniform National Rate For Sales Of Natural Gas Dedicated To Interstate Commerce On Or After January 1, 1973, For The Period January 1, 1975 To December 31, 1976, Docket No. RM75-14, issued July 27, 1976.

Some confusion has arisen because of this statement in that the Commission in Opinion No. 770 set one rate for the period January 1, 1973 to December 31, 1974, and another for January 1, 1975 to December 31, 1976. The prior period is the same as that used by the Commission in its first nationwide new gas rate proceeding, Opinion Nos. 699, et seq., aff'd sub nom, National Rate Cases For New Gas (*Shell Oil Co.* v. *F.P.C.*, 520 F. 2d 1061 (5th Cir. 1975), cert. denied sub nom, *The California Co.* v. *F.P.C.*, ____ U.S. ____, ____ U.S.L.W. ____ (Docket No. 75-1289, June 14, 1976), and the action in Opinion No. 770 represented a reevaluation of the just and reasonable rate authorized for the January 1, 1973 to December 31, 1974 sales.

The Commission does want to clarify that small producers are entitled to a differential for sales that meet the Opinion No. 699 criteria, as modified by Opinion No. 770. In Opinion No. 770, supra, pp. 104-108, the Commission adjusted the Opinion No. 699-H rate of 52¢ per Mcf to reflect changing factors, and found 101¢ to be a just and reasonable rate for the 1973-1974 vintage gas. Applying the 20% rate of return, adjusted to reflect incomes taxes, to the cost components for the 1973-74 vintage gas (Opinion No. 770, supra, Exhibit 24), yields a rate at or slightly in excess of 101¢ rate as modified by a 30% differential. Therefore, qualified small producers may charge 130% of the just and reasonable base rate of $1.01 per Mcf (at 14.73 psia) set forth in Opinion No. 70 for sales covered by that ceiling. Small producers may not charge the 130% differential for sales covered by the Opinion No. 770 base rate of $1.42 per Mcf (at 14.73 psia).

On July 28, 1976, the United States Court of Appeals for the District of Columbia Circuit stayed the effectiveness of Opinion No. 770 ". . . in order to afford [the] Court an opportunity more fully to consider the matter and responses thereto." Until Opinion No. 770 is permitted to become effective, small producers may not charge 130% of the ceiling rate of $1.01 per Mcf for the 1973-74 vintage, nor may small producers charge the Opinion No. 770 base rate of $1.42 per Mcf for the 1975-76 biennium.

The Commission orders: (A) Opinion No. 742-A is clarified consistent with this order.

(B) Ordering Paragraph (B) of Opinion No. 742-A is amended to add a new subsection (3), to read as follows:

All sales of natural gas by small producers for resale in interstate commerce that qualify for the base ceiling rate of $1.01 per Mcf set in Opinion No. 770 shall be made at a maximum rate of 130% of that ceiling rate.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24011 Filed 8-16-76;8:45 am]

[Docket No. CP71-264]

SOUTHERN ENERGY CO.

Petition To Amend

AUGUST 2, 1976.

Take notice that on July 26, 1976, Southern Energy Company (Petitioner), P.O. Box 2563, Birmingham, Alabama 35202, filed in Docket No. CP71-264 a petition to amend the Commission's Opinion No. 622 and order issued June 28, 1972, in said docket (47 FPC 1624), as modified on rehearing by Opinion No. 622-A and order (48 FPC 732), pursuant to Section 7(c) of the Natural Gas Act by permitting Petitioner to include in its tariff a 14 percent allowance on equity, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Applicant states that Opinion No. 622, as modified, authorized it to construct and operate facilities on Elba Island in the Savannah River, Chatham County, Georgia, for the receipt of liquefied natural gas (LNG) from the cryogenic tankers, for the storage of such LNG, for the regasification of such LNG, and for the sale of such regasified LNG. Applicant further states that the tariff approved by Opinion Nos. 622 and 622-A provides for an 11 percent allowance on equity but that since the time of filing

of its application in the instant docket costs of capital have increased dramatically. Accordingly, Petitioner requests that it be permitted to include in its tariff a 14 percent allowance on equity.

Petitioner asserts that it is nearing completion of its facilities and must permanently finance the same in the near future. Petitioner submits that the equity allowance authorized to be included in Petitioner's tariff should accurately reflect the cost of equity capital to Petitioner and Petitioner further submits that the cost of its equity capital is at least 14 percent.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before August 25, 1976, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24001 Filed 8-16-76;8:45 am]

[Docket Nos. RP76-67-2; CP70-7; RP76-67-5]

SOUTHERN NATURAL GAS CO. ETC.

Order Consolidating Proceedings Denying Temporary Extraordinary Relief Providing for Hearing and Granting Interventions

AUGUST 3, 1976.

On Aril 12, 1976, South Carolina Electric and Gas Company (SCE&G) filed a petition in Docket No. RP76-67-2 for extraordinary relief. SCE&G requests that the Commission order Southern Natural Gas Company (Southern Natural) to deliver to SCE&G quantities of natural gas in Priority No. 2 which will be used for injection into SCE&G's LNG plant commencing June 1, 1976. The proposed volume is 6,200 Mcf. per day. SCE&G states that Southern Natural is presently serving gas to various customers in Priority No. 2 for LNG processing. SCE&G further states that to deny it the same classification for LNG processing would violate Section 4(b) of the Natural Gas Act which prohibits undue discrimination. In its petition for extraordinary relief, SCE&G states that the gas to be produced by this peak shaving facility will be for high priority uses as contemplated by Order No. 467-B and Opinion No. 747.

After due notice by publication in the FEDERAL REGISTER on May 11, 1976 (41 FR 20187), timely petitions to intervene were filed by the Alabama Municipal Distributors Group, (Municipal) Carolina Pipeline Company (Carolina), The Board of Water, Light and Sinking Fund Commissioners of the City of Dalton, Georgia (Dalton), Atlanta Gas Light Company (Atlanta), Alabama Gas Corporation (Alagasco) and the Georgia Industrial Group (Georgia). Carolina, Dalton and Georgia have requested a formal hearing. Carolina states that SCE&G continues to burn large volumes of natural gas for steam electric generation boiler fuel use while it seeks additional volumes of gas for its new LNG plant. Dalton states that to grant relief to SCE&G would require the consequent curtailment across Southern Natural's entire system. Georgia requests that SCE&G provide evidence indicating whether existing or new high priority requirements would be served pursuant to its request for relief.

On September 17, 1975, Southern Natural Gas Company filed in Docket No. CP70-7, pursuant to Section 7(c) of the Natural Gas Act, a petition to amend the Commission's Order issued October 29, 1969, in the instant docket. In its filing, Southern Natural requests authorization to reallocate deliveries of the contract demand of natural gas between the City of Trussville, Alabama (Trussville) delivery points, all as more fully set forth in the petition to amend on file with the Commission and open to public inspection.

The Commission's October 29, 1969 order authorized Southern, interalia, to sell and deliver natural gas to Trussville under a service agreement providing for a total contract demand of 16,000 Mcf per day divided between the Huffman Delivery Point (13,600 Mcf per day) and the Trussville Delivery Point (2,400 Mcf per day).

Southern requests herein that said October 29, 1969, order be amended so as to reallocate the contract demand between Trussville's delivery points so that 6,000 Mcf per day will be delivered to the Huffman Delivery Point, and 10,000 Mcf to the Trussville Delivery Point. Southern states that the change is necessary because Trussville is installing a gas liquefaction, storage, and regasification complex LNG facility) which will utilize gas received at the Trussville area Delivery Point. Southern supports the proposed reallocation and states that only minor additional metering facilities will be required to effect the change. An effective date of April 1, 1976 was proposed for the revised exhibit A which sets forth the reallocation.

After due notice by publication in the FEDERAL REGISTER on October 9, 1975 (40 FR 47587) Alabama Gas Corporation (Alagasco) filed a timely petition to intervene. In support of its petition Alagasco states, inter alia, that Southern Natural is presently curtailing deliveries of natural gas to its customers and that the instant application fails to indicate where the LNG output is intended to be sold or what effect, if any, the grant of the instant petition to amend would have on allocations of gas to Southern's other customers, including Alagasco. Accordingly, Alagasco requests that a formal hearing be held as to the latter matter.

On July 12, 1976, Trussville filed in Docket No. RP76-67-5, a petition for permanent extraordinary relief which requests the Commission to direct or allow Southern to deliver to Trussville 5,000 Mcf per day of natural gas in Priority 2 for use in its LNG facility.

We believe that common issues of law and fact exist between Trussville's requests to reallocate delivery points and increase its Priority 2 requirements for the purpose of supplying an LNG facility and SCE&G's request for extraordinary relief to increase its Priority 2 requirements to inject volumes in its LNG facility. Furthermore, we believe that it is necessary to grant the requests for formal hearing requested by interveners in Docket Nos. RP76-67-2 and CP70-7. The consolidated proceeding should be docketed as RP76-67-2 et al. Although SCE-G and Trussville have not explicitly requested temporary relief, we can imply such a request. We do not believe that the facts warrant temporary relief.

We believe that the following issues, inter alia, should be developed by the parties to this proceeding:

(1) Southern should present evidence as to the level of curtailment during the 1975-76 heating season and the projected level of curtailment during the 1976-77 heating season, absent a grant of the relief requested.

(2) Southern should present evidence as to the effect of the relief on the projected level of curtailment during the 1976-77 heating season.

(3) Southern should state its position on the question of increasing Priority 2 to serve LNG injection requirements.

(4) Trussville and SCE&G should present specific evidence as to the end use proposed to be served by the LNG facilities. Trussville and SCE&G shou'd state whether the respective LNG facilities will be used to serve new customers.

(5) Trussville and SCE&G should present their level of curtailment during the 1975-76 heating season and their projected level of curtailment during the 1976-77 heating season, absent the relief requested. In particular, Trussville and SCE&G should discuss their ability to serve existing high priority loads without the relief requested.

The Commission finds: (1) It is desirable and in the public interest to allow the above-named petitioners to intervene in the instant proceeding.

(2) The petition to amend filed by Southern Natural in Docket No. CP70-7 and the petitions for extraordinary relief filed by South Carolina Electric and Gas Company in Docket No. RP76-67-2 and the Utilities Board of the Town of Trussville, Alabama in Docket No. RP76-67-5 contain common issues of law and fact.

(3) It is necessary and proper that the filing by Southern Natural in Docket No. CP70-7 and the petitions for extraordinary relief filed by South Carolina

Electric and Gas Company in Docket No. RP76-67-2 and the Utilities Board of the Town of Trussville, Alabama in Docket No. RP76-67-5 be set for formal hearing.

(4) It is not in the public interest to grant temporary relief to South Carolina Gas and Electric and Trussville.

The Commission orders: (A) The above-mentioned interveners are permitted to intervene in the instant proceeding subject to the rules and regulations of the Commission; *Provided, however,* that participation of such interveners shall be limited to matters affecting asserted rights and interests as specifically set forth in the petitions to intervene; and *Provided, further,* that the admission of such interveners shall not be construed as recognition by the Commission that they might be aggrieved because of any order of the Commission entered in the proceeding.

(B) Based on § 1.20(a) of the Commission's Rules of Practice and Procedure, the filing by Southern Natural in Docket No. CP70-7 (City of Trussville) and the petitions for extraordinary relief filed by South Carolina Electric and Gas Company in Docket No. RP76-67-2 and the Utilities Board of the Town of Trussville, Alabama in Docket No. RP76-67-5 are herein consolidated as Docket No. RP76-67-2 et al.

(D) Pursuant to the authority of the Natural Gas Act, particularly Sections 7 and 15 thereof, as implemented by the Commission's Rules of Practice and Procedure and the Regulations thereunder, a public hearing shall be held commencing on August 31, 1976, at 10:00 a.m. in a hearing room of the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, concerning the matters involved in and the issues presented by the instant filings.

(E) The direct cases of Southern Natural, Trussville, and South Carolina Electric and Gas shall be filed and served on all parties, the Presiding Administrative Judge, and Commission Staff on or before August 13, 1976.

(F) The request for temporary relief are denied.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24007 Filed 8-16-76;8:45 am]

[Docket No. E-6943]

SOUTHWESTERN POWER ADMINISTRATION

Order Confirming and Approving Rates

AUGUST 3, 1976.

Pursuant to Section 5 of the Flood Control Act of 1944 (58 Stat. 890), the Secretary of the Interior (Interior), acting on behalf of the Southwestern Power Administration (SWPA), filed a request on December 9, 1975, seeking Commission confirmation and approval of a new rate schedule for the sale of the entire electrical output of the Corps of Engineers' Narrows Dam Project (Project) to Tex-La Electric Power Cooperative, Inc. (Tex-La). Interior's filing proposes that the rate for the sale of power and energy from the Project be increased from $465,000 to $556,000 annually. Confirmation and approval of the new rate is sought for the period from September 30, 1975, through June 30, 1980.

PREVIOUS RATE ACTIONS

The power output from the Project, located on the Little Missouri River in Arkansas, has been marketed by SWPA as an isolated project. Generation at the Project began in May 1950 when two 8,500-kilowatt generating units began test operations. The hydroelectric energy generated from the initial operation of the Project until February 1951 was sold as dump energy to a predecessor of Southwestern Electric Power Company (SWEPCO) for an annual payment of $137,000. A contract (Ispa 396) between SWPA and SWEPCO became effective in February 1951 in which the total output of the two generating units was sold to SWEPCO for an annual payment of $207,000. Provisions in the contract allowed SWPA to withdraw 5,000 kilowatts and accompanying energy to serve preference customers beginning in January 1952.

The Commission, by order issued February 4, 1951, approved the rate prescribed in Contract Ispa 396 for the period ending February 13, 1953. In its order the Commission recognized that SWPA had used a 100-year period of amortization for the project but indicated that the test of the adequacy of rates should be consistently applied on the basis of a 50-year amortization period. Approval of the annual rate of $207,000 specified in Contract Ispa 396 was extended periodically to September 30, 1960.

A new contract (14-02-0001-921) was entered into on May 11, 1960, under which SWPA sold the entire output of the Project to Tex-La. The new contract became effective on September 30, 1960, and extends for a 25-year period. During the initial period of the contract Tex-La would pay SWPA $300,000 annually for the entire output of the two 8,500-kilowatt units. With completion of the third 8,500-kilowatt unit in October 1969, the annual payment would be increased to $367,992. In a separate contract between Tex-La and SWEPCO, Tex-La agreed to sell SWEPCO the entire output of the Project for the same price that it paid SWPA. Under this latter contract Tex-La also purchases wholesale load center firm power service from SWEPCO for its member cooperatives, delivered to their facilities.

By order issued September 23, 1960, the Commission approved the rates for the sale of the output of the Project to Tex-La under Contract 14-02-0001-921 for the period through June 30, 1965. By order issued August 26, 1965, the Commission approved the same rates for the period through June 30, 1970.

The Commission by order issued January 22, 1971, approved an increase in the rate for the sale of the output of the Project to Tex-La through June 30, 1975. The annual payment was increased from $367,992 to $465,000.

Following Commission approval of the new rate, Tex-La filed a petition for rehearing of the order confirming the rate. In its petition Tex-La maintained that the increase in rates proposed by Interior was in violation of law and in excess of statutory authority, and that the Commission's action in approving the proposed rate was unlawful. On April 29, 1971, the Commission issued an order denying rehearing, finding that the questions and contentions raised in the petition did not require any modification of the order approving the rate.

Beginning in June 1975, Interior has requested a series of extensions of the rate approved by the Commission order of January 22, 1971, to allow SWPA additional time to hold a hearing on a proposed new rate and complete a new rate and repayment study. The latest extension, through December 29, 1975, was approved by the Commission's order issued December 4, 1975. On December 30, 1975, Interior requested a further extension of the approved rates for a period not to exceed 90 days from December 31, 1975.

To support the proposed rate increase, Interior submitted an Average Rate and Repayment Study for Narrows Dam, dated May 1975. On July 24, and 25, 1975 SWPA conducted an on-the-record meeting with Tex-La to discuss the proposed rate increase for the sale of Project power and energy. Included with Interior's filing was a transcript of the meeting along with Exhibits 1 through 53 of the meeting record and a document prepared by SWPA entitled "Evaluation of Statements and Proposal by Interested Parties Resulting from Rate Hearing on Proposed Rate For Sale of Narrows Dam Power and Energy held July 24-25, 1975" (Evaluation).

ANALYSIS OF PRESENT RATE FILING

The proposed rate increase from $465,000 to $556,000 annually is $91,000, or 19.6%. This is equivalent to an annual rate of increase of about 3⅝% over the five-year period. The need for the increase is brought about mainly because the operation and maintenance expense of the Corps of Engineers has escalated rapidly in recent years. The estimated annual operating expense used for the 1975 repayment study, including SWPA's administration expense, is $77,000 greater than the similar figure used in the 1970 repayment study, an increase of 46%.

The increase in operating expense at the Project is not out of line with that experienced at other Corps' projects or with the trend of such expenses over the past five years. The remaining $14,000 of the increase is due to additional interest expense.

The 1975 repayment study continues the criterion used in the 1970 repayment study of repaying the original investment in the entire Project 50 years after the third unit became operational. In effect this means that the investment in

the first two units is not fully recovered until 70 years after those units began operation. The Commission stated in its Order on Rehearing, issued April 29, 1971:

> In our January 22, 1971 order we determined that the currently scheduled amortization of the capital investment allocated to electric power at the Project over an 83 year period running from the date of installation of the Project's third generating unit, or 100 years from the date on which the Project commenced commercial operation, failed to comply with the Act's requirement of "a reasonable period of years" for such amortization. We determined further in our order of January 22, 1971 that the proposed amortization of the investment in electric facilities at the Project within 50 years after its third generating unit commenced commercial operation met the statutory payout test.

Consideration was given to the possible effect of now requiring that repayment of the investment in the first two units be accomplished within 50 years after those units began operation. If SWPA were required to recover the investment in the first two units within 50 years, the total annual revenue would have to be increased to about $630,000 based on a calculation by Commission Staff. Because of factors peculiar to the Project, the Commission's January 22, 1971 order extended the repayment period of the first two units until 50 years after the installation of the third unit. For the first 20 years of operation, the Project operated at a deficit. This can be attributed primarily to two factors: (1) With the full costs of the dam and reservoir included in the costs of the first two units the Project was marginally economic; and (2) because of isolation, the power generated at the Project had limited marketability. In light of these circumstances, a reasonable period to recover the full costs of the Project is 50 years after the installation of the third unit.

The Commission Staff noted some variations in the repayment procedure used by SWPA in 1975 from that used in 1970 or from those generally used by other Interior marketing agencies. These relate to (1) the way interest on replacements was handled, and (2) the effect of inflation on estimated replacement costs.

1. Interest on Replacements:

a. SWPA applied the net revenue each year of the projected payout period, first to pay off the existing deficit (unpaid interest) as of 1975 of $663,475; next to pay off by the year 2012 practically all of unamortized investment in the first two units (interest rate—2½%); then to pay off the accumulated investment in replacements made during the period 1975–2016 (interest rate—6⅛%) some of which accumulation includes the carrying of unamortized investments in replacements for periods exceeding their service lives; and then finally to pay off the investment in the third unit (interest rate—2⅞%) and the remainder of the investment in the first two units. In 1970, and for most other repayment studies, Interior's general practice has been to pay off the highest interest bearing investment first to the extent possible while still paying off each investment within 50 years, or within the service life for replacements. The procedure used by SWPA in 1975 resulted in an increase of about $8,500 in the proposed annual revenue.

b. In the 1975 repayment study, replacements made late in the repayment period were prorated so that only that portion of any replacement applicable to the remaining years of the repayment period was charged against the Project repayment. In so doing, SWPA failed to recognize that interest on the portion to be repaid subsequent to the end of the repayment period would still accrue and be due each year of the repayment period. This oversight of interest resulted in a decrease of about $6,000 in the proposed annual revenue.

The effects on the repayment study of points 1a. and 1b. substantially offset each other.

2. Escalation of estimated replacement costs:

In estimating costs for future replacements, SWPA used the original cost of the item; that is, for replacement items for units 1 and 2, the estimated cost of each item was that prevailing in 1951; for replacement items for unit 3, the estimated cost of each item was that prevailing in 1970. To bring these estimates up to 1975 prices, the costs of replacements for units 1 and 2 should be multiplied by a factor of approximately 3; those for unit 3 should be multiplied by a factor of about 1½. Using the original uninflated estimated replacement costs resulted in a decrease of about $25,000 in the proposed annual revenue.

It is noted with regard to item 2 above that although some replacements are scheduled for every 15 years and some every 20 years, there have not yet been any recorded expenditures for replacements during the first 25 years of the Project's life. It appears that, with improvements in technology and with the active and prudent maintenance program pursued by the Corps, the expected service lives now used may be underestimated. The problem of estimating and accounting for the costs of replacements is common to all Corps' projects and affects the repayment studies of many other projects or systems for which Interior's marketing agencies are responsible. This problem should be addressed by representatives from Interior, the Commission, the General Accounting Office, and the Corps of Engineers. However, if the need for replacements is not as great or as frequent as presently anticipated, this fact would tend to offset the effect of inflation on the replacement costs.

Public Notice

Public notice of Interior's filing of December 9, 1975, was issued on December 17, 1975, and published in the Federal Register on January 6, 1976. Comments or suggestions relative to the filing were requested to be submitted in writing on or before January 9, 1976.

Tex-La's Protest

On January 9, 1976, Tex-La filed "A Petition To Intervene" and a "Protest." Tex-La's enumerated 11 objections to SWPA's proposed rate increase. The following section lists Tex-La's objections and the Commission's response thereto.

1. Tex-La: SWPA's rate filing totally ignores the first two standards of Section 5 of the Flood Control Act of 1944, namely, (1) encouraging the most widespread use of the power, and (2) at the lowest possible rates consistent with sound business principles.

Commission response: The Commission is reasonably assured that the proposed rate is the lowest possible consistent with the sound business principles. In our appraisal, the requirements of Section 5 of the Flood Control Act of 1944 have been satisfied.

2. Tex-La: The rate filing improperly includes among the costs to be recovered from Tex-La an SWPA deficit of $753,671, plus interest thereon totalling $2,645,243.

Commisison response: The loss incurred during the early years of the Project's operation occurred because the power and energy apparently was not marketable at a price that would support the power investment. The Commission, in its order issued February 14, 1951, approving the rates for sale of Project power stated:

> It would appear that the Southwestern Gas and Electric Company is the only presently available outlet for the power produced at the Narrows Project, that the rates and charges contained in the contract are the most the Company is willing to pay under the circumstances, and the revenues represent more than SWPA is presently receiving under the month-to-month contract.

With the addition of the third unit and with increasing energy costs from alternate sources in later years, the rates charged could be increased to a level that would support the present Federal investment and still remain competitive with other electric power and energy sources. The deficit incurred with the Project's earlier operations are legitimate start-up expenses which should be capitalized and paid for along with the other Project investment. Deficits incurred under these circumstances should be recovered during the subsequent repayment period.

3. Tex-La: The rate filing is designed to recover Corps of Engineers' O&M costs which have not been verified by SWPA.

Commission response: Although SWPA informally reviews power costs and investments submitted by the Corps of Engineers it is not responsible for the audit of each individual cost assignment. The General Accounting Office periodically audits the financial records of the Southwestern Federal Power System which includes those of the Corps of Engineers and SWPA.

4. Tex-La: The proposed rate increase is designed to recover Corps' O&M costs which are not part of the "cost of producing the electric energy."

Commission response: From 1965 to 1973, the Corps of Engineers' Vicksburg District Office erroneously charged a percentage of project joint-use costs to recreation and fish and wildlife. In a 1972 audit, the General Accounting Office discovered this error and notified the Corps' Office of the Chief of Engineers (OCE). OCE then instructed its Vicksburg District Office to make the appropriate corrections. In the 1973 Form 1 report to the FPC, the Vicksburg District Office made an adjustment for prior years to power in the amount of $98,041.53. It also adjusted the 1973 accounts to include $41,773.58 of additional O&M costs to be allocated to power. The total of these amounts, $139,815.11, was then mistakenly characterized as recreation O&M costs which had been charged to power. In fact, that amount is a legitimate charge to power.

5. Tex-La: The rate filing is designed to recover SWPA overhead and administrative costs (O&A) which are estimated in an entirely arbitrary manner.

Commission response: SWPA has allocated its O&A costs to the Project on an investment ratio basis. This has been the method utilized by SWPA for all projects for which it markets power for several years. It results in percentages that approximate those obtained by using other methods but is easier to apply.

6. Tex-La: The rate filing is designed to recover purchased power costs and service charges incurred by SWPA in transactions not related to the Project.

Commission response: Pursuant to the terms of a contract between SWPA and SWEPO (Ispa-396), SWPA sold the entire output of the Project to SWEPCO. The contract was terminated in 1960 except for service to three cooperatives which continued through 1962. It allowed SWPA to withdraw up to 5,000 kilowatts with accompanying energy as required to serve the three cooperatives. SWEPCO charged SWPA for the withdrawn power and for the use of SWEPCO facilities in wheeling power and energy to the preference customers. SWPA billed the preference customers for power delivered under rates equivalent to standard system rates. For the years 1951 through 1962, the total purchased power and service charges from these sales exceeded the revenue received by SWPA by approximately $4,900. The sales to the preference customers not only failed to contribute to the amortization of the Project investment but also added to the $750,000 deficit on the books at the time Tex-La became the sole customer for the Project power.

7. Tex-La: The rate filing would recover $619,600 in unidentified future replacements.

Commission reseponse: The question of estimated replacement costs and how they are recovered is previously discussed at pp. 5–6 under "Analysis of Present Rate Filing."

8. Tex-La: The proposed rate improperly includes interest on projected replacement costs.

Commission response: As previously discussed under "Analysis of Present Rate Filing," the annual effects of possible adjustments on the interest charges are substantially offsetting.

9. Tex-La: The proposed rate is discriminatory.

Commission response: The rates charged for power and energy from the Project reflect the actual expeneses incurred in production. The Project is a separate element of SWPA's marketing responsibility. SWPA's system rates are based on the costs of the integrated system of projects. Those rates may be higher or lower than the Project rates which are based on Project costs.

10. Tex-La: The 50-year payout period on which the proposed rate is based violates both the Flood Control Act of 1944 and the SWPA/Tex-La contract of May 11, 1960.

Commission response: The amortization of the capital investment allocated to electric power at the Project over a period of 100 years is not a "reasonable period of years" within the meaning of the Flood Control Act of 1944 In our Order on Rehearing, issued on April 29, 1971 in this docket we said:

> We recognize that there may be circumstances clearly indicating that an amortization period in excess of 50 years would be necessary or appropriate for a certain period to correct or prevent various inequities. In those circumstances we would have no difficulty in finding such a period to be "reasonable" under the Act.

We find today, as we did in our order confirming the present rate, that a reasonable period of years to amortize the investment in electric facilities at the Project is 50 years after its third generating unit commenced commercial operation.

11. Tex-La: The rate-making procedures used by SWPA in the preparation of the proposed rate violates the Administrative Procedure Act.

Commission response: In its Evaluation, SWPA asserts that Tex-La has ignored the fact that the SWPA/Tex-La contract, in Article I, Section 4, provides for rate review and redetermination and the procedure to be followed. It additionally maintains that it followed this procedure explicitly.

If we assume *arguendo* that Tex-La's objection is meritorious, we do not have the authority to fashion a remedy. The Commission is not empowered to oversee SWAP's contractual relationships nor force its compliance with the Administrative Procedure Act. We exercise a special review function with respect to SWPA's filing under the Flood Control Act of 1944, which

> [c]an neither be analogized to an independent rate investigation or to the appellate function of the United States Courts of Appeals over Commission decisions under the Federal Power Act. It evolves from a unique relationship between the Department of the Interior, a part of the Executive Branch, with managerial and ratemaking expertise over its projects, and, the Federal Power Commission, and independent agency of the Congress with special expertise in ratemaking. In establishing this relationship Congress did not limit us to the function of assuring that the Secretary had complied with the bare legal requirements of the statute. It expected us to apply our independent expertise in evaluating the rates set by the Secretary . . . [and] confirm and approve . . . if we conclude, on the basis of our independent judgment, that it comports with the dual statutory standard of providing consumers with the benefits of power at the lowest possible price consistent with good business practices as well as protecting the interest of the United States in amortizing its investment in the projects within a reasonable period.[1]

The Commission has reviewed SWPA's filing and the materials submitted therewith in support of the proposed rate increase. We find that they are generally sound and consistent with the provisions of the Flood Control Act of 1944. There are some areas which SWPA should devote greater attention to with respect to future rate filings. For instance, in the present filing we have noted some problems with the manner in which interest on replacements was calculated and with the estimation of costs for future replacements. For reasons discussed previously under "Analysis of Present Rate Filing," these problems do not have an appreciable effect on the rate increase.

We have also given careful consideration to the issues raised by Tex-La in its Protest. We find that they do not provide sufficient justification for the Commission to withhold its approval of the proposed rate increase.

The Commission finds: The confirmation and approval of an annual rate of $556,000 for the sale of power and energy generated at Narrows Dam to Tex-La Power Cooperative, Inc. as hereinafter provided, will not be inconsistent with the provisions of the Flood Control Act of 1944.

The Commission orders: The confirmation and approval of an annual rate of $556,000 for the sale of power and energy generated at Narrows Dam to Tex-La Power Cooperative, Inc. for the period commencing with the issuance of this order and ending not later than June 30, 1980.

By the Commission.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24009 Filed 8-16-76;8:45 am]

[Docket No. RM76-1]

SPECIFIED REASONABLE RATE OF RETURN AS PROVIDED IN HYDROELECTRIC PROJECT LICENSES

Order Denying Rehearing

AUGUST 3, 1976.

On July 26, 1976, an application for rehearing of Order No. 550,[2] issued June

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[1] Opinion No. 482, United States Department of the Interior, Bonneville Power Administration, Docket Nos. E-6611, E-6905 and E-7242, issued December 14, 1965, 34 FPC 1465; see also Opinion No. 741, United States Department of the Interior, Bonneville Power Administration, Docket No. E-8978, issued August 21, 1975.

[2] Order No. 550 adopted a new specified reasonable rate of return for computing amortization reserves in hydroelectric project licenses.

24, 1976, was filed by The Electric Utility Company Group (Group). The Group complains that the use of the 10-year Government bond series plus four percentage points does not allow a high enough return for the common equity component. The Group also requests that the new specified reasonable rate of return be applied retroactively to January 1, 1970.

As to the first contention, the primary objection of the Group was that by our selection as the rate of return on common equity of the interest rate on 10-year Treasury bond series plus four percentage points, we improperly freeze large amounts of earnings on licensed projects that are clearly not in excess of a fair return. We do not agree that we acted improperly in selecting a rate that approximates but does not exceed the lower level of the recognized zone of reasonableness for a return upon common equity, nor do we anticipate that large amounts of earnings on licensed projects in excess of a fair return will be required to be set aside. By determining a reasonable specified rate of return in the manner that we did, we recognized that it will not necessarily produce a "fair rate of return" for each licensee, nor do we believe that it should. Congress did not provide that the earnings in excess of a "fair rate of return" should be the basis of the computation, but rather, earnings in excess of a "specified reasonable rate of return", which was required to be set forth in the license. Niagara Falls Power Co., 9 F.P.C. 228, 249 (1950).

Simply stated, it is better for the Commission, when setting uniform requirements for the unique purposes of amortization reserves, to err on the low side for most licensees than to err on the high side for some licensees. Ultimately a "fair return" test will be made in takeover proceedings, and if the recorded amounts in the amortization reserve account are found to be in excess of the need for net investment purposes, such excess reserves will be freed from the amortization reserve requirement. However, if we are overly generous when determining a specified reasonable rate of return, we may find upon takeover that there are insufficient amounts in the amortization reserves for net investment purposes if the licensee has had earnings in excess of a fair rate of return during the period of the license. Additionally, we have not been as niggardly with our specified reasonable rate of return requirements as the Group implies, since, consistent with past practices, we will require that only one half of the project's surplus earnings, if any, be set aside in a project amortization reserve.

In its second contention, the Group requests that the effective date of the new specified reasonable rate of return be January 1, 1970, as opposed to the provisions contained on page 4 of Order No. 550.[2] The Group states that the objectives of the Federal Power Act (Act) would be better served if the earlier date were adopted. The Group stated in its application for rehearing that the objective was to encourage the comprehensive development of our water resources. This objective is accomplished in Section 10(d) of the Act in that a licensee is allowed twenty years in the initial license before the amortization reserves are set up. The objective the Group expounds would not be affected by the retroactive application of the new specified reasonable rate of return, because licensees of the newly licensed unconstructed or proposed projects would have the new rate if they so desire when the amortization reserve period begins in the future. The Group's request would only affect those licensees that are past their 20th year of operation and, therefore, would not further the objective.

The Group claims that those licensees that have applied for rehearing are receiving retroactive treatment, while those applying for license amendment would not. In the case of the rehearings, the licensees did not accept the amortization reserve article, providing the six percent per annum, as required by Section 6 of the Act. In order that the license be complete for the entire term, the "new" amortization reserve article would have to have the same effective date as contained in the license. See, Pacific Gas and Electric Co., 45 FPC 28, 30 (1971). Therefore, we do not have, necessarily, retroactive application. As to those applying for an amendment of license, each licensee has an amortization reserve article that has been accepted and is in effect. There is, therefore, no void that has to be covered by the new article. We find no compelling reason in the application for rehearing to alter the effective dates of the new specified reasonable rate of return.

The Commission finds: The application for rehearing filed on July 26, 1976, by the Electric Utility Company Group presents no facts or legal principles which would warrant any change in or modification of Order No. 550.

The Commission orders: The application for rehearing of Order No. 550 is hereby denied.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24012 Filed 8-16-76;8:45 am]

[2] Order No. 550 provides that those licensees with applications for amendment of license pending would be issued an amendment to be effective as of the date of issuance of Order No. 550. The licenses with rehearings pending will have the new specified reasonable rate of return with the effective date that is contained in each license. As to those licensees seeking to amend their licenses, the amendment would be effective as of the date of receipt of their request.

[Docket No. RP76-17]

TEXAS GAS TRANSMISSION CORP.

Proposed Stipulation and Agreement

AUGUST 2, 1976.

Take notice that on July 23, 1976 Texas Gas Transmission Corporation (Texas Gas) tendered for filing a proposed stipulation and agreement in the referenced docket. Texas Gas states that the proposed Stipulation and Agreement resolves all problems and disputes with respect to its total cost of service, except for the item of book depreciation and the inclusion of amounts associated with the acquisition and retention of coal reserves to be used for gasification purposes. These two items are being litigated in Docket No. RP74-25. Texas Gas states that certain other matters are being resolved in Docket No. RP75-19 and the decision therein would govern the instant proceedings.

Any person desiring to be heard or to protest said settlement agreement should file comments with the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before September 3, 1976. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this agreement are on file with the Commission and are available for public inspection.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24002 Filed 8-16-76;8:45 am]

[Docket No. CP76-455]

TRANSCONTINENTAL GAS PIPE LINE CORP. AND FLORIDA GAS TRANSMISSION CO.

Application

AUGUST 3, 1976.

Take notice that on July 23, 1976, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77001, and Florida Gas Transmission Company (Florida Gas), P.O. Box 44, Winter Park, Florida 32789, filed in Docket No. CP76-455 a joint application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation as equal co-owners of a pepeline and appurtenant facilities from Vermilion Area Block 22, offshore Lousiana, to a point of connection with Transco' existing Central Lousiana Gathering System onshore in the Pecan Island Area, Vermilion Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that the proposed facilities, which would be constructed and operated by Transco, consist of approximately 13.84 miles of 24-inch pipeline, a purchase meter and regulator station and onshore separation facilities. The appli-

cation shows the estimated cost of these facilities to be $12,084,000, which cost would be financed initially through revolving credit agreements, short-term loans, and available cash.

Applicants state that they have executed precedent agreements with attached gas purchase contracts with Shell Oil Company, a principal owner of reserves in Block 22, covering the percentages of that producer's interest to which Applicants are entitled in the block, and are currently executing similar precedent agreements with the remaining owners. It is indicated that overall Applicants are presently entitled to one-third of the total working interest reserves in Block 22. Applicants assert that the proposed facilities can be utilized to transport onshore the balance of the Block 22 gas as well as Applicants' gas and, in addition, gas which is expected to be developed in nearby blocks under lease.

Applicants state that it is imperative that they promptly attain, in the most economical manner possible, the Block 22 gas supplies to help alleviate the critical gas supply shortage on their systems and fulfill commitments to their customers. They assert that the proposed joint project would benefit them and their customers by the higher load factor utilization of Applicants' existing onshore pipeline systems and by avoiding the necessity of constructing costly duplicate facilities to attach the common source of supply in Vermilion Block 22.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 24, 1976, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc.76-24008 Filed 8-16-76;8:45 am]

[Project No. 298]

SOUTHERN CALIFORNIA EDISON CO.

Issuance of Annual License(s)

AUGUST 9, 1976.

On May 2, 1975, Southern California Edison Company, Licensee for Kaweah Project No. 298, located on the Kaweah River in Sequoia National Park and Sequoia National Forest, Tulare County, California, filed an application for a new license under the Federal Power Act and Commission Regulations thereunder.

The license for Project No. 298 was issued effective August 7, 1924, for a period ending August 8, 1974. Since the original date of expiration, the project has been maintained and operated under annual licenses, the most recent of which will expire on August 7, 1976. In order to authorize the continued operation and maintenance of the project pursuant to the Federal Power Act, pending Commission action on licensee's application, it is appropriate and in the public interest to issue an annual license to Minnesota Power and Light Company.

Take notice that an annual license is issued to Southern California Edison Company under the Federal Power Act for the period August 8, 1976, to August 7, 1977, or until the issuance of a new license for the project, whichever comes first, for the continued operation and maintenance of the Kaweah Project No. 298, subject to the terms and conditions of the present license. Take further notice that if issuance of a new license does not take place on or before August 7, 1977, a new annual license will be issued each year thereafter, effective August 8 of each year, until a new license is issued without further notice being given by the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-23999 Filed 8-16-76;8:45 am]

FEDERAL RESERVE SYSTEM

INTERNATIONAL BANCORPORATION

Order Approving Formation of Bank Holding Company

International Bancorporation, St. Paul, Minnesota, has applied for the Board's approval under § 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 all of the voting shares (less directors' qualifying shares) of The First National Bank of International Falls, International Falls, Minnesota ("Bank").

Notice of the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with § 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 § 3(c) of the Act (12 U.S.C. § 1842(c)).

Applicant, a nonoperating corporation with no subsidiaries, was organized for the purpose of becoming a bank holding company through the acquisition of Bank. Bank (deposits of $17.8 million) is the largest of three banks operating in the relevant banking market[1] and controls approximately 46 percent of the total deposits in commercial banks in the market.[2] The second largest bank in the relevant market controls approximately 44 percent of total deposits therein. Upon acquisition of Bank, Applicant would control the 82nd largest banking organization in Minnesota, holding .12 percent of the total commercial bank deposits in the State. Inasmuch as the proposed transaction involves a transfer of control of Bank from its principal to a corporation controlled by the same individual, and since Applicant and its principal control no other bank, consummation of the proposal would not eliminate existing or potential competition, nor have any adverse effects on other banks in the relevant market. Therefore, competitive considerations are consistent with approval of the application.

The financial and managerial resources and future prospects of Applicant, which are dependent upon those of Bank, are considered to be satisfactory. Although Applicant will assume a $2 million debt as a result of this proopsal, it appears that the income to be derived from Bank, by way of dividends, should provide Applicant with sufficient revenue to service the debt adequately without impairing the financial condition of Bank. Accordingly, considerations relating to the banking factors are consistent with approval of the application. Consummation of the transaction would have no immediate effect on the area's banking convenience and needs; however, considerations relating to the convenience and needs of the community to be served are regarded as being consistent with approval of the application. It is the Board's judgment that consummation of the proposed transaction would be consistent with the public interest and that the application should be approved.

In connection with the Board's consideration of this application, a question arose concerning the existence of a possible control relationship between Applicant, Bank, and another bank holding company. In order to alleviate this concern, Applicant's principal has agreed and committed to eliminate interlocking director relationships between Applicant and Bank, on the one hand, and the other bank holding company on the other. In concluding that the instant proposal is in the public interest, the Board has relied upon the aforementioned commitments and the Board's approval of this

[1] The relevant banking market is approximated by the northwestern half of Koochiching County.

[2] All banking data are as of December 31, 1975.

application is conditioned upon the fulfillment of those commitments.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be made (a) before the thirtieth calendar day following the effective date of this Order or (b) later than three months after the effective date of this Order, unless such period is extended for good cause by the Board, or by the Federal Reserve Bank of Minneapolis pursuant to delegated authority.

By order of the Board of Governors,[1] effective August 10, 1976.

GRIFFITH L. GARWOOD,
Assistant Secretary of the Board.

[FR Doc.76 24037 Filed 8-16-76;8:45 am]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 76-68]

DR. JAMES KING, JR.

Certification

Pursuant to the provision contained in section 207 of Title 18 U.S.C. (Pub. L. 87-849, 76 Stat. 1124), having found that Dr. James King, Jr., formerly Special Assistant for Stratospheric Research Program, Office of Associate Administrator for Space Science, Office of Space Science, National Aeronautics and Space Administration (NASA), and presently an employee of the California Institute of Technology at the Jet Propulsion Laboratory, possesses outstanding scientific qualifications, I certify that the national interest would be served by the said Dr. James King, Jr. acting as agent for or appearing personally before NASA on behalf of the California Institute of Technology in connection with performance of work under the Institute's Contract No. NAS 7-100 with NASA for the operation of the Labortory, on matters in which he participated personally and substantially as an employee of NASA or which were under his official responsibility as a NASA employee.

This certification is directed to be published in the FEDERAL REGISTER.

Dated: August 9, 1976.

JAMES C. FLETCHER,
Administrator.

[FR Doc.76-23982 Filed 8-16-76;8:45 am]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on August 9, 1976 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, (202-395-4529), or from the reviewer listed.

NEW FORMS

UNITED STATES INTERNATIONAL TRADE COMMISSION

Hanging Planters—Purchasers' Questionnaire, single-time purchasers, Laverne V. Collins, 395-5867.

Hanging Planters—Producers' Questionnaire, Single-time producers. Laverne V. Collins, 395-5867.

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service, Regulations—Part 1421, on occasion, individual, Warren Topelius, 395-5872.

DEPARTMENT OF COMMERCE

Bureau of Census, Survey of County Government Finances, F-28A, single-time, local governments-city and county officials, Ellett, C. A. 395-5867.

REVISIONS

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service: application for participation—national school lunch, school breakfast and special milk programs, FNS66, on occasion, school food authorities, Warren Topelius, 395-5872.

Animal and Plant Health Inspection Service: Processing operations at official establishments, MP-404, weekly, Federally inspected meat processing plants, Warren Topelius, 395-5872.

DEPARTMENT OF COMMERCE

Bureau of Census, Import Questionnaire, export Questionnaire: Survey of Domestic and international Transportation of U.S., Foreign Trade: 1976, TS-501, TS-502, quarterly, survey of sample of importer and exporters, Laverne V. Collins, 395-5867.

EXTENSIONS

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service: Permanent Quarantine Record (zoo animals), vs 17-65C, on occasion, U.S.D.A. approved zoos, Warren Topelius, 395-5872.

Zoological Park Inspection Report, vs 17-65A, annually, U.S.D.A. approved zoos, Warren Topelius, 395-5872.

PHILLIP D. LARSEN,
Budget and Management Officer.

[FR Doc.76-24207 Filed 8-16-76;8:45 am]

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

ADVISORY COMMITTEE PUBLIC PROGRAMS PANEL

Meeting

AUGUST 9, 1976.

Pursuant to the provsions of the Federal Advisory Committee Act (Pub. L. 92-463) notice is hereby given that a meeting of the Public Programs Panel will meet at Washington, D.C., on September 9 and 10, 1976, commencing at 9:00 a.m., at 806 15th Street, N.W.

The purpose of the meeting is to review Humanities Museums and Historical Organizations grant proposals that have been submitted to the Endowment for possible grant funding.

Because the proposed meeting will consider financial information and personnel and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated August 13, 1973, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552(b) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. John W. Jordan, 806 15th Street, N.W., Washington, D.C. 20506, or call Area Code 202-382-2031.

JOHN W. JORDAN,
Advisory Committee Management Officer.

[FR Doc.76-23901 Filed 8-16-76;8:45 am]

NATIONAL SCIENCE FOUNDATION

NSF-SPONSORED DEEP SEA DRILLING PROJECT RESULTS

Availability

As a result of research sponsored by the National Science Foundation under its Deep Sea Drilling Project at the Scripps Institution of Oceanography, La Jolla, California, the preliminary result of organic geochemical studies of ocean core sediments are available. Leg 44 of the Deep Sea Drilling Project included drilling at 5 sites in the western North Atlantic Ocean. Some of the sediments recovered may be of special interest because of the organic geochemical clues they contain regarding potential petroleum sources off the shore of the eastern United States. It is believed that making this preliminary data available to all interested parties will assist in determining the degree of exploration and exploitation of off-shore deposits in this area.

Persons interested in obtaining the "Preliminary Organic Geochemistry Report—Deep Sea Drilling Project, Leg 44", consisting of 90 pages, containing 9 locations in the western North Atlantic

[1] Voting for this action: Chairman Burns and Governors Wallich, Coldwell, Jackson, and Partee. Present and abstaining: Governor Lilly. Absent and not voting: Governor Gardner.

Ocean, may inspect the preliminary report or request it by mail from: Science Services, Deep Sea Drilling Project, Scripps Institution of Oceanography, La Jolla, California 92093.

KURT G. SANDVED,
Deputy Assistant Director for Operations.

[FR Doc.76-23914 Filed 8-16-76;8:45 am]

SMALL BUSINESS ADMINISTRATION

[License Application No. 01/01-5281]

CHINESE AMERICAN INVESTMENT CORP.

Application for License as a Small Business Investment Company

An application for a license to operate as a small business investment company under the provisions of section 301(d) of the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 et seq.), has been filed by Chinese American Investment Corporation (applicant), with the Small Business Administration (SBA), pursuant to 13 CFR 107.102 (1976).

The officers, directors, and stockholders of the applicant are as follows:

Yu-Sing Jung, Chairman of the Board, 8 percent stockholder. 21 Benvenue Street, Wellesley, Massachusetts 02181.

Thomas K. Liu, Vice Chairman of the Board, 8 percent stockholder. 16 Audubon Road, Lexington, Massachusetts, 02173.

George S. Pan, President, Treasurer, Director, 52 percent stockholder. 30 Indian Hill Road, Medfield, Massachusetts 02052.

Raymond T. Lee, Vice President, Controller, Director, 8 percent stockholder. 4 Ivy Circle, Winchester, Massachusetts 01890.

Jeffrey T. Pan, Vice President—Marketing, Director, 8 percent stockholder. 1734 Cy Court, Vienna, Virginia 22180.

Frank F. Chin, Vice President—Finance, Director, 8 percent stockholder. 26 Lexington Road, Wellesley, Massachusetts 02181.

Jeffrey C. Tang, Vice President—Planning, Director, 8 percent stockholder. 14 Olympic Street, Framingham, Massachusetts 01701.

Barry C. Abelson, Secretary, 48 Wheeler Circle, Stoughton, Massachusetts 02072.

The applicant, a Massachusetts corporation, with its principal business located at 45 Diatuo Drive, Randolph, Massachusetts 02368, will begin operations with $500,000 of paid-in capital and paid-in surplus, derived from the sale of 5,000 shares of common stock. The applicant will initially conduct its operations in the Greater Boston Metropolitan area and the New England area.

The applicant intends to invest only in concerns whose activities are related to businesses in which the applicant has the managerial and technical know-how at the time of commitment. However, applicant intends to provide assistance to all qualified socially or economically disadvantaged small business concerns.

As a small business investment company under Section 301(d) of the Act, the applicant has been organized and chartered solely for the purpose of performing the functions and conducting the activities contemplated under the Small Business Investment Act of 1958, as amended from time to time, and will provide assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages.

Matters involved in SBAs consideration of the applicant include the general business reputation and character of the proposed management, and the probability of successful operation of the applicant under their management, including adequate profitability and financial soundness, in accordance with the Small Business Investment Act and SBA rules and regulations.

Any person may, not later than 15 days from the date of publication of this notice, submit to SBA written comments on the proposed applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street, NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Randolph, Massachusetts.

(Catalog of Federal Domestic Assistance Program No. 59.011 Small Business Investment Companies.)

Dated: August 10, 1976.

DANIEL SCHLESINGER,
Acting Deputy Associate Administrator for Investment.

[FR Doc.76-23915 Filed 8-16-76;8:45 am]

[License No. 06/10-0015]

FIRST BUSINESS INVESTMENT CORP.

Small Business Investment Company; Approval of Transfer of Control

On June 16, 1976, a notice was published in the FEDERAL REGISTER (41 F.R. 24469) stating that First Business Investment Corporation, Suite 301 Zidell Building, 7007 Preston Road, Dallas, Texas 75205, had filed an application with the Small Business Administration (SBA), pursuant to Section 107.701 of the Rules and Regulations governing small business investment companies (13 C.F.R. Section 107.701 (1976)), for the transfer of control of this company to Mr. Albert J. Prevot.

Interested parties were given to the close of business July 1, 1976, to submit their written comments to SBA.

There has been an amendment to the original proposal. Mrs. Millicent McCoy and Mr. Walter M. Collie at the present time are officers and directors of the corporation but they will resign these positions. The only changes in the structure of management will be Mr. Prevot replacing Mr. John M. McCoy as president and Mr. John M. McCoy becoming secretary-treasurer of the corporation and remain a director. SBA has no objections to these changes.

Notice is hereby given that, having considered the application and all other pertinent information, SBA approved this application for transfer of control effective August 6, 1976.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: August 10, 1976.

DANIEL SCHLESINGER,
Acting Deputy Associate Administrator for Investment.

[FR Doc.76-23992 Filed 8-16-76;8:45 am]

[Declaration of Disaster Loan Area 1267; Amdt. No. 1]

NEW YORK

Declaration of Disaster Area

The above numbered declaration (41 FR 32815) is amended by adding Herkimer and Washington Counties and adjacent counties within the State of New York, and by extending the time for filing applications to September 27, 1976, for physical damage and April 27, 1977, for economic injury.

Dated: July 30, 1976.

MITCHELL P. KOBEI INSKI,
Administrator.

[FR Doc.76-23916 Filed 8-16-76;8:45 am]

CHARLOTTE DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration Charlotte District Advisory Council will hold a public meeting at 9:00 a.m., Friday, September 17, 1976 at the Howard Johnson's Motor Lodge, I-85 at Brentwood Street, High Point, North Carolina to discuss such matters as may be presented by members, staff of the Small Business Administration, or others present. For further information, write or call George W. Marschall, U.S. Small Business Administration, 230 South Tryon Street, Suite 700, Charlotte, North Carolina 28202, (704) 672-7448.

Dated: August 6, 1976.

HENRY V. Z. HYDE, Jr.,
Deputy Advocate for Advisory Councils.

[FR Doc.76-23991 Filed 8-16-76;8:45 am]

VETERANS ADMINISTRATION

MEDICAL RESEARCH SERVICE MERIT REVIEW BOARDS

Meetings

The Veterans Administration gives notice pursuant to Public Law 92-463 of meetings of the following Merit Review Boards.

Merit review board	Date	Time	Location
Gastroenterology	Sept. 17, 1976	8:30 a.m. to 4:30 p.m.	Room A35, VACO.[1]
Respiration	Sept. 22, 1976	do	Room 817, VACO.
Cardiovascular studies	Oct. 1, 1976	do	Room 139, VACO.
Endocrinology	do	do	Room A35, VACO.
Hematology	do	do	Room 815B, VACO.
Immunology	Oct. 5, 1976	7 p.m. to 11 p.m.	Parlor B, Burlington Hotel.[2]
Do	Oct. 6, 1976	8:30 a.m. to 4:30 p.m.	Room 817, VACO.
Alcoholism and drug dependence (clinical pharmacology).	Oct. 8, 1976	do	Room A35, VACO.
Nephrology	Oct. 13, 1976	do	Room 817, VACO.
Surgery	Oct. 14, 1976	8:30 a.m. to 10 p.m.	Ivy Room, Blackstone Hotel.[3]
Oncology	Oct. 15, 1976	8:30 a.m. to 4:30 p.m.	Room 139, VACO.
Neurobiology	Oct. 18, 1976	7 p.m. to 11 p.m.	Conference room, Holiday Inn.[4]
Do	Oct. 19, 1976	8:30 a.m. to 4:30 p.m.	Room 817, VACO.
Behavioral sciences	Oct. 21, 1976	7 p.m. to 11 p.m.	Presidential Room, Holiday Inn.
Do	Oct. 22, 1976	8:30 a.m. to 4:30 p.m.	Room 139, VACO.
Infectious diseases	Oct. 26, 1976	do	Lake Erie Room, Conrad Hilton.[5]
Basic sciences	Oct. 28, 1976	7 p.m. to 11 p.m.	Parlor 511, Statler Hilton.[6]
Do	Oct. 29, 1976	8:30 a.m. to 4:30 p.m.	Room 139, VACO.

[1] Veterans Administration Central Office, 810 Vermont Ave. NW., Washington, D.C. 20420.
[2] Burlington Hotel, 1120 Vermont Ave. NW., Washington, D.C. 20005.
[3] Blackstone Hotel, 636 South Michigan Ave., Chicago, Ill. 60605.
[4] Holiday Inn, 1501 Rhode Island Ave. NW., Washington, D.C. 20005.
[5] Conrad Hilton, 720 South Michigan Ave., Chicago, Ill. 60605.
[6] Statler Hilton, 16th and K Sts. NW., Washington, D.C. 20036.

These meetings will be for the purpose of evaluating the scientific merit of research conducted in each specialty by Veterans Administration investigators working in Veterans Administration hospitals and clinics.

The meetings will be open to the public up to the seating capacity of the rooms at the start of each meeting to discuss the general status of the program. In accordance with the provision set forth in section 552(b)(5), title 5, United States Code, all of the Merit Review Board meetings will be closed to the public after approximately one-half hour from the start, for the review, discussion and evaluation of initial, and renewal research projects.

The closed portion of the meetings involve: discussion, examination, reference to, and oral review of site visits, staff and consultant critiques of research protocols, and similar documents which are exempt from disclosure under the interagency memoranda exemption (exemption (5)) to section 552(b) of title 5, United States Code. The portion of the meeting which necessitates examination of these documents will be closed to prevent inadvertent disclosure of these exempt records.

Because of the limited seating capacity of the rooms, those who plan to attend should contact Howard M. Berman, Acting Chief, Program Development and Review Division, Medical Research Service, Veterans Administration, Washington, DC, (202) 389-5065 at least five days prior to each meeting. Minutes of the meeting and rosters of the members of the Boards may be obtained from this source.

Dated: August 10, 1976.

R. L. ROUDEBUSH,
Administrator.

[FR Doc.76-23838 Filed 8-16-76;8:45 am]

DEPARTMENT OF LABOR

Employment and Training Administration

MIGRANT AND OTHER SEASONALLY EMPLOYED FARMWORKER PROGRAMS

Submission of Preapplication for Federal Assistance for Fiscal Year 1977

Correction

In FR Doc. 76-23405, appearing at page 33591 in the issue of Tuesday, August 10, 1976, the first line should read as follows:

"Pursuant to 29 CFR 97.211, the Em- . . ."

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

IOWA STANDARDS

Notice of Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrators for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary), (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On July 20, 1973, notice was published in the Federal Register (38 FR 19368) of the approval of the Iowa plan and the adoption of Subpart J to Part 1952 containing the decision.

The Iowa plan provides for the adoption of Federal Standards as State standards (by reference after comments and public hearing). Section 1952.163 of Subpart J sets forth the State's schedule for the adoption of Federal standards. By letter dated July 2, 1976 from Jerry L. Addy, Commissioner of Labor to Vernon A. Strahm, Regional Administrator for Occupational Safety & Health Administration and incorporated as part of the plan, the State submitted State standards comparable to 29 CFR 1928.57 (41 FR 10195, March 9, 1976); 1928.57 (41 FR 11022, March 16, 1976); 1910.1001(i)(1) (41 FR 11504, March 19, 1976); 1910.184 (f)(6) (41 FR 13352, March 30, 1976). These standards, which are contained in Chapter 88 of the Code of Iowa (1975), were promulgated after public comment requested on May 1, 1976, hearings held on June 1, 1976 and resolution adopted by the Iowa Bureau of Labor on June 21, 1976 pursuant to Chapter 17a of the Code. The standards will be effective on August 20, 1976 and notice of their adoption was published by the State on June 14, 1976.

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards it has been determined that the State standards are identical to the Federal standards.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Associate Assistant Secretary for Regional Programs, OSHA, Room N3608, 200 Constitution Avenue, N.W., Washington, D.C. 20210; Technical Data Center, OSHA, Room N3620, 200 Constitution Avenue, N.W., Washington, D.C. 20210; Office of the Regional Administrator, OSHA, Room 3000 Federal Office Building, 911 Walnut Street, Kansas City, Missouri 64106; and Iowa Bureau of Labor, East Seventh and Court Avenue, Fourth Floor, Des Moines, Iowa 50319.

4. *Public participation.* Under § 1953.2 (c) of this chapter, the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Iowa State plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are identical to the Federal standards and are therefore deemed to be at least as effective.

2. The standards were adopted in accordance with the procedural requirements of State law and further participation would be unnecessary.

This decision is effective August 17, 1976.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 667)).

Signed at Kansas City, Missouri this 14th of July 1976.

VERNON A. STRAHM,
Regional Administrator.

[FR Doc.76-24059 Filed 8-16-76;8:45 am]

WASHINGTON STATE STANDARDS

Notice of Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter called the Act) by which the Regional Administrators for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18 (c) of the Act and 29 CFR Part 1902. On January 26, 1973, notice was published in the FEDERAL REGISTER (38 FR 2421) of the approval of the Washington plan and the adoption of Subpart F to Part 1952 containing the decision.

The Washington plan provides for the adoption of State standards which are at least as effective as comparable Federal standards promulgated under section 6 of the Act.

Section 1952.123 of Subpart F sets forth the State's schedule for the adoption of at least as effective State standards. By letter dated February 26, 1976 from John E. Hillier, Assistant Director, Department of Labor and Industries, to James W. Lake, Regional Administrator, U.S. Department of Labor, and incorporated as part of the plan, the State submitted State standards comparable to 29 CFR Part 1910, Subpart F, Powered Platforms, Manlifts and Vehicle-mounted Work Platforms. These standards, which are contained in WAC 296–24–870, WAC 296–24–885, and WAC 296–24–900 of the General Safety and Health Standards, were promulgated by the State following hearings held in Olympia, Washington, February 19, 1976 pursuant to 34.04 RCW and of the Open Public Meetings Act of 1971, chapter 42.30 RCW.

This subpart as proposed in the original State plan submission was initially approved as part of the Washington State Plan and a notice of approval appeared in the FEDERAL REGISTER (38 FR 2421) of January 26, 1973. Subsequently, changes were introduced during the State's adoption process which resulted in a less effective standard. The State has now amended the standard and thereby corrected the deficiencies. The State has also adopted standards corresponding to 29 CFR 1910.67, Vehicle-mounted Elevating and Rotating Work Platforms promulgated by OSHA in the FEDERAL REGISTER Vol. 40, No. 59, dated March 26, 1975.

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are at least as effective as the comparable Federal standards and accordingly should be approved. It is noted that § 1910.67(b)(4) requires specified clearances between aerial lifts and power lines. However, 1910.67(b)(4)(i)(c)(1) provides an exemption for this requirement in the case of insulated aerial lifts. The State chooses not to avail itself of this exemption and the State standard is therefore more effective.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6048, Federal Office Building, 909 First Avenue, Seattle, Washington 98174; Department of Labor and Industries, General Administrative Building, Olympia, Washington 98504; and the Technical Data Center, Room N3620, 200 Constitution Avenue, Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c) the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Washington plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reason.

The standards were adopted in accordance with the procedural requirements of State law which included public comment and further public participation would be repetitious.

This decision is effective August 17, 1976.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667).)

Signed at Seattle, Washington this 28th day of May, 1976.

JAMES W. LAKE,
Regional Administrator, OSHA.

[FR Doc 76–24060 Filed 8–16–76;8:45 am]

WASHINGTON STATE STANDARDS

Notice of Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter called the Act) by which the Regional Administrators for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18 (c) of the Act and 29 CFR Part 1902. On January 26, 1973, notice was published in the FEDERAL REGISTER (38 FR 2421) of the approval of the Washington plan and the adoption of Subpart F to Part 1952 containing the decision.

The Washington plan provides for the adoption of State standards which are at least as effective as comparable Federal standards promulgated under section 6 of the Act.

Section 1952.123 of Subpart F sets forth the State's schedule for the adoption of at least as effective State standards. By letter dated February 26, 1976 from John E. Hillier, Assistant Director, Department of Labor and Industries, to James W. Lake, Regional Administrator, U.S. Department of Labor and incorporated as part of the plan, the State submitted State standards comparable to 29 CFR Parts 1915, 1916, and 1917. These standards, which are contained in chapter 296–304 WAC, Ship Repairing, Shipbuilding, and Shipbreaking, were promulgated after due notice and a public hearing held at Olympia, Washington on April 26, 1974 pursuant to 34.04 RCW and of the Open Public Meetings Act of 1971, chapter 42.30 RCW.

2. *Decision.* Having reviewed the State submision in comparison with the Federal standards, it has been determined that the State standards are at least as effective as the comparable Federal standards and accordingly should be approved. The Region's review and evaluation indicates that the State standards are more effective than the Federal standards in that the State has combined the requirements of 29 CFR Parts 1915, 1916, and 1917 under one scope statement, thereby covering similar hazards wherever they occur in shipbuilding, shipbreaking, and ship repair.

3. Location of *supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6048, Federal Office Building, 909 First Avenue, Seattle, Washington 98174; Department of Labor and Industries, General Administrative Building, Olympia, Washington 98504; and the Technical Data Center, Room N3620, 200 Constitution Avenue, Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c) the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Washington plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reason.

The standards were adopted in accordance with the procedural requirements of State law which included public comment and further public participation would be repetitious.

This decision is effective August 17, 1976.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667).

Signed at Seattle, Washington this 28th day of May, 1976.

JAMES W. LAKE,
Regional Administrator, OSHA.

[FR Doc.76-24061 Filed 8-16-76;8:45 am]

WASHINGTON STATE STANDARDS

Notice of Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter called the Act) by which the Regional Administrators for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On January 26, 1973, notice was published in the FEDERAL REGISTER (38 FR 2421) of the approval of the Washington plan and the adoption of Subpart F to Part 1952 containing the decision.

The Washington plan provides for the adoption of State standards which are at least as effective as comparable Federal standards promulgated under section 6 of the Act.

Section 1952.123 of Subpart F sets forth the State's schedule for the adoption of at least as effective standards. By letter dated February 26, 1976 from John Hillier, Assistant Director, Department of Labor and Industries, to James W. Lake, Regional Administrator, U.S. Department of Labor, and incorporated as part of the plan, the State submitted State standards comparable to 29 CFR Part 1910, Subparts G and Z. These standards, which are contained in Chapter 296-62 WAC, General Occupational Health Standards, were promulgated after due notice and public hearings held at Olympia, Washington on August 24, 1973, May 2, 1974 and February 19, 1976 pursuant to 34.04 RCW and of the Open Public Meetings Act of 1971, Chapter 42.30 RCW.

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are at least as effective as the comparable Federal standards and accordingly should be approved.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6048, Federal Office Building, 909 First Avenue, Seattle, Washington 98174; Department of Labor and Industries, General Administrative Building, Olympia, Washington 98504; and the Technical Data Center, Room N3620, 200 Constitution Avenue, Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c) the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Washington plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reason.

The standards were adopted in accordance with the procedural requirements of State law which included public comment and further public participation would be repetitious.

This decision is effective August 17, 1976.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 667)).

Signed at Seattle, Washington this 28th day of May, 1976.

JAMES W. LAKE,
Regional Administrator, OSHA.

[FR Doc.76-24062 Filed 8-16-76;8:45 am]

Office of the Secretary

[TA-W-1,013]

A. JACOBS AND SONS, INC.

Investigation Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance

On August 6, 1976 the Department of Labor received a petition dated July 28, 1976 which was filed under Section 221 (a) of the Trade Act of 1974 ("the Act") on behalf of the workers and former workers of A. Jacobs and Sons, Inc., Lynn, Massachusetts (TA-W-1,013).

Accordingly, the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted an investigation as provided in Section 221(a) of the Act and 29 CFR 90.12.

The purpose of the investigation is to determine whether absolute or relative increases of imports of articles like or directly competitive with athletic shoes produced by A. Jacobs and Sons, Incorporated or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision. The investigation will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved. A group meeting the eligibility requirements of Section 222 of the Act will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90.

Pursuant to 29 CFR 90.13, the petitioner or any other person showing a substantial interest in the subject matter of the investigation may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

Interested persons are invited to submit written comments regarding the subject matter of this investigation to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

The petition filed in this case is available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 6th day of August 1976.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc.76-24063 Filed 8-16-76;8:45 am]

[TA-W-800]

ADVANCE MANUFACTURING CORP., CLEVELAND, OHIO

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-800: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on April 16, 1976 in response to a worker petition received on April 16, 1976 which was filed by the United Automobile, Aerospace and Agricultural Implement Workers of America on behalf of workers and former workers producing tools, dies, jigs and fixtures at the Advance Manufacturing Corporation, Cleveland, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on May 14, 1976 (41 FR 20040). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Advance Manufacturing Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all the criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of production workers at Advance Manufacturing Corporation declined 37 percent in 1975 compared to 1974 and declined 22 percent in the first quarter of 1976 compared to the same period of 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales of tools, dies, jigs, and fixtures at Advance Manufacturing declined 16 percent in 1975 compared to 1974 and declined 42 percent in the first quarter of 1976 compared to the same period in 1975.

INCREASED IMPORTS

When compared with each preceding year imports of tools, dies, jigs and fixtures increased in terms of value in 1972, 1973 and 1974 and decreased in 1975. The ratios of imports to domestic production increased from 1.18 percent in 1974 to 1.69 percent in 1975, surpassing the 1971–1974 average of .81 percent.

CONTRIBUTED IMPORTANTLY

The Department's investigation indicated that customers of Advance Manufacturing Corporation, Cleveland, Ohio have shifted their purchases of tools, dies, jigs and fixtures from Advance to off-shore manufacturers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with tools, dies, jigs and fixtures produced by Advance Manufacturing Corporation, Cleveland, Ohio contributed importantly to the total or partial separation of the workers of that plant. In accordance with the provision of the Act, I make the following certification:

All workers engaged in employment at the Cleveland, Ohio plant of Advance Manufacturing Corporation who became totally or partially separated from employment on or after April 7, 1975 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 4th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24064 Filed 8-16-76;8:45 am]

[TA-W-731]

CHICOPEE COAT CO., CHICOPEE, MASS.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-731: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on March 26, 1976 in response to a worker petition received on March 26, 1976 which was filed by the Amalgamated Clothing Workers of America on behalf of workers and former workers producing women's outerwear at Chicopee Coat Company, Chicopee, Massachusetts, a wholly-owned subsidiary of Davis Sportswear, Lawrence, Massachusetts.

The notice of investigation was published in the FEDERAL REGISTER on April 13, 1976 (41 FR 15486). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Chicopee Coat Company, Davis Sportswear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation reveals that although the first two criteria have been met, the third and fourth criteria have not been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of workers at Chicopee Coat increased 1.1 percent from 1973 to 1974 and then declined 14.6 percent from 1974 to 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales data for Chicopee Coat were not available. All sales were made by Davis Sportswear which maintains sales data on a consolidated basis for all subsidiaries.

Production at Chicopee declined 2.5 percent from 1973 to 1974 and then declined 12 percent from 1974 to 1975.

INCREASED IMPORTS

Imports of women's coats declined 18.8 percent in absolute terms from 1974 to 1975. The ratios of imports to domestic production and consumption declined from 7.8 percent and 7.2 percent, respectively, in 1974 to 5.4 percent and 5.1 percent, respectively, in 1975. In the first four months of 1976, imports increased 32.6 percent in absolute terms when compared to the same period in 1975. The ratios of imports to domestic production and consumption increased from 6.9 percent and 6.5 percent, respectively, in the first four months of 1975 to 7.3 percent and 6.8 percent, respectively, in the first four months of 1976.

CONTRIBUTED IMPORTANTLY

The Department's investigation revealed that customers of Davis Sportswear which sells all women's coats produced by Chicopee Coat did not switch to imports. A representative sample of all customers reduced purchases of women's coats from Davis Sportswear from 1974 to 1975 and shifted purchases to other domestic suppliers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women's coats produced at the Chicopee, Massachusetts plant of Chicopee Coat Company did not contribute importantly to the total or partial separation of the workers at such plant.

Signed at Washington, D.C. this 5th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24065 Filed 8-16-76;8:45 am]

[TA-W-1,014]

ELECTRO-MECHANICAL PRODUCTS

Investigation Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance

On August 6, 1976 the Department of Labor received a petition dated July 27, 1976 which was filed under Section 221 (a) of the Trade Act of 1974 ("the Act") on behalf of the workers and former workers of Oglesby, Ill. plant of the Indiana General Division of Electro-Mechanical Products, a division of Electronic Memories & Magnetics Corp., Los Angeles, Calif. (TA-W-1,014). Accordingly, the Director, Office of Trade Adjustment Assistance, Bureau of Inter-

national Labor Affairs, has instituted an investigation as provided in Section 221 (a) of the Act and 29 CFR 90.12.

The purpose of the investigation is to determine whether absolute or relative increases of imports of articles like or directly competitive with office and technical services provided by Electro-Mechanical Products or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision. The investigation will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved. A group meeting the eligibility requirements of Section 222 of the Act will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90.

Pursuant to 29 CFR 90–13, the petitioner or any other person showing a substantial interest in the subject matter of the investigation may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

Interested persons are invited to submit written comments regarding the subject matter of this investigation to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

The petition filed in this case is available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20210.

Signed at Washington, D.C. this 6th day of August 1976.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc.76-24066 Filed 8-16-76;8:45 am]

[TA-W-732]

LAWRENCE GARMENT CO., LAWRENCE, MASS.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-732: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on March 26, 1976 in response to a worker petition received on March 26, 1976 which was filed by the Amalgamated Clothing Workers of America on behalf of workers and former workers producing women's outerwear at Lawrence Garment Company, Lawrence, Massachusetts, a wholly-owned subsidiary of Davis Sportswear, Lawrence, Massachusetts.

The notice of investigation was published in the FEDERAL REGISTER on April 13, 1976, (41 FR 15490). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Lawrence Garment Company, Davis Sportswear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that although the first two criteria have been met, the third and fourth criteria have not been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of workers at Lawrence Garment Co. remained unchanged from 1973 to 1974 and then declined 10.6 percent from 1974 to 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales data for Lawrence Garment were not available. All sales were made by Davis Sportswear which maintains sales data on a consolidated basis for all subsidiaries.

Production at Lawrence Garment declined 6.7 percent from 1973 to 1974 and declined 8.3 percent from 1974 to 1975.

INCREASED IMPORTS

Imports of women's coats declined 18.8 percent in absolute terms from 1974 to 1975. The ratios of imports to domestic production and consumption declined from 7.8 percent and 7.2 percent, respectively, in 1974 to 5.4 percent and 5.1 percent, respectively, in 1975. In the first four months of 1976, imports increased 32.6 percent in absolute terms when compared to the same period in 1975. The ratios of imports to domestic production and consumption increased from 6.9 percent and 6.5 percent, respectively, in the first four months of 1975 to 7.3 percent and 6.8 percent respectively, in the first four months of 1976.

CONTRIBUTED IMPORTANTLY

The Department's investigation revealed that customers of Davis Sportswear which sells all women's coats produced by Lawrence Garment did not switch to imports. A representative sample of all customers reduced purchases of women's coats from Davis Sportswear from 1974 to 1975 and shifted purchases to other domestic suppliers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women's coats produced at the Lawrence, Massachusetts plant of Lawrence Garment Company did not contribute importantly to the total or partial separation of the workers at such plant.

Signed at Washington, D.C. this 5th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24067 Filed 8-16-76;8:45 am]

[TA-W-1,011]

MARLBORO FOOTWEAR CORP.

Investigation Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance

On August 6, 1976 the Department of Labor received a petition dated June 11, 1976 which was filed under Section 221 (a) of the Trade Act of 1974 ("the Act") on behalf of the workers and former workers of Marlboro Footwear Corporation, Marlboro, Massachusetts (TA-W-1,011). Accordingly, the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted an investigation as provided in Section 221(a) of the Act and 29 CFR 90.12.

The purpose of the investigation is to determine whether absolute or relative increases of imports of articles like or directly competitive with footwear for women produced by Marlboro Footwear Corporation or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision. The investigation will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved. A group meeting the eligibility requirements of Sec-

tion 222 of the Act will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90.

Pursuant to 29 CFR 90.13, the petitioner or any other person showing a substantial interest in the subject matter of the investigation may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

Interested persons are invited to submit written comments regarding the subject matter of this investigation to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

The petition filed in this case is available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 6th day of August 1976.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc.76-24068 Filed 8-16-76;8:45 am]

[TA-W-851]

MASSILLON SPRING AND RIVET CORP., MASSILLON, OHIO

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-851: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on April 30, 1976 in response to a worker petition received April 30, 1976 which was filed by the United Steelworkers of America AFL-CIO on behalf of workers and former workers producing specialty U bolts at the Massillon, Ohio plant of Massillon Spring and Rivet Corporation, Massillon, Ohio.

The notice of investigation was published in the Federal Register (41 FR 20954) on May 21, 1976. No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Massillon Spring and Rivet Corporation, its customers, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard as to whether or not the other criteria have been met, the third criterion has not been met.

Since its founding approximately forty years ago, Massillon Spring and Rivet Company has made a wide variety of products. Since 1971, the only product of the company has been U bolts. The firm operates one plant in Massillon, Ohio which is equipped with cutting machines, heat treating furnaces, and machines for producing both cut threads and rolled threads. All of the U bolts produced at Massillon Spring and Rivet Company are built to the customer's specifications.

There are no separately identifiable import statistics on U-bolts in the Tariff Schedules of the United States (TSUSA). Such products produced by Massillon are commonly classified as specialty fasteners. However, specially fasteners also are not identifiable in the import statistics under the TSUSA classification system. The evidence developed by the Department in the course of the investigation reveals that almost all firms producing specially fasteners, including U-bolts, do not believe their business is subject to any import influence. Foreign trade in specialty fasteners is inhibited by user requirements of on-site quality control, speed of delivery and order scheduling flexibility. Further inhibiting foreign trade in specialty fasteners is the limited market for a single specialized product such as U-bolts.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with specialty U-bolts produced at Massillon, Ohio plant of Massillon Spring and Rivet Corporation did not contribute importantly to the total or partial separations of the workers at such plant.

Signed at Washington, D.C. this 5th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24069 Filed 8-16-76;8:45 am]

[TA-W-744]

SAN-TORO MANUFACTURING CO., FALL RIVER, MASS.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-744: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on March 26, 1976 in response to a worker petition received on March 26, 1976 which was filed by the Amalgamated Clothing Workers Union on behalf of workers and former workers producing men's suits and sportcoats at the Fall River, Massachusetts plant of San-Toro Manufacturing Company.

The notice of investigation was published in the FEDERAL REGISTER on April 16, 1976 (41 FR 16235). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the San-Toro Manufacturing Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that although criteria one, two and three have been met, criterion four has not been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATION

Employment at the Fall River, Massachusetts plant of San-Toro Manufacturing increased 6.2 percent from 1973 to 1974 and then decreased 3.4 percent from 1974 to 1975. In the first three quarters of 1975, employment declined 7 percent from the same quarters of the previous

year. The average number of hours worked decreased 4.9 percent from 1973 to 1974 and 16.5 percent from 1974 to 1975. In the first three quarters of 1975, average hours worked declined 21 percent from the same period of the previous year. Labor turnover data for San Toro indicated that layoffs occurred in the first and second quarters of 1975.

SALES OR PRODUCTION OR BOTH

Sales of sportcoats, suitcoats and leisure jackets by San-Toro Manufacturing decreased 2.6 percent from 1973 to 1974 and 31.8 percent from 1974 to 1975. Sales decreased in each quarter of 1975 compared to the same quarter of the previous year.

Since production at San-Toro is based upon orders received, production is equivalent to sales.

INCREASED IMPORTS

Imports of men's and boys' tailored dress coats and sportcoats increased both absolutely and relatively in each year from 1971 to 1973 and then increased relatively from 1973 to 1974. Imports of men's and boys' tailored dress coats and sportcoats increased both absolutely and relatively from 1974 to 1975. The ratio of imports to domestic production and consumption increased from 21.2 percent and 17.5 percent, respectively, in 1974 to 28.2 percent and 22.0 percent, respectively, in 1975.

Imports of men's and boys' tailored suits increased absolutely and relatively from 1971 through 1975. Imports increased 26.9 percent from 1974 to 1975. Domestic production of men's and boys' suits declined 9.3 percent during the same period. The ratio of imports to domestic production and consumption increased from 12.2 percent and 10.9 percent, respectively, in 1974 to 17.2 percent and 14.6 percent, respectively, in 1975.

CONTRIBUTED IMPORTANTLY

Evidence developed during the Department's investigation indicated that customers of San-Toro did not switch to imports. Customers which reduced purchases did so because of decreased consumer demand resulting from the recession.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with men's sportcoats, suitcoats and leisure jackets produced at the Fall River, Massachusetts plant of San-Toro Manufacturing did not contribute importantly to the total or partial separations of the workers at the plant.

Signed at Washington, D.C. this 6th day of August 1976.

JAMES F. TAYLOR,
Director,
Planning and Evaluation Staff.

[FR Doc.76-24070 Filed 8-16-76;8:45 am]

[TA-W-730]

STAFFORD CLOTHING MANUFACTURING CO., FALL RIVER, MASS.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-730: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on March 26, 1976, in response to a worker petition received on March 26, 1976 which was filed by the Amalgamated Clothing Workers of America on behalf of workers and former workers producing women's outerwear at Stafford Clothing Manufacting Company, Fall River, Massachusetts, a wholly-owned subsidiary of Davis Sportswear, Lawrence, Massachusetts.

The notice of investigation was published in the FEDERAL REGISTER on April 13, 1976 (41 FR 15493). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Stafford Clothing Manufacturing Company, Davis Sportswear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivisions have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that although the first two criteria have been met, the third and fourth criteria have not been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of workers at Stafford Clothing increased 32.5 percent in 1974 compared to 1973 and then declined 7.5 percent from 1974 to 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales data for Stafford Clothing were not available. All sales were made by Davis Sportswear which maintains sales data on a consolidated basis for all subsidiaries.

Production at Stafford Clothing increased 18.3 percent in 1974 compared to 1973 and then declined 21.1 percent from 1974 to 1975.

INCREASED IMPORTS

Imports of women's coats declined 18.8 percent in absolute terms from 1974 to 1975. The ratios of imports to domestic production and consumption declined from 7.8 percent and 7.2 percent, respectively, in 1974 to 5.4 percent and 5.1 percent, respectively, in 1975. In the first four months of 1976, imports increased 32.6 percent in absolute terms when compared to the same period in 1975. The ratios of imports to domestic production and consumption increased from 6.9 percent and 6.5 percent, respectively, in the first four months of 1975 to 7.3 percent and 6.8 percent, respectively, in the first four months of 1976.

CONTRIBUTED IMPORTANTLY

The Department's investigation revealed that customers of Davis Sportswear which sells all women's coats produced by Stafford Clothing did not switch to imports. A representative sample of all customers reduced purchases of women's coats from Davis Sportswear from 1974 to 1975 and shifted purchases to other domestic suppliers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women's coats produced at the Fall River, Massachusetts plant of Stafford Clothing Manufacturing Company did not contribute importantly to the total or partial separation of the workers at such plant.

Signed at Washington, D.C. this 5th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the
Deputy Under Secretary.

[FR Doc.76-24071 Filed 8-16-76;8:45 am]

[TA-W-717]

STYLECRAFT CLOTHING CO., WEST ORANGE, N.J.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-717: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on March 26, 1976 in response to a worker

petition received on March 26, 1976 which was filed by the Amalgamated Clothing Workers of America on behalf of workers and former workers producing men's leisure suits, for Stylecraft Clothing Co., in West Orange, New Jersey.

The notice of investigation was published in the FEDERAL REGISTER on April 13, 1976 (41 FR 15494). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Stylecraft Clothing Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales, production or both, of the firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separation, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation reveals that all the above criteria have been met for men's leisure suits, but that the second, third and fourth criteria have not been met for military uniforms.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Employment was not separately identifiable as to hourly and salaried workers. The average number of weekly workers at Stylecraft declined 26 percent from 1973 to 1974, and declined 15 percent from 1974 to 1975. Beginning in the second quarter of 1975 and continuing through the first quarter of 1976, employment declined in each quarter compared to the same quarter of the previous year. Labor turnover data was not available.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales and production at Stylecraft are the same, since the clothing is produced to order on a contract basis. Men's leisure suits comprised 91 percent of total sales in 1974 and 84 percent of total sales in 1975. Sales of men's leisure suits declined 41 percent in value from 1973 to 1974, and declined 21 percent in value from 1974 to 1975. Sales declined 20 percent in value in the first quarter of 1976 compared to the first quarter of 1975. Sales of leisure suits ceased in the beginning of April, 1976, when Stylecraft's manufacturer terminated the contract.

Sales of military uniforms comprised 9 percent of total sales in 1975. Sales of military uniforms increased 58 percent in value from 1973 to 1974 and increased 53 percent from 1974 to 1975. Sales increased 245 percent in the first quarter of 1976 from the first quarter of 1975.

INCREASED IMPORTS

Imports of men's and boys' tailored suits increased absolutely and relatively in each year from 1971 to 1975. The ratios of imports of men's and boys' tailored suits to domestic production and consumption increased from 12.2 percent and 10.9 percent, respectively, in 1974 to 17.2 percent and 14.6 percent, respectively, in 1975.

Military and security type uniforms are not imported due to the "Buy American Act," which requires that in the procurement of supplies and services, only domestic sources and products shall be used and acquired for public use. Another consideration is the time factor involved in delivery and the customized tailoring-to-individual size specfications.

CONTRIBUTED IMPORTANTLY

The evidence developed by the Department's investigation indicated that retail customers of the manufacturer for whom Stylecraft produced leisure suits reduced domestic purchases of leisure suits from 1974 to 1975 and increased purchases of imports in the same period.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with men's leisure suits produced at Stylecraft Clothing Company, West Orange, New Jersey contributed importantly to the total or partial separation of the workers of that plant. In accordance with the provision of the Act, I make the following certification:

All workers at Stylecraft Clothing Company, West Orange, New Jersey who became totally or partially separated from employment related to the production of men's leisure suits on or after March 22, 1975 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

All workers related to the production of military uniforms are denied certification.

Signed at Washington, D.C. this 5th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24072 Filed 8-16-76;8:45 am]

[TA-W-661]

TARRA HALL CLOTHES, INC., NEW YORK, N.Y.

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-661; investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on March 12, 1976 in response to a worker petition received on March 12, 1976 which was filed by the Amalgamated Clothing Workers of America on behalf of workers and former workers producing men's suits at Tarra Hall Clothes, Inc., New York, New York. The Department's investigation revealed that Tarra Hall was made up of three divisions: Tarra Hall, Arreta Hall and American Sportswear. An investigation regarding eligibility to apply for adjustment assistance for workers of American Sportswear was terminated on May 21, 1976 (41 FR 20972).

The notice of investigation was published in the FEDERAL REGISTER on March 26, 1976 (41 FR 12754). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Tarra Hall Clothes, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in such workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated,

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all of the above criteria have been met for the Tarra Hall division. However for the Arreta Hall Division Criterion two has not been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of production workers at the Tarra Hall Division declined 14.0 percent from 1973 to 1974 and 32.4 percent from 1974 to 1975. Employment declined in the first three quarters of 1975 compared to the same quarter of 1974.

The average number of production workers at Arreta Hall increased 15.2 percent from 1974 to 1975. No employment figures were available for 1973.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Production at Tarra Hall Division declined 13.1 percent in 1974 compared to 1973 and 15.1 percent in 1975 compared to 1974. Production declined in each quarter of 1975 compared to the corresponding quarters in 1974.

Production at Arreta Hall decreased 20.7 percent in 1974 compared to 1973 and increased 63.5 percent in 1975 compared to 1974. Production increased in each quarter of 1975 compared to the corresponding quarter in 1974.

INCREASED IMPORTS

Imports of men's and boys' suits increased absolutely and relative to domestic production in each year from 1971 through 1975. Absolute imports increased 26.9 percent from 1974 to 1975. The ratios of imports to domestic production and consumption increased from 12.2 percent and 10.9 percent, respectively in 1974 to 17.2 percent and 14.6 percent, respectively, in 1975.

CONTRIBUTED IMPORTANTLY

The Department's investigation revealed that customers of Tarra Hall Clothes, Inc. decreased their purchases of men's suits from Tarra Hall relative to purchases of lower priced imported men's suits. This had a direct impact on the production and employment at the Tarra Hall Division.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with men's suits produced at the New York, New York plant of the Tarra Hall Division of Tarra Hall Clothes, Inc., have contributed importantly to the total or partial separation of the workers of the plant. In accordance with the provisions of the Act, I make the following certification:

All workers engaged in employment related to the production of men's suits at the New York, New York plant of the Tarra Hall Division of Tarra Hall Clothes, Inc., who became totally or partially separated from employment on or after March 12, 1975 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

I further conclude that neither sales nor production has decreased absolutely at Arreta Hall. Therefore workers at the Arreta Hall Division of Tarra Hall Clothes, Inc., are denied certification.

Signed at Washington, D.C. this 6th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24073 Filed 8-16-76;8:45 am]

[TA-W-880]

TELEDYNE PITTSBURGH TOOL STEEL, MONACA, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-880: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 19, 1976 in response to a worker petition received on May 19, 1976 which was filed by the United Steelworkers of America on behalf of workers and former workers producing tool steel at the Monaca, Pennsylvania plant of Teledyne Pittsburgh Tool Steel.

The notice of investigation was published in the Federal Register on June 11, 1976 (41 FR 23821). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Teledyne Pittsburgh Tool Steel, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of production workers declined 9.2 percent in 1975 compared to 1974 and 11.9 percent in the second quarter of 1975 compared to the like quarter in 1974.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Plant sales, in quantity, declined 26.9 percent in 1975 compared to 1974 and 39.6 percent in the sceond quarter of 1975 compared to the like quarter in 1974. Plant production, in quantity, declined 25.2 percent in 1975 compared to 1974 and 38.1 percent in the second quarter of 1975 compared to the like quarter in 1974.

INCREASED IMPORTS

Imports of alloy tool steel increased in each year from 12,700 net tons in 1971 to 21,700 net tons in 1973 before declining to 13,700 net tons in 1974. Imports then increased to 19,100 net tons in 1975. The ratios of imports of alloy tool steel to domestic shipments and consumption increased from 12.1 percent and 11.6 percent, respectively, in 1974 to 27.7 percent and 23.4 percent, respectively in 1975.

CONTRIBUTED IMPORTANTLY

The Department's investigation indicated that the major customers of tool produced at the Monaca, Pennsylvania plant of Teledyne Pittsburgh Tool Steel are increasing their purchases of tool steel from foreign sources due to price competition.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with the tool steel produced at the Monaca, Pennsylvania plant of Teledyne Pittsburgh Tool Steel contributed importantly to the total or partial separation of the workers at the Monaca, Pennsylvania plant. In accordance with the provisions of the Act, I make the following certification:

"All employees of Teledyne Pittsburgh Tool Steel, Monaca, Pennsylvania who become totally or partially separated from employment on or after April 15, 1975 are eligible to apply for adjustment assistance benefits under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C. this 6th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary

[FR Doc.76-24074 Filed 8-16-76;8:45 am]

[TA-W-887]

WASHBURN WIRE CO., INC., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-887: investigation regarding certification of eligibility to apply for worker adjustment assistance prescribed in Section 222 of the Act.

The investigation was initiated on May 19, 1976 in response to a worker petition received on May 19, 1976 which was filed by the United Steelworkers of America on behalf of workers and former workers producing quality spring steel at the Washburn Wire Company, New York, New York.

The notice of investigation was published in the Federal Register on June 15, 1976 (41 FR 24236). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Washburn Wire Company, its customers, the United Steelworkers of America, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment as-

sistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The Department's investigation reveals that all of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Employment of production workers declined 33.8 percent in 1975 compared to 1974 and declined 40.9 percent in the second quarter of 1975 compared to the second quarter of 1974.

SALES, PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Plant sales declined 44.8 percent in quantity in 1975 compared to 1974 and declined 65.7 percent in the second quarter of 1975 compared to the like 1974 quarter.

INCREASED IMPORTS

The ratio of imports of stainless steel wire and wire products to domestic shipments and consumption increased in quantity in each year from 26.3 percent and 21.1 percent, respectively, in 1973 to 43.9 percent and 31.7 percent, respectively, in 1975.

CONTRIBUTED IMPORTANTLY

The evidence developed during the Department's investigation indicates that imports of quality spring steel have increased in recent years.

Customers of the Washington Wire Company have increased purchases of imported quality spring steel and have reduced purchases from the Washburn Wire Company.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of quality spring steel have contributed importantly to the total or partial separation of workers at the Washburn Wire Company, New York, New York. In accordance with the provisions of the Trade Act of 1974, I make the following certification:

All employees at the Washburn Wire Company, Inc., New York, New York who became totally or partially separated from employment on or after April 30, 1975 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974

Signed at Washington, D.C. this 4th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24075 Filed 8-16-76;8:45 am]

[TA-W-879]

WESCO INDUSTRIES CORP., PLAINVIEW, N.Y.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-879: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 19, 1976 in response to a worker petition received on that date which was filed on behalf of workers and former workers producing stop motion devices for circular knitting machines at WESCO Industries Corporation, Plainview, New York.

The notice of investigation was published in the Federal Register on June 11, 1976 (41 FR 23822). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of WESCO Industries Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (3) has not been met.

WESCO Industries Corporation was established in 1907 and became a subsidiary of the Ingersoll Rand Company in 1972. The firm produces stop motion devices which are filament sensing devices and cloth sensing devices for circular knitting machines.

The evidence developed in the Department's investigation reveals that there are no separately identifiable imports of stop motion devices. The product is not listed as a separate item of any U.S. Tariff Schedule grouping. In addition, industry spokesmen indicated that there are no imports of this item.

Imports of circular knitting machines which incorporate stop motion devices of the same origin are not like or directly competitive with stop motion devices produced by WESCO Industries.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that articles like or directly competitive with those produced by WESCO Industries Corporation are not being imported in increasing quantities, either actual or relative to domestic production, as required in Section 222 of the Trade Act of 1974.

Signed at Washington, D.C. this 5th day of August 1976.

JAMES D. HOOVER,
Acting Executive Assistant to the Deputy Under Secretary.

[FR Doc.76-24076 Filed 8-16-76;8:45 am]

[TA-W-788]

WHITE PINE COPPER CO., WHITE PINE, MICH.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-788; investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initated on April 9, 1976 in response to a worker petition received on that date which was filed by the United Steelworkers of America on behalf of workers and former workers producing refined copper at the White Pine Copper Company, White Pine, Michigan, a subsidiary of the Copper Range Company.

The notice of investigation was published in the Federal Register on April 23, 1976 (41 FR 17036). No public hearing was requested, and none was held.

The information upon which the determination was made was obtained principally from the White Pine Copper Company, its customers, the U.S. Department of the Interior, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) that a significant number or proportion of the workers in the workers'

firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) that articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) that such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production.

The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation revealed that all four criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Total employment of hourly and salaried workers at White Pine decreased four percent from 1974 to 1975 and dropped 44 percent in January–April 1976 compared to the same period in 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Dollar sales of refined copper by White Pine decreased 25 percent from 1974 to 1975 and dropped 41 percent in January–April 1976 compared to the like period in 1975. Sales of copper in pounds increased nine percent from 1974 to 1975 and declined 44 percent in January–April 1976 compared to the like period in 1975.

INCREASED IMPORTS

Imports of refined copper increased absolutely and relatively in each year from 1971 through 1974. Copper imports decreased from 314 thousand short tons in 1974 to 147 thousand short tons in 1975. Imports rose from 33 thousand short tons in January–April 1975 to 130 thousand short tons in January–April 1976. The ratio of imports to domestic production declined from 14.6 percent in 1974 to 8.2 percent in 1975 and increased from 5.1 percent in January–April 1975 to 21.3 percent in the same period of 1976.

CONTRIBUTED IMPORTANTLY

In May 1974, when U.S. Government price controls expired on refined copper, White Pine adopted a new pricing policy under which all its domestic copper sales would be based on prevailing COMEX (New York Commodity Exchange) prices. Using the COMEX price quotes also allowed White Pine to expand its market for refined copper beyond its regular customers.

From 1974 to 1975, when both domestic production and imports were declining, White Pine's unit production and unit sales increased. COMEX prices dropped sharply throughout 1975 from 1974 levels, reflecting the transition in the world copper market from a period of shortage to a recessionary period of low demand and excess copper supply.

Although the company was able to sell all the copper it could produce because COMEX prices in 1975 were substantially below U.S. producer prices, White Pine also realized COMEX prices were below production costs. Faced with continued losses and uncertain prospects for price recovery, White Pine decided on January 5, 1976, to cut costs by curtailing its mining operations by about 76 percent and by laying off approximately 70 percent of its hourly and salaried workers. The depressed state of COMEX prices throughout the second half of 1975 was a reflection of increased world copper stocks. In February 1976, White Pine decided to set copper prices at the U.S. producer price to avoid the volatile fluctuations in the speculative COMEX and LME markets.

Sales and production declined 41 percent and 44 percent, respectively, in January–April 1976 compared to the same period in 1975. The decline is attributable to furnace repair and cost reduction policies undertaken by White Pine and to the loss of COMEX sales.

Customers of White Pine reported a relative increase in purchases of imported refined copper in the first half of 1976 compared to the like period in 1975.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with the refined copper produced at the White Pine Copper Company, White Pine, Michigan contributed importantly to the total or partial separations of the workers at such plant. In accordance with the provisions of the Act, I make the following certification:

All workers at the White Pine Copper Company, White Pine, Michigan who became totally or partially separated from employment on or after January 1, 1976 are certified eligible to apply for worker adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 6th day of August 1976.

JAMES F. TAYLOR,
Director,
Planning and Evaluation Staff.

[FR Doc.76-24077 Filed 8-16-76;8:45 am]

[TA-W-1,012]

WILLIAMS MANUFACTURING CO.

Investigation Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance

On August 6, 1976 the Department of Labor received a petition dated July 31, 1976 which was filed under Section 221 (a) of the Trade Act of 1974 ("the Act") by the Boot and Shoe Workers' Union on behalf of the workers and former workers of Williams Manufacturinfi Company, Portsmouth, Ohio (TA-W-1,012).

Accordingly, the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted an investigation as provided in Section 221(a) of the Act and 29 CFR 90.12.

The purpose of the investigation is to determine whether absolute or relative increases of imports of articles like or directly competitive with women's and children's shoes produced by Williams Manufacturing Company or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision. The investigation will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved. A group meeting the eligibility requirements of Section 222 of the Act will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90.

Pursuant to 29 CFR 90.13, the petitioner or any other person showing a substantial interest in the subject matter of the investigation may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

Interested persons are invited to submit written comments regarding the subject matter of this investigation to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 27, 1976.

The petition filed in this case is available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C. this 6th day of August 1976.

MARVIN M. FOOKS,
Director, Office of
Trade Adjustment Assistance.

[FR Doc.76-24078 Filed 8-16-76;8:45 am]

INTERSTATE COMMERCE COMMISSION

[Notice No. 119]

ASSIGNMENT OF HEARINGS

AUGUST 12, 1976.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC-C-7570, Federal Highway Administration V. Cross Transportation, Inc., now assigned September 8, 1976 at Washington, D.C., has been postponed indefinitely.
MC 119792 (Sub-No. 52), Chicago Southern Transportation Co., Inc., now assigned November 15, 1976, at Miami, Fla. is canceled and application dismissed.
MC 124692 (Sub-No. 164), Sammons Trucking, now assigned September 14, 1976, at Denver, Colo. is canceled and application dismissed.
MC 136595 (Sub-No. 5, Eastside Enterprises, Inc., d/b/a Eastside Mobile Home Transporting, Inc., now being assigned November 30, 1976 (4 days) at Portland, Oregon, in a hearing room to be later designated.
MC-C-8932, Garrett Freightlines, Inc., Et Al, v. ABC Truck Lines, Inc., Et Al, now being assigned December 6, 1976 (2 days), at Reno, Nevada; in a hearing room to be later designated.
MC 97526 (Sub-No. 2), Nevada Freight Lines, Inc., now being assigned December 8, 1976 (8 days), at Reno, Nevada; in a hearing room to be later designated.
MC 139488 (Sub-No. 15), International Contract Carriers, Inc., now assigned September 16, 1976, at Denver Colo., is canceled and application dismissed.
MC-C-8778, Hilt Truck Line, Inc.—Investigation and Revocation of Certificates now being assigned September 27, 1976 at Omaha, Nebraska and will be held in Room 616, Union Pacific Plaza, 110 North 14th Street.
MC 124211 (Sub 273), Hilt Truck Line, Inc. now assigned September 29, 1976 at Omaha, Nebraska and will be held in Room 616, Union Pacific Plaza, 110 North 14th Street.
MC 129387 (Sub 23), Bill Payne, dba Bill Payne Trucking Company now assigned October 7, 1976 at Omaha, Nebraska and will be held in Room 616, Union Pacific Plaza, 110 North 14th Street.
MC 134477 (Sub 109), Scanno Transportation, Inc. now assigned October 7, 1976 at Omaha, Nebraska and will be held in Room 616, Union Pacific Plaza, 110 North 14th Street.
MC-C-9002, Crouse Cartage Company—Investigation and Revocation of Certificates now assigned October 8, 1976 at Omaha, Nebraska and will be held in Room 616, Union Pacific Plaza, 110 North 14th Street.
AB 1 (Sub 51), Chicago and Northwestern Transportation Company Abandonment Between Burt and Halfa in Kossuth, Palo Alto and Emmet Counties, Iowa now assigned October 4, 1976 at Algona, Iowa and will be held at the Security State Bank, One East State Street.
MC 59856 (Sub 67), Salt Creek Freightways, A Corp., now being assigned November 8, 1976 (1 Week), at Helena, Montana, in a hearing room to be later designated.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.76-24056 Filed 8-16-76;8:45 am]

[Notice No. 11]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under Section 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) 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.

Protests against approval of the application, which may include a request for oral hearing, must be filed with the Commission within 30-days after the date of this publication. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the Act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

No. MC-FC-76668 filed July 22, 1976. Transferee: DON H. FREYMILLER, RALPH HUNTINGTON, and THOMAS F. McARDLE, a partnership, doing business as F. H. & M. TRUCKING CO., INC., P.O. Box 98, Shullsburg, Wisconsin, 53586. Transferor: A & W Trucking Co., Inc., P.O. Box 129, Mosinee, Wisconsin, 54455. Applicants' representative: Carl E. Munson, 469 Fischer Building, Dubuque, Iowa, 52001. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate Nos. MC-113535 (Sub-No. 8); MC-113535 (Sub-No. 15); MC-113535 (Sub-No. 18); MC-113535 (Sub-No. 19); and MC-113535 (Sub-No. 23) issued June 23, 1969, March 4, 1971, October 26, 1971, April 17, 1972, and May 8, 1973, as follows; Sub-8—*Feed*, from Chicago and Forest Park, Ill., to Colesburg, Iowa, and points in Iowa within 12 miles of Colesburg; *Horses*, from points in Delaware and Clayton Counties, Iowa, to points in Wisconsin; *Farm machinery and parts, tractors and parts, and agricultural implements and parts*, from Chicago, Sandwich, Rock Falls, Canton Rock Island, Moline, and East Moline, Ill., to points in Perry, Ox Creek, Volga, Jefferson, Cass, Lodomillo, Elk, Mallory, Millville, and Buena Vista Townships, Clayton County, Iowa, and points in that part of Delaware County, Iowa, on and north of U.S. Highway 20; *Livestock*, From New Vienna, Iowa, and points within 20 miles of New Vienna, to Chicago, Ill.; *Washing machines*, From Newton, Iowa, to points in Columbia, Crawford, Dane, Grant, Green, Iowa, Lafayette, Richland, Rock, Sauk and Vernon Counties, Wis.; *Cocoa, chocolate, and paper boxes* From Milwaukee, Wis., to Dubuque, Iowa; *Canned goods*, From Cassville and Prairie du Chien, Wis., to points in that part of Iowa (except Dubuque) on and east of U.S. Highway 69, and points in that part of Illinois on and North of U.S. Highway 36.

From points in that part of Wisconsin (except points in a described part of Wisconsin) on and south of U.S. Highway 10, to Dubuque, Iowa; *Machinery and machinery parts*, From Rock Island, Rock Falls, Canton, Moline, Dixon, and Rochelle, Ill., and Waterloo, Davenport, Newton, Charles City, Mason City, and Cedar Rapids, Iowa, to Bloomington, Cassville, Potosi, and Prairie du Chien, Wis.; *Paper and paper products*, From Mosinee, Green Bay, Nekoosa, Port Edwards, Appleton, and Menasha, Wis., to Dubuque, Iowa; *Plumbing and heating supplies*, From Kohler, Wis., to Dubuque, Iowa; *Such merchandise as is dealt in by retail grocery and food business houses*, From Dubuque, Iowa, to points in that part of Wisconsin (except points in a described part of Wisconsin) south and west of a line beginning at La Crosse, Wis., and extending along Wisconsin Highway 33 to Portage, Wis., thence along U.S. Highway 51 to Madison, Wis., and thence along Wisconsin Highway 69 to the Wisconsin-Illinois State Line, including points on the indicated portions of the highways specified; *Butter and cheese*, From points in the towns of Millville, Woodman, Marion, Watterstown, Hickory Grove, Castle Rock, Wingville, Clifton, and Lima, Grant County, Wis., points in the towns of Clyde, Eden, Mifflin, Pulaski, and Wyoming, Iowa County, Wis., and points in the towns of Benton, Kendall, Seymour, Shullsburg, White Oak Springs, and Willow Springs, Lafayett County, Wis., to Dubuque, Iowa; and *empty butter tubs*, and *empty cheese boxes*, From Dubuque, Iowa, to point of origin in the Wisconsin towns specified immediately above; *Cheese*, From Dubuque, Iowa, to Dixon, Ill., and Plymouth, Wis.; and *empty cheese boxes*, from Dixon, Ill., and Plymouth, Wis., to Dubuque, Iowa; *Butter, and butter tubs and containers*, Between Dubuque, Iowa, on the one hand, and, on the other, points in a described portion of the State of Wisconsin; *Malt beverages*, and *carbonated beverages*, From Chicago, Ill., to McGregor, Iowa; and *Empty containers* for malt and carbonated beverages, From McGregor, Iowa, to Chicago, Ill.; *Beer, empty beer containers*, and *brewery supplies*, Between Cassville, and Potosi, Wis., on the one hand, and, on the other, Sioux City and Council Bluffs, Iowa, Preston, Austin, Spring Valley, and Winona, Minn., points in that part of Iowa (except Dubuque) on and East of U.S. Highway 69, and points in that part of Illinois on and North of U.S. Highway 36.

Sub-15—*Meats, meat products and meat by-products, and articles, distributed by meat packinghouses*, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and

766 (except hides, skins, and pieces thereof), From Dubuque, Iowa, to Milwaukee, Wis.; Sub-18—*Meats, meat products, and meat by-products,* and *articles distributed by meat packinghouses,* as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), From Dubuque, Iowa, to points in Wisconsin (except Milwaukee, Wis., and points in the Milwaukee, Wis., Commercial Zone as defined by the Commission). Restriction: The authority is restricted to the transportation of traffic originating at *by-products,* and *articles distributed by meat packinghouses,* as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates;* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), From the plant sites and storage facilities of Dubuque Packing Company, at or near Dubuque, Iowa, to points in Indiana and Illinois, Restriction: The authority is restricted to the transportation of shipments originating at the above-named origins and destined to the named destinations; Sub-23—*Meats, meat products, meat by-products, articles distributed by meat packinghouses, and such commodities as are used by meat packers* in the conduct of their business when destined to and for use by meat packers as described in Sections A, C, and D of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk, in tank vehicles), Between the plant and warehouse facilities of the Dubuque Packing Company at or near Dubuque, Iowa, and Duluth, Minn., restricted to the transportation of shipments originating at or destined to the above origin and destination points; From points in Wisconsin to Dubuque, Iowa, restricted to the transportation of shipments destined to Dubuque, Iowa. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76669 filed July 20, 1976. Transferee: SANTO CONTINO and JAMES GUARIGLIA, a partnership, 433 Murray Hill Parkway, East Rutherford, New Jersey, 07073. Transferor: Daleo Trucking Co., Inc., 71 Warren Street, Paterson, New Jersey, 07524. Applicants' Representative: John M. Zachara, P.O. Box Z, Paterson, New Jersey 07509. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC-129737, issued December 16, 1970, as follows: General commodities, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, commodities requiring special equipment and those injurious or contaminating to other lading, Between New York, N.Y., on the one hand, and, on the other, Paterson and Passaic, N.J.

Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.76-24057 Filed 8-16-76;8:45 am]

[Notice No. 10]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

AUGUST 17, 1976.

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 C.F.R. 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 August 30, 1976.

Pursuant to Section 17(8) 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-75836. By order of July 1, 1976, the Commission, Division 3, acting as an Appellate Division, approved the transfer to C & E Trucking Co., Inc., Paramount, Calif., of that portion of Certificate No. MC-108398 Sub-33 issued by the Commission, March 15, 1965, to Ringsby-Pacific Ltd., Littleton, Colo., authorizing the transportation of machinery, materials, supplies, and equipment incidental to, or used in, mining, milling, building construction, and highway building and maintenance, requiring special equipment, between points in California south of a specified line on the one hand, and, on the other, north of said line; machinery, materials, supplies, and equipment incidental to, or used in, mining, milling, building construction, and highway building and maintenance, between points in a described area in California on the one hand, and, on the other, points in California outside said area; between points in California on the one hand, and, on the other, points in Nevada, and between points in Nevada; and structural steel, between San Francisco, Calif., and points within 20 miles of San Francisco on the one hand, and, on the other, points in Nevada; and all of the above-described authority is subject to specified restrictions.

Jerry Solomon Berger, Esquire, 9454 Wilshire Boulevard, Beverly Hills, Calif. 90212.

No. MC-FC-76121. By order of July 11, 1976, the Motor Carrier Board approved the transfer of Mosaic Trucking Company, Inc., Avanel, N.J., of the operating rights in Certificate No. MC-134962 issued January 8, 1971, to Fred Tamasco, doing business as Fred's Delivery Service, Irvington, N.J., authorizing the transportation of general commodities, with exceptions, between points is Essex County, N.J., on the one hand, and, on the other, New York, N.Y.

Edward L. Nehez, 744 Broad St., Newark, N.J., 07102, representative for transferee.

Robert B. Pepper, 168 Woodbridge Ave., Highland Park, N.J. 08904, representative for transferor.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.76-24053 Filed 8-16-76;8:45 am]

[Ex Parte No. MC-43]

RINGBY-PACIFIC LTD.

Lease and Interchange of Vehicles by Motor Carriers

AUGUST 12, 1976.

At a Session of the Interstate Commerce Commission, Motor Carrier Leasing Board, held at its office in Washington, D.C., on the 29th day of July, 1976.

It appearing, That a petition has been filed by Ringsby-Pacific Ltd. (MC 108398 and various subs), and Arizona-Pacific Tank Line (MC 109584 and numerous subs), under common control, for waiver of paragraph (c) of Section 1057.4 of the Lease and Interchange of Vehicles Regulations (49 CFR 1057), concerning equipment leased between petitioners;

It further appearing, That petitioners maintain a jointly supervised program applying the same standards of inspection and maintenance to equipment in accordance with the motor carrier safety regulations of the U.S. Department of Transportation;

It further appearing, That the Department offers no objection to granting the petition;

It is ordered, That waiver of paragraph (c) of Section 1057.4, be, and, it is hereby granted provided that the equipment is inspected on the day it is to be leased and found to meet the requirements of the motor carrier safety regulations of the U.S. Department of Transportation and that petitioners remain in satisfactory compliance with those regulations and under common control.

By the Commission, Motor Carrier Leasing Board, Members Teeple and Sibbald.

ROBERT L. OSWALD, *Secretary.*

[FR Doc.76-2405 Filed 8-16-76;8:45 am]

[AB 122]

TERMINAL RAILROAD ASSOCIATION OF ST. LOUIS

Abandonment of Operation

AUGUST 4, 1976.

The Interstate Commerce Commission hereby gives notice that its Environmental Affairs Staff has concluded that the proposed abandonment by the Terminal Railroad Association of St. Louis of St.

Louis Union Station in St. Louis, Mo., if approved by the Commission, does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, et seq., and that preparation of a detailed environmental impact statement will not be required under section 4332(2)(C) of the NEPA.

It was concluded, among other things, that the proposed abandonment, coupled with relocation of Amtrak passenger service to an alternate facility still to be constructed, will have a negligible impact on the environment since there will be no diversion to less efficient transport modes and the number of rail miles traveled will remain essentially unchanged.

Although Union Station, a site listed on the National Register of Historic Places, will be converted into a multifunctional commercial complex, current plans contemplate retention of the station's exterior essentially without change and renovation of the building's interior in a manner conforming with the original design. In light of these plans, there should not be an adverse effect on the station's historical attributes.

Commercial development of the station property is expected to have a beneficial impact on community development because it will encourage tourism and create new jobs.

This conclusion is continued in a staff-prepared environmental threshold assessment survey, which is available on request to the Interstate Commerce Commission, Office of Proceedings, Washington, D.C. 20423; telephone 202–275–7011.

Interested persons may comment on this matter by filing their statements in writing with the Interstate Commerce Commission, Washington, D.C. 20423, on or before September 15, 1976.

It should be emphasized that the environmental threshold assessment survey represents an evaluation of the environmental issues in the proceeding and does not purport to resolve the issue of whether the present or future public convenience and necessity permit discontinuance of the line proposed for abandonment. Consequently, comments on the environmental study should be limited to discussion of the presence or absence of environmental impacts and reasonable alternatives.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.76-24058 Filed 8-16-76;8:45 am]

TRANSPORTATION OF "WASTE" PRODUCTS FOR REUSE OR RECYCLING

Special Certificate Letter Notice(s)

The following letter notices request participation in a Special Certificate of Public Convenience and Necessity for the transportation of "waste" products for reuse or recycyling in furtherance of a recognized pollution control program under the Commission's regulations (49 CFR 1062) promulgated in "Waste" Products, Ex Parte No. MC–85, 124 MCC 583 (1976).

An original and one copy of protests against applicant's participation may be filed with the Interstate Commerce Commission within 20 days from the date of this publication. A copy must also be served upon applicant or its representative. Protests against the applicant's participation will not operate to stay commencement of the proposed operation.

If the applicant is not otherwise informed by the Commission, operations may commence September 16, 1976, subject to its tariff publication effective date.

P–5–76 (Special Certificate—Waste Products), filed August 8, 1976. Applicant: DANNY HERMAN TRUCKING, INC., 15626 Old Valley Blvd., City of Industry, Calif. 91744. Authority sought to operate pursuant to a certificate of public convenience and necessity authorizing operations in interstate or foreign commerce, as a *common carrier* by motor vehicle, over irregular routes, in the transportation of *waste products for recycling or reuse*, between points in the United States (including Alaska, but excluding Hawaii), in furtherance of a recognized pollution control program sponsored by Industrial Silver Company of Fontana, Calif., for the purpose of recovery of waste products containing silver for recycling.

By the Commission.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.76-24055 Filed 8-16-76;8:45 am]

federal register

TUESDAY, AUGUST 17, 1976



PART II:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

NEW ANIMAL DRUG APPLICATIONS

Proposals, Withdrawal of Proposals and Opportunities for Hearings

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 510, 526, 540, 556 and 558]

[Docket Nos. 76N—0173, 0228, 0229, 0230]

FURAZOLIDONE, NIHYDRAZONE, FURALTADONE, NITROFURAZONE

Withdrawal of Proposals and Notice of Proposed Rule Making

Elsewhere in this issue of the FEDERAL REGISTER, the Director of the Bureau of Veterinary Medicine of the Food and Drug Administration (FDA) is issuing notices of opportunity for hearing on proposals to withdraw approval of new animal drug applications (NADA's) Nos. 12–738 and 14–283 (formerly FDC–D–283; now Doc. No. 76N–0229), and NADA No. 65–059 for the use of furaltadone (NF–260); NADA Nos. 13–195 and 13–200 (formerly FDC–D–282; now Doc. No. 76N–0228) for the use of nihydrazone (NF–64); and NADA Nos. 6–395, 6–475, 6–649, 7–801, 8–129, 8–142, 8–324, 8–410, 8–529, 8–784, 9–013, 9–415, 10–741 and 11–154 (formerly FDC–D–280; now Doc. No. 76N–0230), for the use of nitrofurazone (NF–7) in food-producing animals in accordance with section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 306b(e)(1)(B)) on the grounds that new evidence not available to him when the applications were approved, evaluated together with the evidence available to him at the time of the approval, shows that those drugs are not shown to be safe for use under either the approved or currently labeled conditions of use. These notices, in addition to that published in the FEDERAL REGISTER of May 13, 1976 (41 FR 19907), regarding furazolidone, constitute due notice that furazolidone, furaltadone, nihydrazone and nitrofurazone are new animal drugs pursuant to section 201(w)(1) of the act (21 U.S.C. 321(w)(1)).

Consistent with this action, the Director is hereby withdrawing the proposal on furaltadone published in the FEDERAL REGISTER of August 4, 1971 (36 FR 14335), and those covering nihydrazone and nitrofurazone published in the FEDERAL REGISTER of March 31, 1971 (36 FR 5918) and is reproposing to revoke the regulations on which these drugs rely as a condition of their approval. Interested persons may submit comments on or before September 16, 1976.

The Director has reviewed the potential environmental impact of the proposal to withdraw approval of NADA's for furaltadone (NF–260); for nitrofurazone (NF–7) and nihydrazone (NF–64) which are subjects of companion notices published elsewhere in this issue of the FEDERAL REGISTER; and for furazolidone (NF–180) which was the subject of notices published in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906 and 19907). He has concluded that the proposed action against these four drugs would not significantly affect the quality of the human environment. An environmental impact analysis report and assessment is on file at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

The Director has carefully considered the inflation impact of the proposed action against the four nitrofuran drugs. Since furazolidone (NF–180) accounts for approximately 97 percent of the usage of nitrofuran compounds in food-producing animals, his review of the inflation impact focused only on the uses of furazolidone. A major inflation impact has been found, as defined in Executive Order 11821, OMB Circular A–107, and the Guidelines issued by the Department of Health, Education, and Welfare. Copies of the inflation impact statement on nitrofurans are on file with the Hearing Clerk, Food and Drug Administration. The major conclusions found in the inflation impact statement are summarized in the May 13, 1976 FEDERAL REGISTER notice concerning furazolidone (NF–180) (41 FR 19906).

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.29) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), the Director proposes that Parts 510, 526, 540, 556, and 558 of Chapter I of Title 21 of the Code of Federal Regulations be amended, taking into consideration the specific revocations related to furazolidone referred to in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906; formerly FDC–D–281, now Doc. No. 76N–0173), in addition to those relating to furaltadone, nihydrazone, and nitrofurazone, as follows:

§ 510.515 [Amended]

1. Section 510.515 *Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act* is amended:

a. By revoking paragraphs (a) (4) and (5);

b. By revoking and reserving paragraph (b) (11) and (15); by redesignating paragraph (b) (17) (i) as (b) (17) and by revoking paragraph (b) (17) (ii);

c. By revoking and reserving in the table in paragraph (c), items 8, 9, and 10.

§ 526.1014 [Revoked]

2. By revoking § 526.1014 *Furaltadone.*

3. By revising § 540.274c(a) (1) and (4), to delete references to furaltadone, as follows:

§ 540.274c Procaine penicillin G in oil.

(a) * * *

(1) *Standards of identity, strength, quality, and purity.* It is exempt from the potency requirement in § 440.274a(a) (1) of this chapter. It is not required to be sterile if it is packaged and labeled solely for udder instillations of cattle. If it is packaged and labeled solely for udder instillations of cattle, the penicillin used is exempt from the requirements of § 40.74a(a) (1) (ii), (iii), and (iv) of this chapter.

* * * * *

(4) *Requests for certification; samples.* If the batch of procaine penicillin in oil is intended solely for udder instillations of cattle, test results for toxicity, sterility, and pyrogen are not required.

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§ 540.380a [Amended]

4. By deleting from paragraph (a) (1) of § 540.380a *Penicillin ointment* the second sentence, "If it is intended solely for topical veterinary use and not for udder instillation in dairy animals and is conspicuously so labeled, it may contain nitrofurazone."

§ 540.874g [Revoked]

5. By revoking § 540.874g *Procaine penicillin G—furaltadone.*

§ 556.280 [Revoked]

6. By revoking § 556.280 *Furaltadone.*

§ 556.290 [Revoked]

7. By revoking § 556.290 *Furazolidone.*

§ 556.450 [Revoked]

8. By revoking § 556.450 *Nihydrazone.*

9. By amending § 558.15 by deleting references to nitrofuran in the section heading, in paragraph (a), in the introductory text of paragraph (b), and in (b) (1) and (3); by deleting from the table in paragraph (g) (1) the entries for Norwich Pharmacal, and for Hess & Clark and Norwich Pharmacal Co., and by deleting from the table in paragraph (g) (2) the entries for Norwich Pharmacal Co.; as amended ,§ 558.15 (a), (b) introductory text), (b) (1) and (3), and the tables in (g) (1) and (2) read as follows:

§ 558.15 Antibiotic and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic and sulfonamide drugs pursant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, pencillin, and the sulfonamides; for all other antibiotics by October 17, 1973. The Food and Drug Administration encourages sponsors to consult with the Bureau of Veterinary Medicine on protocol design and plans for future studies.

* * * * *

(3) By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

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(g) * * *

(2) * * *

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Commercial Solvents Corp., Thompson-Hayward Chemical Co.	Zinc bacitracin	Chickens, turkeys, swine, pheasants, and quail.	Sec. 558.78	Sec. 558.78.
Do	do	Cattle	Sec. 558.78	Sec. 558.78.
S. B. Penick & Co., Diamond Shamrock Chemical Co.	Bacitracin methylene disalicylate	Chickens, turkeys, and swine.	Sec. 558.76	Sec. 558.76.
Do	do	Cattle	Sec. 558.76	Sec. 558.76.
Do	do	do	Sec. 558.76	Sec. 558.76.
Elanco Products Co	Hygromycin B	Chickens and swine.	Sec. 558.274	Sec. 558.274.
Do	Tylosin	Chickens, swine, and beef cattle.	Sec. 558.625	Sec. 558.625.
Abbott Laboratories	Erythromycin	Chickens, turkeys, and swine.	Sec. 558.248	Sec. 558.248.
The Upjohn Co	Lincomycin	Chickens	Sec. 558.325	Sec. 558.325.
Pfizer, Inc	Oleandomycin	Chickens, turkeys, and swine.	Sec. 558.435	Sec. 558.435.
Hoechst Pharmaceuticals.	Bambermycins	Chickens	Sec. 558.95	Sec. 558.95.
Elanco Products Co	Tylosin	Swine	Sec. 558.630	Sec. 558.630.
Do	Sulfamethazine	do	Sec. 558.630	Sec. 558.630.
American Cyanamid Co., Diamond-Shamrock Chemical Co., Hess & Clark, Rachelle Labs, Inc., and Vitamin Premixers of Omaha.	Chlortetracycline	Chickens, turkeys, swine and cattle.	Sec. 558.128	Sec. 558.128.
Merck Sharp & Dohme Research Labs.	Procaine penicillin.	Chickens, turkeys, swine, pheasant, and quail.	Sec. 558.460	Sec. 558.460.
E. R. Squibb & Sons, Inc.	do	do	Sec. 558.460	Sec. 558.460.
Merck Sharp & Dohme Research Labs.	Sulfaquinoxaline	Chickens	Sec. 558.460	Sec. 558.460.
Do	do	Turkeys	Continuously, 0.0125 to 0.025 pct.	Aid in prevention of coccidiosis due to *Eimeria tenella, E. necatrix, E. acervilina, E. brunetti, E. maxima.*
Do	do	Rabbits	Continuously, 0.0175 pct.	Aid in the prevention of coccidiosis due to *Eimeria meleagrides, E. meleagrimites* and *E. adenocides.*
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline	Chickens and turkeys.	Continuously, 0.025 pct.	Aid in prevention of coccidiosis due to *Eimeria stirdae, E. perforans.*
Do	do	Swine (10 to 30 lb).	Sec. 558.450	Sec. 558.450.
Do	do	Swine (30 to 200 lb).	25 to 50 g/ton	To increase rate of gain and improve feed efficiency.
Do	do	Swine	7½ to 10 g/ton	Do.
Do	do	do	50 g/ton	As an aid in the prevention of bacterial enteritis, also known as scours, baby pig diarrhea, vibrio dysentery, bloody dysentery, and salmonellosis (necro or necrotic enteritis).
Do	do	do	100 g/ton	As an aid in the treatment of bacterial enteritis, also known as scours, baby pig diarrhea, vibrio dysentery, bloody dysentery, and salmonellosis (necro or necrotic enteritis).

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Do	do	do	50 to 150 g/ton	As an idain the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.
Do	do	do	500 g/ton	In presence of porcine leptospirosis reduces instances of abortion, gives higher survival rate, heavier and healthier newborn pigs, reduces urinary shedding of leptospirae and aids in maintenance of normal weight gains and feed consumption. Feed 7 to 14 d, approximately 1 mo before farrowing.
Do	do	Calves	0.05 to 0.1 mg/lb of body weight daily or 25 to 75 mg per head daily.	To increase rate of gain and improve feed efficiency.
Do	do	do	0.5 mg/lb of body weight daily or in complete feed at 50 g/ton.	As an aid in the prevention of bacterial diarrhea.
Do	do	do	0.5 to 5.0 mg/lb of body weight daily or complete feed at 50 g/ton.	As an aid in the treatment of bacterial diarrhea.
Do	do	Cattle	75 to 80 mg per head daily.	As an aid in reducing incidence and severity of bloat. As an aid in reducing incidence and severity of liver abscesses (for cattle weighing over 400 lb). To increase rate of gain and improve feed efficiency. As an aid in increasing milk production in lactating dairy cows.
Do	do	do	0.1 to 0.5 mg/lb of body weight daily.	As an aid in the prevention of bacterial diarrhea.
Do	do	do	0.5 to 5.0 mg/lb of body weight daily.	As an aid in the treatment of bacterial diarrhea, also known as scours.
Do	do	do	0.5 to 2.0 g per head daily.	For the prevention and treatment of the early stages of shipping fever complex. Oxytetracycline is effective prophylaxis when fed 3 to 5 d preceding shipment and/or 3 to 5 d following arrival in feedlots. For treatment of shipping fever, these levels should be fed at onset of the disease symptoms until symptoms disappear.
Do	do	Sheep	10 to 20 g/ton	To increase rate of gain and improve feed efficiency during finishing period.
Do	do	do	50 g/ton	As an aid in the prevention of bacterial diarrhea, also known as scours, lamb dysentery, and white scours of lambs.
Do	do	do	100 g/ton	As an aid in the treatment of bacterial diarrhea, also known as scours, lamb dysentery, and shite scours of lambs.
Do	do	do	25 mg per head daily.	As an aid in reduction of losses due to enterotoxemia, also known as overeating disease.
Pfizer, Inc	Penicillin	Chickens, turkeys, and swine.	Secs. 558.460 and 510.515 of this chapter.	Secs. 558.460 and 510.515 of this chapter.
Do	Penicillin and streptomycin.	do	do	Do.
American Cyanamid Co.	Chlortetracycline	Cattle	Sec. 558.128	Sec. 558.128.
Do	Sulfamethazine	do	Sec. 558.128	Sec. 558.128.
Merck Sharp & Dohme Research Labs.	Procaine penicillin and streptomycin sulfate.	Sec. 558.460	Sec. 558.460	Sec. 558.460.
Abbott Laboratories	Erthromycin	Cattle	37 mg per head per day.	Sec. 558.248.
Hoffman-La Roche, Inc.	Sulfadimethoxine and ormetoprim.	Chickens and turkeys.	Sec. 558.575	Sec. 558.575.
Pfizer, Inc	Oxytetracycline and neomycin.	Chickens, turkeys, swine, and calves.	As provided in paragraph (g)(2) of this section.	As provided in paragraph (g)(2) of this section.
American Cyanamid Co. and Rachelle Labs, Inc.	Chlortetracycline, sulfamethazine, and penicillin.	Swine	do	Do.
Diamond Shamrock Chemical Co.	Chlortetracycline, sulfathiazole, and penicillin.	do	do	Do.

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Do	Chlortetracycline	do	10 to 50 g/ton	Enhancement of growth and feed efficiency.
Do	Arsanilic acid	do	0.005 to 0.01 pct	Do.
American Cyanamid Co.	Chlortetracycline and sulfamethazine.	Cattle	Sec. 558.128	Sec. 558.128.
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline	Chickens	50 g/ton	Prevention of diseases from oxytetracycline susceptible organisms during periods of stress. As aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	Chickens (first 2 weeks).	50 to 100 g/ton	Prevention of early chick mortality due to oxytetracycline-susceptible organism. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Necomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	Chickens	50 to 100 g/ton	To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at time of stress: As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, culling, extreme temperature changes, and worming; to improve livability of progeny when losses are due to oxytetracycline-susceptible organisms, to improve egg shell quality, prevention of blue comb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	do	100 to 200 g/ton	Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Pfizer, Inc	Oxytetracycline	Turkeys	50 g/ton	As an aid in the prevention of disease from oxytetracycline-susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	do	50 to 100 g/ton	To extend period of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and to improve egg shell quality prevention of hexamitiasis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	Turkeys (first 4 weeks).	50 to 100 g/ton	As an aid in the prevention of early poult mortality due to oxytetracycline - susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	do	100 to 150 g/ton	As an aid in reducing mortality in birds which have suffered an attack of airsacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).
Do	Neomycin base	do	35 to 100 g/ton	Do.
Do	Oxytetracycline	Turkeys	100 to 150 g/ton	As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 100 g/ton	Do.
Do	Oxytetracycline	do	100 to 200 g/ton	Control of blue comb (mud fever or nonspecific enteritis), infectious sinusitis and hexamitiasis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	do	200 g/ton	Control of infectious synovitis. For the treatment of bacterial enteritis and blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	70 to 140 g/ton	Do.
Pfizer, and Vitamin Premixers of Omaha.	Oxytetracycline	Swine	50 g/ton	As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibrionic dysentery, bloody dysentery and salmonellosis (necro or necrotic enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	do	50 to 150 g/ton	As an aid in the maintenance of weight gains and feed consumption in the presence of atrophic rhinitis. As an aid in the treatment of bacterial enteritis.
Do	Neomycin base	do	70 to 140 g/ton	Do.
Pfizer, Inc	Oxytetracycline	Calves	50 g/ton	As an aid in the prevention of bacterial enteritis (scours).
Do	Neomycin base	do	35 to 140 g/ton	Do.
Do	Oxytetracycline	do	100 g/ton	As an aid in the treatment of bacterial enteritis (scours).
Do	Neomycin base	do	70 to 140 g/ton	Do.
Do	Oxytetracycline	do	8 to 100 mg/gal reconstituted milk replacer.	As an aid in the prevention of bacterial diarrhea (scours).
Do	Neomycin base	do	100 to 200 mg/gal reconstituted milk replacer.	Do.
Do	Oxytetracycline	do	40 to 200 mg/gal reconstituted milk replacer.	Do.
Do	Neomycin base	do	200 to 400 mg/gal reconstituted milk replacer.	Do.
The Upjohn Co	Lincomycin, amprolium, and ethopabate.	Chickens	Secs. 558.58 and 558.325.	Secs. 558.58 and 558.325.
Do	Lincomycin and zoalene.	do	Secs. 558.325 and 558.680.	Secs. 558.325 and 558.680.
Do	Lincomycin, amprolium, ethopabate, and 3-nitro-4-hydroxyphenylasonic acid.	do	Secs. 558.58 and 558.325 and 558.530.	Secs. 558.58 and 558.325 and 558.530.
Do	Lincomycin, monensin, and 3-nitro-4-hydroxyphenylarsonic acid.	do	Secs. 558.325 and 558.355 and 558.530.	Secs. 558.325 and 558.355 and 558.530.
Merck Sharp & Dohme Research Labs. and Pfizer, Inc.	Procaine penicillin.	Chickens and turkeys.	2.4 to 7.5 g/ton	Sec. 558.460.
Do	Streptomycin	do	12.0 to 37.5 g/ton	Sec. 558.460.
Do	Procaine penicillin.	Chickens	3.75 to 7.5 g/ton	Sec. 558.460.
Do	Streptomycin	do	18.75 to 37.5 g/ton	Sec. 558.460.
Do	Procaine penicillin.	do	3.75 to 30 g/ton	Sec. 558.460.
Do	Streptomycin	do	18.75 to 150 g/ton	Sec. 558.460.
Do	Procaine penicillin.	Turkeys	15 to 30 g/ton	Sec. 558.460.
Do	Streptomycin	do	75 to 150 g/ton	Sec. 558.460.
Do	Procaine penicillin.	Chickens	2.4 to 25 g/ton	Sec. 510.515 of this chapter.

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Do	Streptomycin	do	15 to 75 g/ton	Do.
Do	Procaine penicillin.	Swine	1.5 to 7.5 g/ton	Sec. 558.460.
Do	Streptomycin	do	7.5 to 37.5 g/ton	Sec. 558.460.
Do	Procaine penicillin.	do	7.5 to 45 g/ton	Sec. 558.460.
Do	Streptomycin	do	37.5 to 225 g/ton	Sec. 558.460.
Do	Procaine penicillin.	do	5 to 25 g/ton	Sec. 510.515 of this chapter.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Merck Sharp & Dohme Research Labs.	Procaine penicillin.	do	1.5 to 7.5 g/ton	Do.
Do	Streptomycin	do	7.5 to 37.5 g/ton	Do.
Do	Arsanilic acid	do	45 to 90 g/ton	Do.
Do	Nicarbazin	Chickens	0.01 to 0.02 pct	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	Nicarbazin	do	0.01 to 0.02 pct	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Nicarbazin	do	0.01 to 0.02 pct	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 pct	Do.
Do	Nicarbazin	do	0.01 to 0.02 pct	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.025 pct	Do.
Do	Amprolium	Chickens and turkeys.	0.0125 to 0.025 pct	Sec. 558.55
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.55.
Do	Amprolium	Chickens	0.0125 to 0.025 pct	Sec. 558.55.
Do	Ethopabate	do	0.0004 pct	Sec. 558.55.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.55.
Do	Amprolium	do	0.0125 to 0.025 pct	Secs. 558.55 and 558.530.
Do	Ethopabate	do	0.0004 pct	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 pct	Do.
Do	Amprolium	Chickens and turkeys.	0.004 to 0.025 pct	Sec. 558.55.
Do	Procaine penicillin	do	2.4 to 50 g/ton	Do.
Do	Amprolium	Chickens	0.004 to 0.025 pct	Secs. 558.55 and 558.530.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 pct	Do.
Do	Amprolium	do	0.0125 to 0.025 pct	Sec. 558.55.
Do	Ethopabate	do	0.0004 pct	Sec. 558.55.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Sec. 558.55.
Do	Erythromycin	do	4.6 to 18.5 g/ton	Sec. 558.55.
Do	Amprolium	do	0.0125 to 0.025 pct	Sec. 558.55.
Do	Erythromycin	do	4.6 to 18.5 g/ton	Sec. 558.55.
Do	Amprolium	do	0.0125 to 0.025 pct	Sec. 558.55.
Do	Ethopabate	do	0.0004 pct	Sec. 558.55.
Do	Amprolium	do	0.012 to 0.025 pct	Sec. 558.55.
Do	Arsanilic acid	do	0.01 pct	Sec. 558.55.
Do	Erythromycin	do	4.6 to 18.5 g/ton	Sec. 558.55.
Do	Amprolium	do	0.0125 to 0.025 pct	Sec. 558.55.
Do	Arsanilic acid	do	0.01 pct	Sec. 558.55.
Do	Ethopabate	do	0.0004 pct	Sec. 558.55.
Do	Amprolium	do	0.0125 pct	Sec. 558.55.
Do	Ethopabate	do	0.004 pct	Sec. 558.55.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.55.
Do	Amprolium	do	0.0125 pct	Sec. 558.55.
Do	Ethopabate	do	0.004 pct	Sec. 558.55.
Do	Bacitracin methylene disalicylate.	do	5 to 35 g/ton	Sec. 558.55.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.00375 pct	Sec. 558.55.
Commercial Solvents Corp.	Zinc bacitracin	do	4 to 50 g/ton	Prevention of coccidiosis; Growth promotion and feed efficiency. Sec. 558.78.
Do	Amprolium	do	0.0125 to 0.025 pct	Do.
Do	Ethopabate	do	0.004 pct	Do.

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Do	Zinc bacitracin	do	4 to 50 g/ton	Prevention of coccidiosis. Growth promotion and feed efficiency. Improving pigmentation. Sec. 558.78.
Do	Amprolium	do	0.0125 to 0.025 pct	Do.
Do	Ethopabate	do	0.0004 pct	Do.
Do	3-nitro-4-hydroxy-phenylarsonic acid.	do	0.0025 to 0.005 pct	Do.
Do	Zinc bacitracin	Swine	10 to 50 g/ton	Increased rate of weight gain and improved feed efficiency.
Do	Arsanilic acid	do	0.005 to 0.01 pct	Do.
Merck Sharp & Dohme Research Labs.	Amprolium	do	0.0125 to 0.025 pct	Secs. 558.55 and 558.530.
Do	Ethopabate	do	0.0004 pct	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxy-phenylarsonic acid.	do	0.002o to 0.005 pct	Do.
Pfizer, Inc	Penicillin	Chickens and turkeys.	2.4 to 25 g/ton	Sec. 510.515 of this chapter.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Do	Penicillin	Swine	5 to 25 g/ton	Do.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Dow Chemical Co	Zoalene	Chickens	0.0125 pct	Sec. 558.680.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	3-nitro-4-hydroxy-phenylarsonic acid.	do	0.005 pct	Sec. 558.680.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	Zinc bacitracin	do	4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	3-nitro-4-hydroxy-phenylarsonic acid.	do	0.0005 pct	Sec. 558.680.
Do	Zinc bacitracin	do	4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	Penicillin	do	2.4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	3-nitro-4-hydroxy-phenylarsonic acid.	do	0.005 pct	Sec. 558.680.
Do	Penicillin	do	2.4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	Arsanilic acid	do	0.01 pct	Sec. 558.680.
Do	Bacitracin methylene disalicylate or zinc bacitracin.	do	4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.0125 pct	Sec. 558.680.
Do	Arsanilic acid	do	0.01 pct	Sec. 558.680.
Do	Penicillin	do	2.4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.004 to 0.0125 pct	Sec. 558.680.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.680.
Do	Zoalene	do	0.004 to 0.0125 pct	Sec. 558.680.
Do	3-nitro-4-hyrdoxy-phenylarsonic acid.	do	0.005 pct	Sec. 558.680.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Sec. 558.680.
Whitmoyer Labs. Inc	Carbarsone and bacitracin.	Turkeys	Sec. 121.310 of this chapter.	Sec. 558.120.

§ 558.262 [Revoked]

10. By revoking § 558.262 *Furazolidone.*

§ 558.368 [Revoked]

11. By revoking § 558.368 *Nihydrazone.*

§ 558.370 [Revoked]

12. By revoking § 558.370. *Nitrofurazone.*

Interested persons may, on or before September 16, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the appropriate Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal, except that comments pertaining to issues which are the subject of the related notice of opportunity for hearing published elsewhere in this issue of the FEDERAL REGISTER shall be filed in accordance with that notice. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday. Comments that have been received in response to th enotice published in the FEDERAL REGISTER of May 13, 1976, regarding furazolidone, will be included with those comments received in response to this notice.

Dated: August 9, 1976.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc.76-23620 Filed 8-10-76;11:19 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 76N-0172]

HESS AND CLARK ET AL.

Furazolidone (NF-180); Opportunity for Hearing on Proposal To Withdraw Approval of Certain New Animal Drug Applications; Corrections

In FR Doc. 76-13969 appearing on page 19907 in the FEDERAL REGISTER of Thursday, May 13, 1976, the following corrections are made:

1. On page 19907 in the second column, the fourth full paragraph is corrected by deleting the last sentence which reads, "Copies of these studies have been placed on file with the Hearing Clerk, Food and Drug Administration." The studies referred to in this sentence are part of a new animal drug application and are therefore confidential under § 514.111 (21 CFR 514.111).

2. On page 19909 in the first column, in paragraph (4), the words "Project No. 375.09E" are corrected to read, "Project No. 475.09E."

3. On page 19920 in the second column, in paragraph 3., "Vol. 16" is corrected to read, "Vol. 13."

4. On page 19918 in the second column, in the second full paragraph, "May 16, 1972" is corrected to read, "May 26, 1972."

Dated: August 9, 1976.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc.76-23619 Filed 8-10-76;11:19 am]

[Docket No. 72N-0231]

HESS & CLARK, ET AL.

Furaltadone (NF-260); Opportunity for Hearing on Proposal To Withdraw Approval of Certain New Animal Drug Applications

The Director of the Bureau of Veterinary Medicine of the Food and Drug Administration (FDA) is issuing a notice of opportunity for hearing on a proposal to withdraw approval of approved new animal drug applications (NADA's) Nos. 12-738, 14-283 and 65-059 for the use of furaltadone (NF-260) in food-producing animals in accordance with section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b (e)(1)(B)) (hereinafter, "the act") on the grounds that new evidence not available when the applications were approved, evaluated together with the evidence available at the time of approval, shows that furaltadone is not shown to be safe for use under either the approved or currently labeled conditions of use. Holders of approved NADA's have until September 16, 1976 to submit requests for a hearing in accordance with § 514.200 (21 CFR 514.200).

In FR Doc. 76-23620 appearing elsewhere in this issue of the FEDERAL REGISTER, the Director is issuing a notice of proposed rule making to revoke the appropriate provisions of sections affected by the proposed withdrawal.

Furaltadone (NF-260) is a member of a class of chemicals called "nitrofurans," which have prophylactic and therapeutic uses in food-producing animals as antibacterial and antiprotozoan agents. In addition to furaltadone (NF-260), which is the subject of this notice, there are three other nitrofurans that are used in food-producing animals and are or have been subject to agency action: Nitrofurazone (NF-7) and nihydrazone (NF-64), which are subjects of companion notices in this issue of the FEDERAL REGISTER; and furazolidone (NF-180), which was the subject of notices in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906, 19907). A fifth nitrofuran, furamazone (NF-84), is not at this time the subject of contemplated agency action for withdrawal. Another proposed agency action concern-furaltadone (NF-260) was published in the FEDERAL REGISTER of August 30, 1974 (39 FR 31678).

Furaltadone (NF-260) was approved in 1962 for treating mastitis in dairy cows via infusion into the mammary gland. It is used in products that are marketed in single-dose units containing 500 milligrams of furaltadone and as a combination drug with each single-dose unit containing 50 milligrams of furaltadone and 100,000 units of procaine penicillin G. The approved treatment in lactating cows is the infusion of one squeeze jet in each infected quarter (an individual mammary gland, including the teat) immediately after milking. Medication remains in the quarter until the next milking. Treatment is repeated after each milking up to a limit of three infusions. For dry cows with a history of mastitis, one squeeze jet is infused into each quarter at the end of the last normal lactation. A second infusion may be given after 5 days.

The NADA's for furaltadone alone are approved with a 36-hour withdrawal for milk, which involves discarding the milk for three milkings. The sponsors, Norwich Pharmacal Co., Division of Morton-Norwich Products, Inc., and Hess & Clark, currently a Division of Rhodia, Inc., voluntarily revised the labels in January 1971, to require a 48-hour withdrawal for milk, which involves discarding the milk from four milkings. The furaltadone combination with penicillin carries a 96-hour withdrawal or eight-milkings discard.

The Food and Drug Administration issued a notice of opportunity for hearing, published in the FEDERAL REGISTER of August 4, 1971 (36 FR 14343), proposing to withdraw approval of NADA's for furaltadone (NF-260) on grounds that:

> Information available to the Commissioner establishes that the drugs, when administered to laboratory animals, have been shown to produce tumors. The drugs are, therefore, not considered to be safe for use in the absence of appropriately sensitive methods of analysis to establish their absence in food derived from treated animals.

Similar notices were published for furazolidone in the FEDERAL REGISTER of August 4, 1971 (36 FR 14343) and for nitrofurazone (NF-7) and nihydrazone (NF-64) on March 31, 1971 (36 FR 5926 and 5927). The history leading to the publication of the 1971 notices is discussed in the May 13, 1976 notice for furazolidone (NF-180).

Norwich and Hess & Clark responded to the August 4, 1971 notice concerning furaltadone (NF-260) by filing requests for a hearing. Norwich assured FDA that it had adequate methods of analysis to determine residues and adequate data to show that under the currently labeled conditions of use, the drugs were safe. In addition, Norwich set forth a hypothesis that nitrofurans were not primary tumorigens but stimulated spontaneous tumor growth by disrupting the normal hormone balance.

Norwich has continued to submit data pertaining to the use of furaltadone (NF-260) in food-producing animals. The Food and Drug Administration has determined that new evidence, evaluated together with the evidence available when the approvals were granted, fails to demonstrate that either the approved or currently labeled uses of furaltadone are shown to be safe. The Director is withdrawing the August 4, 1971 notice of opportunity for hearing concerning furaltadone (NF-260), and is issuing this new notice, which presents in detail all of the evidence now available to him and the basis on which he proposes to withdraw approval of all uses of furaltadone in food-producing animals in accordance with section 512(e)(1)(B) of the act.

Section 512(e)(1)(B) of the act requires that FDA withdraw approval of an NADA when "new evidence * * * evaluated together with the evidence available * * * when the application was approved, shows that such drug is not shown to be safe * * *." Under this provision, the new evidence and the evidence submitted at the time the application was approved must be evaluated to determine whether all of the requirements for safety contained in section 512 of the act continue to be fulfilled.

THE DETERMINATION OF "SAFETY" IN SECTION 512

Section 512 of the act requires that the use(s) of a new drug in food-producing animals must be supported by adequate data supplied by the sponsor in applications that include, among other things, demonstration that the drug use will not result in unsafe residues in human food.

Under section 512(b) of the act, whenever a drug use may result in residues of the drug in food, an application must include not only full reports of investigations to show that the use of the drug is safe, but also a description of practicable methods for monitoring food to assure there are no unsafe residues in human food attributable to the drug use, and demonstration that the conditions of use are adequate to assure there are no unsafe residues.

Under section 512(d)(2) of the act, FDA is required, in the evaluation of the supporting safety data, to consider, among other things:

1. The probable consumption of such drug and of any substance formed in or on food because of the use of such drug, i.e., probable human consumption of residues including the parent drug and metabolites.

2. The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, i.e., toxicological effects of the compounds comprising the residues.

3. Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, i.e., establishing "safe" levels of residues using appropriate safety factors to extrapolate animal data on cumulative effects to humans.

Under section 512(d)(1)(H) of the act, additional requirements must be met if the drug is a carcinogen.

The determination of safety within the meaning of section 512 of the act for a drug whose use may result in residues in the edible products of the treated animal, whether or not the drug is a carcinogen, requires a multistep process. These steps form an orderly procedure by which information is derived to satisfy each of the three considerations stated above.

Step 1. Assessment of the total residues in edible products and the depletion of those residues with time following cessation of drug treatment in order to determine probable human consumption (section 512(b)(1) and (d)(2)(A) of the act).

Step 2. Assessment of information about the residues to determine the appropriate testing in laboratory animals required to estimate the cumulative effects of human exposure to the residues (section 512 (b)(1) and (d)(2)(A) of the Act).

Step 3. Acquisition of dose-response data in test animals to determine the cumulative effects of dietary exposure to the residue compounds from which the maximum acceptable concentration of residues in food can be established using appropriate safety factors to assure that human exposure to residues in the total diet does not exceed a level deemed safe (section 512 (b)(1) and (d)(2) (B) and (C) of the act). In the case of a carcinogenic drug, a conservative statistical extrapolation of the tumor data is used to estimate a level of residue exposure that could be considered insignificant and poses essentially no risk of cancer and operationally defines "no residue" for purposes of computing the residue assay requirements under section 512(d)(1)(H) of the act.

Step 4. Acquisition of information about the residues to (a) determine the tissue (called the target tissue) from which residues require the longest time to deplete to safe levels, and which, therefore, must be monitored by the regulatory assay, and (b) determine the compound (called the marker) that is to be measured in the regulatory assay (step 5) so that by its measurement there is assurance that no unsafe residues occur from the use of the drug (section 512 (b)(7) of the act).

Step 5. Development of a practicable method of analysis that can measure the marker in the target tissue at a concentration which assures that total residues in the daily diet of humans do not exceed the level established in step 3 as safe (section 512(b)(7) of the act).

Step 6. Demonstration that practical conditions of use can be prescribed on the label of the product to assure there will be no unsafe residues in the food products from treated animals (section 512 (b)(8) and (d)(2)(D) of the act).

Each of the steps involves principles that are essential for a determination of food safety and compliance with the requirements of the act to assure there are no unsafe residues in human food from the animal drug use. Each step builds upon the preceding step. Therefore, failure to accomplish any one of the six steps in whole or in part for any drug ordinarily will preclude a sponsor's fulfilling its obligation under the act to determine probable consumption of residues and cumulative effects of exposure, and to establish safe conditions of use with appropriate regulatory methods of analysis to control residues when deemed necessary.

New evidence concerning furaltadone (NF–260) not available when the applications were approved includes, among other things, a demonstration that furaltadone induces mammary adenocarcinomas in female rats and may be a more potent carcinogen than furazolidone (NF–180). The Director has evaluated all of the data now available, including the new data received since 1962 when NADA's for furaltadone (NF–260) were first approved and the data available to FDA at the time of approval, and has concluded that the approval of NADA's for furaltadone (NF–260) must be withdrawn under section 512(e)(1)(B) of the act because:

1. Adequate investigations have not been provided to show that the uses of furaltadone are safe, as required by section 512(b)(1) of the act. Adequate information has not been provided on the probable consumption of residues, and the cumulative effects of exposure have not been determined by appropriate tests, as required by section 512(d)(2)(A) and (B) of the act. Therefore, "safe" levels of residue cannot be determined using appropriate safety factors, as required by section 512(d)(2) (C) of the act.

2. Adequate, reliable, and practicable methods of analysis are not available for monitoring food to assure there are no unsafe residues in edible tissues and milk that are attributable to the use of furaltadone, as required by section 512 (b)(7) of the act.

3. Practical conditions of use cannot be specified in the labeling to assure there are no unsafe residues attributable to the use of furaltadone, as required by section 512(b)(8) and (d)(2)(D) of the act.

The data on which these conclusions are based are presented in the succeeding sections of this notice. The Director first describes all the relevant new evidence bearing on the determination of safety for the uses of furaltadone. Then he evaluates all the evidence before him using the six-step procedure necessary to satisfy a human safety determination for the use of furaltadone (NF–260) and to meet the considerations required in section 512 of the act.

I. New Evidence

In October 1966 and January 1967, Norwich submitted reports of the effect in rats of feeding diets containing nitrofurans for 45 weeks. These studies included tests on furaltadone (NF–260) and furazolidone (NF–180). In these studies it was shown that both furaltadone (NF–260) and furazolidone (NF–180) induced mammary tumors in female rats; that furaltadone (NF–260) caused an increase in the number of mammary adenocarcinomas (cancers) which developed in female rats compared with control rats maintained on drug-free diets; and that furaltadone (NF–260) may be a more potent tumor-inducer than furazolidone (NF–180).

Subsequently, more extensive, longer term testing of furazolidone (NF–180) was conducted, but further testing of the carcinogenic potential of furaltadone (NF–260) has not been undertaken. The more extensive testing of furazolidone (NF–180), as described in the May 13, 1976 Federal Register, shows that the drug induces cancer in both rats and mice and that the tumors and cancers were not limited to the mammary gland or the endocrine tissues of female rats.

The Director is including in this notice information available on the toxicological propertes of furazolidone (NF–180) as well as furaltadone (NF–260) because of the structural similarities of the drugs and their similar biological properties, which have been observed in the limited comparative data available. The new evidence showing that furazolidone (NF–180) is a carcinogen has a significant bearing on the Director's conclusions that the uses of furaltadone (NF–260) are not shown to be safe.

Although it is appropriate to consider data on furazolidone (NF–180) to judge the adequacy of existing data to support the safe use of furaltadone (NF–260) in food-producing animals, these data are not a substitute for the data on furaltadone (NF–260) that are required by the statute. Basic data are required for each drug, recognizing that slight differences in chemical structure can result in significant differences in metabolism, residues, and toxicity. Although comparative data on the biochemical and toxicological properties of related drugs may be useful and appropriate in making decisions about the degree of testing required for each drug to show there is no probable hazard, these data cannot be used as a substitute for the basic information necessary on each drug to determine the probable exposure to residues and cumulative effects of exposure.

A. *Carcinogenic Potential of Furaltadone.* Norwich submitted data in October

1966 and January 1967 on the cumulative effects in rats of feeding diets containing furaltadone (NF–260) for 45 weeks ("Effects of Long Term Feeding of Various Nitrofurans," October 13, 1966 and January 4, 1967, Project No. 440.07, submitted to FDA as part of a June 2, 1967, Drug Experience Report). These studies included testing in female Sprague-Dawley (Holtzman strain) rats and testing in both male and female Carworth Farms (CFE strain) rats.

1. The Sprague-Dawley female rat study: Thirty-five female Sprague-Dawley (Holtzman strain) rats were fed furaltadone at a level of about 0.15 percent (85 milligrams per kilogram (mg/kg) body weight) in their diet for 45 weeks, followed by maintenance on an unmedicated diet for an additional 8 weeks before sacrifice. A comparable control group of female rats was maintained on a furaltadone-free diet for 53 weeks. At termination of the study the animals were autopsied, and tissues were examined for histopathological lesions.

The most prominent drug-related effect was the induction of tumors in the mammary glands of the female rats. Although rats develop mammary tumors spontaneously as they age, the incidence of spontaneous mammary tumors in rats just over 1 year old, depending upon the strain of rat used, can be quite low. The furaltadone-treated female rats had an increased number of mammary tumors, particularly the number of fibroadenomas, as compared with the control rats. Even more impotrant, the furaltadone-treated female rats had an increased number of mammary adenocarcinomas compared with the control rats.

Norwich reported that no mammory tumors of any type were observed in the 33 control rats examined. It reported a total of 77 mammary tumors in 25 of the 33 furaltadone-treated rats examined for histopathology. Three of the mammary tumors were reported by Norwich as adenocarcinomas. The report did not indicate which rats had multiple tumors or whether the three adenocarcinomas were in three different rats or included any multiple malignancies.

An Ad Hoc Committee was established to review the pathology data on all the nitrofurans tested in the Sprague-Dawley rat study and the Carworth Farms rat study. One member of the Ad Hoc Committee was the director of the Eppley Institute for Research in Cancer, University of Nebraska. He and his associate pathologists reviewed the pathology slides of the mammary tissues from 33 of the furaltadone-treated rats provided by Norwich and submitted a detailed report to FDA. They did not review all of the mammary gland slides from the control rats. Each of the reviewed slides had a rat identification number, and there were several slides for each rat. However, there was no information on the number of tumors in each rat. Therefore, it was not possible, in many cases, for the pathologists to determine which slides represented different tumors in the same rat and which were different sections of a single tumor.

The Eppley pathologists diagnosed mammary adenocarcinoma in 10 of the furaltadone-treated female rats, and found apparent multiple tumors, predominantly fibroadenomas, in 25 of the treated rats. However, because the Norwich report did not indicate which 25 rats had tumors, it is not possible from the data available to determine if the tumors reported by the Eppley pathologists were from the same 25 rats in which Norwich had reported tumors. The Eppley pathologists did report a considerably higher number of rats with mammary adenocarcinoma than was reported by Norwich. However, because the Eppley pathologists did not review all of the mammary gland slides from the control rats, a comparative incidence of mammary cancer cannot be determined from the reports.

A pathologist from the Bureau of Foods of FDA, not a member of the Ad Hoc Committee, later reviewed the pathology slides of the mammary tumors from the 25 furaltadone-treated rats in which the Eppley pathologists had reported mammary tumors. From his examination of the histopathological preparations provided, he reported 4 slides of mammary fibroma from 3 rats, 70 slides of mammary fibroadenoma from 23 rats, and 14 slides of mammary adenocarcinoma from 10 rats. The mammary adenocarcinomas were diagnosed in the same 10 rats in which the Eppley pathologists had diagnosed adenocarcinoma.

The Bureau of Foods pathologist also did not have information indicating which slides were multiple sections of single tumors or which represented different tumors. He did have information on the rat identification number for each set of slides. Because the Bureau of Foods pathologist did not review all of the slides in the study, tumor incidence and the comparison of incidence with the control rats cannot be determined from his report. However, his report supports the Eppley pathologists' findings that mammary tumors were found in at least 25 of the furaltadone-treated rats, and mammary adenocarcinoma was found in at least 10 of the furaltadone-treated rats.

2. The Carworth Farms rat study: Furaltadone (NF–260) was fed to 20 male and 20 female Carworth Farms (CFE strain) rats at about 0.15 percent in the diet (67 to 84 mg/kg body weight) daily for 45 weeks, followed by maintenance on an unmedicated diet for an additional 7 weeks before sacrifice. A comparable control group of rats was maintained on a furaltadone-free diet for 52 weeks. At termination of the study the animals were autopsied, and the tissues were examined for histopathological lesions.

As in the previous Sprague-Dawley rat study, the most prominent drug-related effect seen was the induction of tumors in the mammary glands of the female rats. This included an increase in the number of mammary fibroadenomas and an increase in the number of mammary adenocarcinomas.

No mammary tumors were found by Norwich in the 15 female control and 18 male control rats examined. Norwich reported that 14 out of the 17 furaltadone-treated female rats examined had a total of 49 mammary tumors. Norwich also reported that five mammary adenocarcinomas were found in the furaltadone-treated female rats but did not report whether these adenocarcinomas were seen in five different rats or whether some of these were multiple tumors in the same rat.

The Eppley pathologists reviewed the slides of the mammary tissues from 17 furaltadone-treated rats provided by Norwich. They concluded that 5 of the furaltadone-treated female rats had adenocarcinoma of the mammary gland and that mammary tumors, primarily fibroadenomas, were present in 14 of the furaltadone-treated rats. Slides of the mammary tumors reported by the Eppley pathologists were later reviewed by the Bureau of Foods pathologist. He reported mammary tumors in each of the 14 rats. From his examination of the histopathological preparations provided, he reported 4 slides of fibroma from 4 rats, 38 slides of fibroadenoma from 8 rats, and 11 slides of adenocarcinoma from the same 5 rats in which the Eppley pathologists had reported adenocarcinoma.

Because Norwich did not report the number of rats in which mammary adenocarcinoma was found, and because the Eppley and Bureau of Foods reviewing pathologists did not review mammary tissue slides from control rats, and because the Bureau of Foods pathologist did not examine all the slides from the treated rats, the incidence of mammary cancer cannot be determined from the available reports. However, the Eppley and Bureau of Foods reviewing pathologists did concur in the finding of mammary adenocarcinoma in at least five furaltadone-treated female rats from the study.

Food and Drug Administration scientists recognize that there are uncertainties and limitations in the examination of tumors to determine if they have malignant potential. For example, in the early stages of a mammary tumor growth, the mass may be chiefly adenomatous. As the growth continues, the supporting white fibrous connective tissue may also begin to proliferate, resulting in a fibroadenoma. Later the adenomatous part of the neoplastic mass may entirely disappear, leaving a fibroma. Finally, a part of the adenoma or fibroadenoma may develop malignant tendencies and that portion may then become an adenocarcinoma. All four tumor types, i.e., adenoma, fibroadenoma, fibroma, and adenocarcinoma may be present in the same tumor mass. A small focus of adenocarcinoma in the early stage of a malignant tumor may be overlooked in the tumor growth unless adequate multiple sections of the tumor are made.

Also, unless great care is exercised in the evaluation of the spread of an adenocarcinoma of the mammary gland, the metastasis along the lymphatic routes passing through, under or near other

mammary glands may be considered to be separate primary adenocarcinomas rather than a single primary growth with multiple metastases.

The reports from Norwich indicate that furaltadone caused an increase of mammary tumors in female rats just over 1 year old and caused an increase in the number of mammary adenocarcinomas compared with control rats.

Food and Drug Administration scientists conclude that both studies show that furaltadone is tumorigenic in rats, and that the data raise questions about the carcinogenic potential and potency of furaltadone. They conclude that neither of the studies is adequate to assess the cumulative effects of exposure to furaltadone and its carcinogenic potential and potency because the studies were not of sufficient duration and the number of animals used was not sufficient. In the Sprague-Dawley rat study only female animals were used, so it is not possible to determine whether furaltadone might have produced effects in the male rats. In the Carworth Farms rat study, the number of males was too small to determine with any confidence that furaltadone did not have an adverse effect. In both studies drug treatment was for only 45 weeks and included only one dose-level. In spite of the weaknesses in the reports available, it is evident that a 45-week treatment was sufficient to induce tumors in female rats, and that some of these tumors were mammary cancers. The dose level, frequency, and duration of exposure to a compound are related not only to whether or not cancer is induced but also to the latency period before the expression of cancer. Therefore, the 45-week treatment with furaltadone is not considered a sufficient period of exposure to determine adequately the cancer potential or potency.

The Director concludes that the available data provide sufficient cause for concern that furaltadone may be a carcinogen and that adequate lifetime testing in appropriate animal species is required to evaluate its carcinogenic in potential and potency. The Director concludes that because furaltadone is a tumorigen, dose-response data in lifetime studies, using several dose levels, are necessary to develop the information required to assess the cumulative affects of exposure and to establish conditions of safe use. Although the demonstration of cancer induction may be made on the basis of testing at only one dose level and it may be possible from the results of this testing to conclude that a drug requires regulation under the provisions of section 512(d)(1)(H) of the act, dose-response data are necessary to provide information from which FDA can establish the operational definition of "no residue" for purposes of determining the required conditions for the regulatory assay for residues of a carcinogenic drug. Regardless of whether adequate testing were to show that furaltadone induced cancer or induced only benign tumors, dose-response information would be required to establish the conditions of safe use.

The Norwich data from these two studies were available at the time FDA issued the August 1971 FEDERAL REGISTER notice of opportunity for hearing on the proposed withdrawal of approvals for furaltadone (NF–260). In response to the August 1971 notice, Norwich stated that all four nitrofurans (NF–260, NF–7, NF–64, and NF–180) caused an early development of mammary tumors that were of the type normally found in aging rats, and it postulated that the nitrofurans caused these tumors only at high levels of exposure in the female rats because of disruption in the hormonal system. Norwich presented data purporting to show that the hormonal disruption resulting in the tumors involved a process not applicable to humans and that the proposed methods of analysis for control of residues were more than adequate to assure that levels of residues were below any level which might adversely affect humans.

The Norwich hormonal hypothesis is described in detail in the May 13, 1976 FEDERAL REGISTER notice on furazolidone (NF–180). The supporting information provided by Norwich for the hypothesis was primarily limited to data on furazolidone (NF–180) and some very limited comparative data on nitrofurazone (NF–7). No data were presented on furaltadone (NF–260) related to a hormonal mechanism of action.

B. *Comparative Data on Furaltadone and Furazolidone.* Norwich has provided data on furazolidone (NF–180) from the Sprague-Dawley female rat study and the Carworth Farms rat study. It has also supplied data on testing of furazolidone (NF–180) in three chronic rat studies and one mouse study; the tests are described in the May 13, 1976 FEDERAL REGISTER notice. The data have a bearing on the Director's proposed action in this notice for furaltadone (NF–260) and his decision to reject the Norwich hormonal hypothesis for furaltadone (NF–260) and furazolidone (NF–180). They also have a bearing on his decision to reject the sponsors' claims that adequate studies have been provided for furaltadone (NF–260) to support a determination that the drug uses are shown to be safe.

In the Sprague-Dawley female rat study and Carworth Farms study, furazolidone (NF–180) was also tested in the protocols using a dietary level of about 0.1 percent as compared to the furaltadone (NF–260) dietary level, which was about 0.15 percent.

In the first study, Norwich reported that 14 of the furazolidone-treated Sprague-Dawley female rats out of 32 rats examined had mammary tumors. The total number of tumors reported by Norwich was roughly half the number of tumors reported for the furaltadone-treated rats. Norwich reported 5 adenocarcinomas in the mammary glands of the furazolidone-treated rats but did not specify in which rats these were found or whether any were multiple malignancies.

The Eppley pathologists reviewed the mammary tissue slides from 32 furazolidone-treated female rats and reported tumors in 14 of the rats. The Bureau of Foods pathologist later reviewed slides of the mammary tumors from the 14 rats and reported tumors in all of these rats. Both the Eppley and Bureau of Foods pathologists reported only one mammary adenocarcinoma and one mammary squamous cell carcinoma, each in a different rat, from the slides of the furazolidone-treated rates they had examined. In contrast to these furazolidone-treated rats, the Eppley and Bureau of Foods pathologists had reported mammary adenocarcinomas in slides from 10 rats treated with furaltadone, indicating a significant increase in the number of mammary adenocarcinomas from the furaltadone-treated rats compared to the furazolidone-treated rats.

In the Carworth Farms rat study, 15 of the furazolidone-treated female rats out of 17 examined were reported by Norwich as having mammary tumors. In comparison, Norwich had reported that 14 of the female rats treated with furaltadone (NF–260) had mammary tumors. The total number of mammary tumors in the furazolidone-treated female rats was greater than the total number of mammary tumors in the furaltadone-treated female rats, but the number of mammary adenocarcinomas and the incidence of rats with adenocarcinomas was greater for the furaltadone-treated female rats compared to the furazolidone-treated female rats. Norwich reported only two mammary adenocarcinomas in the furazolidone-treated female rats, but did not designate whether these were in one or two rats. The Eppley pathologists diagnosed mammary adenocarcinomas in two furazolidone-treated female rats. The Burau of Foods pathologist also reported adenocarcinoma in the same two rats. He further diagnosed tumors from two additional rats as also showing low-grade mammary adenocarcinoma. Tumors from these two additional rats had been diagnosed as fibroadenomas by the Eppley pathologists. In contrast Norwich had reported five adenocarcinomas in the furaltadone-treated rats and the Eppley and Bureau of Foods pathologists diagnosed mammary adenocarcinomas in five of the furaltadone-treated rats, indicating an increase in the number of adenocarcinomas for furaltadone-treated rats compared to furazolidone-treated rats.

Based on these comparative data, the Director concludes that furazolidone (NF–180) and furaltadone (NF–260) qualitatively exhibit very similar tumorigenic effects in female rats. Because the dose levels of the two drugs were not the same (furaltadone (NF–260) at about 0.15 percent in the diet and furazolidone (NF–180) at about 0.1 percent in the diet) and because the studies are not adequate to assess the cumulative effects of exposure and carcinogenic potential and potency, the data are not sufficient for a precise comparison of the tumorigenic potencies. However, based on the limited comparative data available, furaltadone (NF–260) may have a greater carcinogenic potential than furazolidone (NF–180).

More definitive studies of the carcinogenic potential of furazolidone (NF–180) in male and female rats and mice provided by Norwich are described in the May 13, 1976 FEDERAL REGISTER notice. A summary of the findings from the three chronic rat studies and the mouse study include the following:

1. Furazolidone induced malignancies in both rats and mice.

2. Furazolidone also induced nonmalignant tumors.

3. In most cases, the induced malignant and nonmalignant tumors were found at the same sites.

4. There is some evidence that the induction of benign tumors is related to the induction of, or progression to, malignancies as a function of dose.

5. There are marked sex differences in the tumor responses in the rats. There are also some commonalities in the tumor sites for the male and female rats.

6. Mammary tumors were the predominant effect in the female rats.

7. Nonmammary tumors were induced in the Sprague-Dawley male rats, with no one type singularly significant. In the Fischer rats, however, several specific nonmammary tumors were induced in both male and female rats.

8. The major target tumor site in the mouse was the lung. There was no evidence of a significant difference between male and female mice in tumor response, and there were no tumorigenic effects in the endocrine tissues.

9. The induction of tumors involved not only increased incidence of animals with tumors but also an increased number of tumors per animal.

The Director has rejected the data supplied by Norwich to support the hormonal hypothesis for furazolidone (NF–180). A discussion of these data and his basis for rejection are also presented in the May 13, 1976 FEDERAL REGISTER notice. The Director also rejects the Norwich reply to the 1971 FEDERAL REGISTER notice on furaltadone (NF–260) attempting to explain the tumorigenic effects of furaltadone primarily on the basis of the furazolidone (NF–180) data relative to the hormonal hypothesis. The Director finds that the new evidence provided by the more extensive chronic testing data for furazolidone (NF–180), which shows that tumors were induced in both male and female rats and mice and were not limited to tumors of the mammary gland or the endocrine tissues, is inconsistent with the hormonal hypothesis.

Therefore, the Director concludes that the comparative data available on furazolidone (NF–180) and furaltadone (NF–260) in the Sprague-Dawley female rat study and the Carworth Farms rat study, together with the data on the four chronic studies of furazolidone (NF–180) in rats and mice, indicate that adequate testing of furaltadone (NF–260) has not been provided to assess the cumulative effects of exposure necessary for a determination of safety.

II. USES OF FURALTADONE ARE NOT SHOWN TO BE SAFE

To assess the safety of residues using criteria described in section 512(b) of the act and elaborated on in section 512(d)(2) of the act requires a multistep process that must take into account consideration of the metabolism of the drug, determination of the resulting residues, including parent drug and the metabolites, the depletion of those residues with time after drug treatment, and the cumulative effect of human ingestion of the residues. The six basic steps involved in this evaluation process have been previously described in this notice.

A. *The Amount of Total Residue in the Edible Products and the Depletion of Residues with Time Has Not Been Determined (Step 1).* When a drug is administered to an animal, the drug may be altered by the animal into a variety of compounds called metabolites. The process of alteration may be such that little residue of the parent drug remains in the animal tissue, but the amount of metabolites may be substantial. Therefore, the total residue with which FDA is concerned includes both the parent drug and the metabolites.

The nature and amount of each of the residues depend in part upon the metabolism in a particular species. Because there are species differences in metabolism, it is necessary to determine metabolism and residues in each of the species for which the drug is used. Therefore, § 514.1(b)(7)(i) (21 CFR 514.1(b)(7)(i)) includes metabolism and residue depletion studies among those kinds of studies that are used to determine residues.

Exposure to furaltadone in the diet induced mammary tumors and adenocarcinomas in female rats. It is not known whether the parent drug was the active agent or whether the responses were due to one or more active metabolites produced as a result of ingestion of the parent drug by the rats. Such lack of knowledge is not unique to furaltadone; it is typical of many tumorigenic and carcinogenic agents that the mechanism of the induction of tumors or the identification of the active agent is not known. Therefore, when considering the safety of food from furaltadone-treated animals, all drug-related residues to which humans may be exposed must be assumed to be potentially carcinogenic unless convincing evidence is presented to the contrary. Such evidence consists of not only the identification of the residues that are claimed to be safe, but also adequate toxicological studies showing that the levels of each of the identified claimed to be safe are in fact safe. All residues not identified or not shown to be safe must be considered potentially carcinogenic and must be required to be below a level of measurement that can be considered insignificant and to pose essentially no risk of cancer in humans.

The use of chemical assays to determine initially the total residues would require knowledge about what residues occur (parent drug and metabolites) and would require the availability of adequate methods of analysis to measure each one of the residues at the level of interest in the edible tissues. Therefore, this chemical approach is usually not feasible. Instead, a radiolabeled parent drug is used to provide a practical and adequate approach to the initial measurement of total residues in the edible tissues. In this approach, the drug is synthesized with a radioisotope so that when the drug is administered to the animal according to label directions, all resulting residues of potential interest can be measured in the edible products. This is accomplished by counting the radioactivity in the tissues and converting these measurements to an estimation of the amount of residue expressed as parent drug equivalents.

No data have been provided by the sponsors to measure total residues in milk or in edible tissues from furaltadone-treated animals. Similarly no data have been provided to characterize the residues occurring in the edible products. It has been shown that furaltadone is found as a residue in milk following drug treatment, as will be described in paragraph F. (step 6) below in this section, but it has not been shown what proportion of the total residue is the parent drug.

In FDA experience with the use of drugs injected into the mammary gland for treatment of mastitis, it has been shown that such drug use may result in systemic absorption leading to residues in the edible tissues as well as in the milk. No data have been supplied by the sponsors of furaltadone to show whether or not the use of furaltadone results in residues in the edible tissues.

Although no data of any type have been supplied on the metabolism of furaltadone in cows, very limited information in the following references has been provided regarding rats and dogs.

1. Paul, M. F., et al., "Studies on Distribution and Excretion of Certain Nitrofurans," Antibiotics and Chemotherapy, 10:287–302, 1960.

2. Bugard, J. A. and J. D. Conklin, "Distribution of Furaltadone in the Rat," Antibiotics and Chemotherapy, 11:89–96, 1961.

Data from these studies show that in the rat, furaltadone is absorbed from the small intestine and colon, and that in the excreta less than 5 percent of the administered dose is eliminated as the intact parent drug. The in vivo data are limited to the examination of blood and excreta and do not include any structural characterization of metabolites or the examination of tissue storage and distribution. The references also provide the results of some in vitro studies using liver, kidney, and intestinal homogenates prepared from rats and dogs. Furaltadone was added to the homogenates, and it was shown under these conditions that the biological half-life of the parent drug was about 35 minutes in the rat and 37 minutes in the dog. Both rats and dogs appear to rapidly metabolize furaltadone. These data reinforce the Director's conclusion that consideration must be given to metabolism in the animal of the intended drug use to assess the residues and their significance as contaminants in food.

The Director concludes that adequate information on metabolism of furaltadone in the cow and the determination of total drug residues and their depletion in both edible tissues and milk has not been provided. Therefore, the first step necessary to estimate probable consumption of residues, which is a required consideration of section 512(d)(2)(A) of the act, has not been fulfilled.

B. *Sufficient Information Has Not Been Provided about the Residues to Determine the Appropriate Testing Required in Laboratory Animals to Estimate the Cumulative Effects of Human Exposure to the Residues (Step 2).* The composition of a drug's residue may vary from the extremes of less than 1 percent parent drug and more than 99 percent metabolites to less than 1 percent metabolites and more than 99 percent parent drug, though the latter case would be rare. The Food and Drug Administration must assess the toxicity of the total residue because this is what man will be exposed to in food. Ideally, this assessment would be based on the identification of each of the metabolites in the residue, their synthesis, and subsequent testing of the parent drug and all of the metabolites for the cumulative effects of exposure. However, this approach is usually impractical.

Various approaches are available to limit the number of residue compounds for which toxicity testing is required to provide a sufficiently conservative estimate of the toxicity of the total residue. However, Norwich has not presented any quantitative or qualitative information about the total residues of furaltadone in edible tissues or milk.

Therefore, the Director concludes that not only is the toxicological testing provided for furaltadone inadequate, but he is unable to determine whether testing of metabolites in addition to the parent drug is required to determine the safe level of human exposure to residues in food. Step 2 has not been fulfilled; therefore the requirements for step 3 cannot be fully determined.

C. *Adequate Dose-Response Data in Test Animals to Determine the Cumulative Effects of Dietary Exposure to the Residue Compounds Have Not Been Provided; Therefore, the Maximum Acceptable Concentration of Residues in Food Cannot be Established Using Appropriate Safety Factors to Assure that Human Exposure to Residues in the Total Diet Does Not Exceed a Level Deemed Safe (Step 3).* As discussed under section I of this notice, the Director has concluded that adequate testing of the parent drug furaltadone has not been provided. Also, under paragraphs A and B (steps 1 and 2) of this section, the Director concluded that adequate information has not been provided about the residues to determine if toxicity testing of residue compounds in addition to the parent drug is required to estimate conservatively the cumulative effects of exposure to the residues.

The Director concludes that without such essential information about the residues and adequate toxicity testing data, he cannot, in light of the new evidence, determine if furaltadone requires regulation as a carcinogenic animal drug nor can he reasonably estimate a maximum acceptable level of residue in food that can be deemed safe. Therefore, he concludes that adequate information has not been provided to assess the cumulative effects of exposure and to determine the appropriate safety factors required in section 512(d)(2)(B) and (C) of the act.

D. *Sufficient Information about the Residues Has Not Been Provided to Establish the Conditions Necessary for the Analytical Method Used to Control Residues (Step 4).* The evaluation of an analytical method for residues first requires a determination of the tissues to be analyzed, the compound to be measured, and the lower limit of measurement that must be achieved to control total residues adequately. Only then, after selection of these parameters, is it meaningful to consider whether the method proposed by the sponsor meets other characteristics necessary for a practicable reliable method.

1. Determination of the target tissue: A probability exists that residues of furaltadone occur not only in milk, which must be monitored, but may also occur in edible carcases tissues. The most practical approach to monitoring and controlling residues in the field is dependent on the selection of that edible tissue in which residues require the longest time to deplete to a "safe" concentration." Therefore, by monitoring this tissue to assure that residues are below a "safe concentration," it can be assured that all residues in the carcass are below "safe concentrations." In lieu of this determination (identification of the target tissue), all edible tissues, including milk where applicable, must be monitored. This would place an additional burden on public funds for monitoring.

The target tissue is readily identified if the requirements of step 1 of the evaluation process are met: either by showing that there is no systemic absorption of the drug from the udder that causes residues in tissues at any time after drug treatment, or by showing that if tissue residues occur, from what edible tissues the total residues require the longest time to deplete. Norwich has failed to meet these requirements. Therefore, it cannot be determined if analytical methods are required for tissues in addition to methods of analysis for milk.

2. Determination of the compound (marker) which can be measured by the analytical method to assure control of total residues: Because the radiolabeled drug approach used initially to estimate total residues is not applicable to regulatory use, an alternative approach must be developed to assure control of total residues after drug approval. This is achieved by selecting an appropriate residue compound, which may be the parent drug or one or more metabolites, in such a way that its measurement serves as a valid indicator that when the marker compound is below a certain level in the target tissue, all residues in edible tissues are at safe levels. This step is essential to determine if the method of analysis for regulatory use is adequate. To determine a valid marker, adequate information (e.g., information derived from conducting an adequate metabolism study) is required that relates the proportionate amount of each of the residues to the total residue and their change in quantitative relationships with time. The marker must be a known proportion of the total residue when the total residue depletes to the "safe concentration" in the target tissue. It also must be structurally identified so that an adequate and specific method of analysis can be developed for its determination.

This information must be provided for milk. It would also be required for edible carcass tissues if systemic absorption occurs. Because the resulting residues in milk may be different from the residues in edible carcass tissue, it is possible that a marker compound for milk may be different from a marker compound in edible carcass tissue. Norwich has not provided the necessary information from which a valid marker can be selected to monitor total residues in either milk or edible carcass tissues. The regulatory method proposed by Norwich to control residues in milk uses furaltadone as the marker. Norwich has not substantiated that the measurement of furaltadone is adequate to control total residues of potential concern in milk or alternatively to show that all other residues are safe and do not need to be controlled.

3. Determination of the lower limit of measurement required for the analytical method: Establishment of the lower limit of measurement required for the assay begins with the availability of adequate toxicological testing to determine the cumulative effects of exposure. As described in section I and in steps 2 and 3 of this section, the sponsors have not provided adequate testing. Therefore, an estimate of the acceptable level of exposure to total residues in food cannot be determined.

If it were shown by adequate testing that furaltadone (NF–260) and furazolidone (NF–180) were of comparable carcinogenic potencies, and if it were shown that the estimate of the carcinogenic potency for the total residue could be based on the testing results of the parent drug without the need for further testing of metabolites, then the estimate of the maximum human exposure in the daily diet that could be deemed insignificant for purposes of establishing the minimum assay requirements would be about 0.5 part per billion (ppb). The derivation of this estimate is described in detail in the May 13, 1976 FEDERAL REGISTER notice for furazolidone (NF–180).

Milk may comprise essentially the entire diet of infants. For this reason, no additional adjustments to this amount of daily consumption would be permitted and, under the same assumptions, 0.5 ppb would be the maximum allowed con-

centration of total residues from furaltadone treatment in milk.

No information has been provided on the composition of residues in milk or any measurement of total residues in milk. Therefore, the essential information required to determine a marker for measuring total residues in milk, as described above, is not available. Without this information, even if it were assumed that 0.5 ppb of total residues is "safe," it is not possible to determine the concentration of the marker at the time when total residues in milk would be below 0.5 ppb

Norwich has proposed that the measurement of furaltadone is adequate to assure control of residues, but it has not provided any information to show if furaltadone may be, for example, 80 percent of the total residue or 10 percent of the total residue. Therefore, it is not possible to determine at what concentration the marker must be measured to assure that total residues are at a "safe concentration."

After making the adjustment for the percent of total residue that the marker represents, one further adjustment is necessary to determine the lower limit of measurement required for the assay. This last adjustment takes into account the degree to which the method of analysis recovers the residue from the sample. Minimum standards for recovery for the acceptance of the method take into account that 100 percent recovery is rarely achieved and that a combined evaluation of the precision and accuracy for measurement of the marker must be considered.

Even if very liberal assumptions were made to accept that furaltadone (NF–260) would not be a more potent carcinogen than furazolidone (NF–180) and would be the most potent of the residue compounds that required testing, and if it was determined that furaltadone was a valid marker and was a major constituent of the total residue, and that an analytical method would achieve good recovery of furaltadone, even then it is likely that a method that can measure 0.2 ppb of furaltadone would be required as a minimum to assure safe use.

Under similar assumptions, even if they could be made, methods of analysis in tissue would be required to measure residues at 1 ppb or less in lieu of data demonstrating that no systemic absorption occurred from the udder.

Norwich is aware of the principles just described for the selection of a target tissue, marker compound, and the adjustments required to establish conditions for the assay; this is evidenced by Norwich's citation of a paper prepared by two FDA scientists in a submission for furazolidone (NF–180) to FDA on November 11, 1975. The cited paper by M. K. Perez and N. E. Weber, entitled "Requirements for Metabolic Studies—Impact on Food Safety Regulation" was presented at the Gordon Research Conference on Drug Metabolism, June 23–27, 1975.

The Director concludes that he cannot make an assessment of the toxicity, including the carcinogenic potency, of furaltadone without adequate testing data; he cannot conclude that furaltadone serves as a valid marker for control of total residues of toxicological interest; and therefore he cannot without adequate supporting data determine the conditions necessary for the analytical method used to control residues. The requirements of step 4 have not been fulfilled. He concludes that the new evidence on furaltadone (NF–260) and furazolidone (NF–180) leads to a determination that the methods of analysis for residues for furaltadone (NF–260) are not shown to be adequate.

E. *Practicable Methods of Analysis are Not Available to Assure that Total Residues in the Daily Diet of Humans Do Not Exceed a Level Deemed Safe (Step 5).* Section 514.1(b)(7) (21 CFR 514.1(b)(7)) requires the sponsor of a new animal drug application to provide a practicable method of analysis to be used for the control of residues of its product. A "practicable" method is defined by FDA as one that reliably measures the compound throughout all residue levels of interest, and also is sufficiently rapid and reasonable in terms of the expertise and equipment required to be applicable for use in the surveillance and control of residues. "Reliability" is a combination of accuracy, precision, and specificity. Accuracy and precision are quantitative terms. "Accuracy" is the measure of deviation from the true value, and "precision" refers to the variability of measurement in replications, either by one analyst or within a laboratory or between laboratories. A method may provide reliable measurement if the measurements are not too variable, even though it measures less than or more than 100 percent of the true value. Therefore, accuracy and precision must be considered together.

"Specificity" is a qualitative term. The measurements obtained by the method must reflect only the compound of interest. Because the method will be used on samples from animals for which exposure history is unknown, the techniques used in the method must be adequate to assure not only the integrity of the measurements, but also the identity of the residue to the exclusion of other interfering substances. Therefore, when the quantitative measurements are made by techniques that are not inherently specific, a confirmatory test is required as part of the official method to assure the identity of the residue.

The submitted methodology for furaltadone is based on chromatographic separation and fluorometric determination, which are both nonspecific techniques.

Before receiving reports that furaltadone induced tumors in female rats, FDA had accepted a colorimetric method of analysis for furaltadone, which could detect furaltadone in milk as low as 10 ppb. This method was accepted based on a desk review of recovery data provided by Norwich on the analysis of milk samples to which known amounts of the drug were added (spiked samples). At that time FDA did not require validation trials of methods before acceptance and also did not require evidence that the method satisfactorily recovered the residues when they were naturally incurred through drug treatment (dosed samples).

After FDA received reports of the tumorigenic effects of furaltadone, the drug sponsors were advised in 1969 that their method for determining residues in milk was no longer adequate and that a method capable of determining 0.2 ppb of the drug in milk was required. At a meeting with FDA on January 4, 1971, Norwich representatives stated that they had developed an analytical method for furaltadone (NF–260) in milk capable of detecting 0.2 ppb and had analytical methods for furazolidone (NF–180) in tissue capable of detecting to 2 ppb, which they felt could be adapted to provide acceptable methods for the other nitrofurans.

Both methods were submitted to FDA for evaluation on January 31, 1971. In 1971, the current practice of subjecting potential regulatory methods to validation trials in U.S. Department of Agriculture (USDA) and/or FDA laboratories was in effect.

A discussion of the results on the evaluation of the furazolidone (NF–180) method for tissue analysis is presented in the May 13, 1976 FEDERAL REGISTER notice for furazolidone. In that notice the Director concluded that the methods for edible tissue were not shown to be adequate. No data have been supplied to show that methods of analysis for furazolidone (NF–180) in tissue are adaptable for furaltadone (NF–260). No methods for furaltadone (NF–260) in edible tissues have been provided, except for a method with a claimed lower limit of measurement of 0.1 part per million (ppm), which FDA does not consider to be adequately sensitive

The method presented by the sponsors for milk in 1971 was a thin layer chromatography (TLC) ultraviolet-based method which the sponsors claimed was capable of detecting 0.2 ppb of furaltadone (NF–260). This method was found deficient in a desk review based on the supporting data supplied by Norwich. Subsequently, a revised procedure using TLC–fluorometry for the determination of furaltadone in milk was submitted to FDA and was accepted for laboratory validation trials on May 26, 1972.

The method presented was not quantitative. Norwich and FDA agreed that any positive reading where a peak was observed at the same R_f value as the furaltadone standard would be taken as indicative of a violative residue. (R_f is defined as the ratio of the distance traveled by the solute to the distance traveled by the mobile phase.)

Two FDA laboratories participated in evaluation of the revised TLC-fluorometric analytical method for furaltadone residues in milk. A total of five replicate analyses were performed in the two laboratories on samples of milk from unmedicated cows before and after fortification by the analyst with 0.2 ppb

of furaltadone. Before fortification, four control milk samples produced a zero response (one control sample was lost). Recoveries from milk fortified at the 0.2 ppb level were found to be highly variable, ranging from 10 percent to 55 percent. It was concluded, on the basis of these results, that the method was capable of detecting, but not quantitating, the presence of furaltadone in milk at 0.2 ppb.

Norwich was informed of the results of the validation trial in conferences and of the FDA rejection of the assay method for furazolidone (NF–180) in tissue. Norwich was informed that methods for furaltadone (NF–260) in tissue were required and that a confirmatory method was required for both milk and tissue to provide adequate identification of the residue. The inherent lack of specificity of the TLC-fluorometric method of analysis for furaltadone (NF-260) and the increased probability of unpredictable interference from impurities in solvents, reagents, etc., when measuring residues at extremely low levels, combine to make the need for confirmatory tests for furaltadone in milk and tissues especially acute.

In 1974, as part of its annual Drug Experience Report to the Bureau of Veterinary Medicine, Norwich submitted results of a residue depletion study of furaltadone (NF–260) in milk conducted using a modification of the previously submitted analytical method. The modification consisted of the use of a new technique called programmed multiple development (PMD), which should, in theory, improve the results obtained by thin layer chromatography as it is used in the analysis of furaltadone. However, Norwich reported that it had to discontinue use of the PMD technique in this experiment because of the presence of an extraneous blue fluorescing band that overlapped the critical zones and interfered with the measurement of the drug.

The Director concludes that practicable methods of analysis for milk and tissue residues of furaltadone are not available. No adequate methods have been provided for the analysis of tissue, nor have data been submitted to show cause for exemption from the need for control of residues in edible carcass tissues. Appropriate data have not been provided to determine if furaltadone can be used as a marker to control total residues in milk, nor to determine the lower limit of measurement required for a method to assure that total residues do not exceed safe levels. The Director concludes that the method provided by Norwich for the determination of furaltadone in milk at 0.2 ppb is not quantitative and is not specific and, therefore, is not a quantitatively or qualitatively reliable practicable method for regulatory use, even if it were established that measurement of furaltadone at 0.2 ppb was adequate to control total residues. Therefore, step 5 and the requirements of section 512(b)(7) of the act have not been met.

F. *Practical Conditions of Use Cannot be Prescribed on the Label of Products to Assure Safe Use (Step 6).* Section 512(b)(8) of the act requires that conditions of use assure there are no unsafe residues, and section 512(d)(2)(D) of the act adds a further requirement that these conditions be such that they are "reasonably certain to be followed in practice."

Norwich has provided data that demonstrate that furaltadone is present in milk after use of the drug, and the milk must be discarded for a period of time because of the presence of residues. No data have been provided to show if residues occur in tissues or if a withdrawal period following drug use is required for residues in edible tissues to deplete to safe levels.

A withdrawal period is the time following drug treatment when because of residues, a treated animal cannot be slaughtered for food and its milk must be discarded. A withdrawal period must be sufficiently long to assure adequate residue depletion, but it cannot be so long that it is impractical and would not likely be followed in practice. The maximum withdrawal period considered practical for milk is 96 hours or the discard of eight successive milkings.

It is required by FDA that residue depletion studies be conducted for each drug use under simulated field use conditions to develop data for establishing the withdrawal period. An adequate analytical method for residues, preferably the same method that will be approved for regulatory use, must be used to measure the residues in the depletion studies.

For mastitis products, the residue depletion studies in milk should be conducted with normal lactating cows (disease-free) and mastitic cows to determine if the disease state produces a different rate of residue depletion. The drug treatment in the study must be at the maximum dose for the drug use.

A total of 11 studies of the depletion of furaltadone in milk, using a chemical method of analysis for furaltadone, has been presented to FDA.

Three of these studies used methodology with a lower limit of measurement of furaltadone in milk of 1.0 ppm. Several milk samples collected at 32 hours following medication were shown in these studies to contain levels of furaltadone in excess of 1.0 ppm.

Three more studies used chemical methods with a lower limit of measurement of furaltadone in milk of 10 ppb. On the basis of the results from these experiments, FDA required a 36-hour or three-milking discard period for milk from animals medicated with furaltadone as a condition of approval of the NADA's in 1962.

The following five studies were submitted since the approval of the NADA's. In these studies the chemical methods of analysis used are those described in the preceding section, which Norwich claimed were capable of detecting furaltadone as low as 0.2 ppb.

1. NADA 12–738, Vol. 5, Letter from Norwich dated March 15, 1971.

A single lactating cow with mastitis was treated at the label-recommended dose with furaltadone. Milk collected at 24, 36, 48, and 60 hours after medication was reported to contain furaltadone at 11 ppb, 3 ppb, 1 ppb and less than 0.2 ppb at the respective withdrawal periods. The method of analysis used was presumably the TLC ultraviolet-based method that was judged to be inadequate, on the basis of erratic recovery data, in a desk review by FDA. No supporting raw data were presented. No explanation was given of the significantly lower levels of furaltadone observed in 24- and 36-hour milkings from this cow compared to those found in previously reported studies using less sensitive methodology.

2. NADA 12–738, Vol. 5, Project No. 469–02, dated June 22, 1971.

Five healthy lactating cows were treated with Altapen, a product containing procaine penicillin G in addition to furaltadone. The furaltadone dose was identical to that recommended for formulations containing only furaltadone, and the penicillin was shown not to interfere with the analysis of furaltadone. Milk was collected every 12 hours from each cow, and samples were analyzed for furaltadone using the TLC ultraviolet-based method of analysis that was judged to be inadequate, on the basis of erratic recovery data, in a desk review by FDA. Levels of furaltadone in milk were reported by Norwich to fall from a range of 180 ppb to 3,500 ppb in the five 12-hour post-medication samples, to a range of 1.4 ppb to less than 0.2 ppb in the 48-hour samples. Furaltadone in milk was reported by Norwich to be below 0.2 ppb in all five 60-hour milk samples.

3. Project No. 469.02 and 469.11, Special Report, dated October 25, 1971. Hearing Clerk Docket No. FDC–D–283.

Five dry cows were given two injections of Altapen, 5 days apart, into each udder segment. Cows were not milked until they calved—between 1 and 2 months after the second injection. No furaltadone was found in the first (24-hour) post-parturition sample of colostral milk. The method of analysis was the same TLC ultraviolet-based method discussed under study 2 above.

4. Project No. 469.02 and 469.11. Special Report, dated October 29, 1971. Hearing Clerk Docket No. FDC–D–283.

Five lactating cows (disease state unknown) were treated with a preparation containing only furaltadone according to label-recommended directions. Milk samples were collected every 12 hours, beginning 24 hours after the last injection. Three of the five cows produced 48-hour milk samples reported to contain 0.26 to 0.4 ppb of furaltadone. The method of analysis was the TLC ultraviolet-based method discussed under study 2 above.

5. NADA 12–738–34A, Drug Experience Report submitted to FDA November 1975.

This report contains the results of three residue studies of furaltadone in milk following medication of five mastitic cows in each study with a pathogen-

free formulation of the product. (The drug is marketed as a sterile formulation.) Norwich used the PMD modification of the TLC fluorometric method of analysis discussed under paragraph E (step 5) of this section.

In the first study, furaltadone at levels ranging from 0.2 ppb to more than 24 ppb was found in the five 108-hour post-medication milk samples. Norwich blamed probable contamination of the collection equipment for these results.

In the second study, the milk samples at 72- or 84-hour withdrawal from all five treated cows were reported to contain less than 0.2 ppb of furaltadone. However, later milkings from three of the five animals were reported to contain 0.4 to 1.6 ppb of furaltadone. Norwich blamed these unusual results on improper sampling techniques.

In the third study the PMD modification of the method subjected to validation in 1971 was used initially, but it was discontinued because of the presence of an extraneous blue fluorescence band that overlapped the critical zones and interfered with the measurement of furaltadone. The study was completed using the TLC fluorometric method that was previously determined by FDA in method trials to be capable of detecting, but not quantitating, furaltadone at 0.2 ppb. Furaltadone was found in one of five 84-hour post-medication milk samples. Furaltadone was not found in the milk collected at 96, 108, and 120 hours following drug treatment.

The Director concludes that all the depletion studies submitted on milk are inadequate for the establishment of a milk discard time that will assure no unsafe residues. His reasons are as follows:

a. Adequate information is not available to determine if measurement of furaltadone can be used to assure adequate depletion of total residues.

b. Adequate information is not available to determine the level of residues that can be deemed safe for human consumption.

c. Data obtained in the various studies on the amount of furaltadone in milk are not consistent. For this reason, FDA cannot rely on results of any one of these experiments to predict the levels of furaltadone that may be present in milk from furaltadone-treated cows.

d. The methods of analysis that are claimed by Norwich to be capable of detecting 0.2 ppb of furaltadone are not quantitative at this level. Results at the limit of detection are of necessity extremely variable by definition. The agency can agree only that any positive reading would indicate the possible presence of furaltadone in a milk sample, but it cannot agree that a reading equivalent to less than 0.2 ppb (or a reading below the average reading obtained with samples fortified at 0.2 ppb) as used by Norwich denotes the absence of furaltadone.

The Director concludes that withdrawal periods are required for the safe use of furaltadone; that for products containing only furaltadone, as the active drug, the officially approved withdrawal period for milk of 36 hours or three-milkings discard is not shown to be adequate; that the currently labeled withdrawal period for milk voluntarily used by the sponsors, i.e., 48 hours or four-milkings discard, has not been shown to be adequate; and that for products containing furaltadone and penicillin, the withdrawal period for milk of 96 hours or eight-milkings discard has not been shown to be adequate in light of new evidence presented since the uses of furaltadone were approved. The Director further concludes that withdrawal periods may be required for dairy cows culled from the herd to assure adequate residue depletion from edible tissues before slaughter. He concludes that adequate information has not been provided to show what withdrawals are required for milk discard or slaughter to assure safe conditions of use for furaltadone, as required by section 512(b)(8) and (d)(2)(D) of the act. The requirements of step 6 have not been fulfilled.

Therefore, the Director is hereby withdrawing the notice of opportunity for hearing issued August 4, 1971, proposing to withdraw approval of NADA's providing for the use of furaltadone in food-producing animals. Under section 512(e)(1)(B) of the act (21 U.S.C. 360b(e)(1)(B), the Director proposes to withdraw approval of certain existing NADA's providing for the use of furaltadone in food-producing animals on the grounds that such use violates section 512 of the act in that such use has not been shown to be safe.

This notice applies to all outstanding NADA's for the use of furaltadone in food-producing animals. All such applications known to FDA are listed below by NADA number and by each applicant's name and last known address in FDA records. Copies of this notice are being forwarded by registered or certified mail to each of the known applicants. Notice to other applicants or holders of NADA's whose identity is not known to FDA is given by this publication.

12-738, 65-059, Eaton Laboratories, Division of Morton-Norwich Products, Inc., P.O. Box 181, Norwich, NY 13815.

14-283, Hess and Clark, Division of Rhodia, Inc., 7th and Orange St., Ashland, OH 44805.

Any holder of an approved application that elects to avail itself of an opportunity for hearing pursuant to section 512(e)(1) of the act and § 514.200 of Chapter I of Title 21 of the Code of Federal Regulations must file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, a written appearance requesting such hearing by September 16, 1976, giving the reasons why approval of the application should not be withdrawn, and providing a well-organized and full-factual analysis of the scientific and other investigational data such holder is prepared to prove in support of its opposition to the Director's proposal. A request for hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is one or more genuine and substantial issue(s) of fact requiring a hearing. Responses to this notice and copies of published literature cited in this notice may be seen in the office of the Hearing Clerk, Food and Drug Administration, during regular business hours, Monday through Friday.

If a hearing is requested and is justified by any holder's response to this notice of opportunity for hearing, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

Any hearing on the withdrawal of approval of the foregoing NADA's will be open to the public. If, however, the Director finds that portions of the applications that serve as a basis for such a hearing contain information concerning a method or process that is entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.29) (recodification published in the FEDERAL REGISTER of June 16, 1976 (41 FR 24262)).

A discussion of the economic and environmental impact of this action is set forth in the notice of proposed rule making on furaltadone published elsewhere in this issue of the FEDERAL REGISTER.

It is hereby certified that the economic and inflation effects of this proposal have been carefully evaluated in accordance with Executive Order 11821.

Dated: August 6, 1976.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc.76-23621 Filed 8-10-76;11:19 am]

[Docket No. 76N-0232]

HESS & CLARK, ET AL.

Nitrofurazone (NF-73); Opportunity for Hearing on Proposal To Withdraw Approval of Certain New Animal Drug Applications

The Director of the Bureau of Veterinary Medicine of the Food and Drug Administration (FDA) is issuing a notice of opportunity for hearing on a proposal to withdraw approval of approved new animal drug applications (NADA's) Nos. 6-395, 6-475, 6-649, 7-801, 8-129, 8-142, 8-324, 8-410, 8-529, 8-784, 9-013, 9-415, 10-741, and 11-154 for the use of nitrofurazone (NF-7) in food-producing animals in accordance with section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(1)(B)) (hereinafter, "the act") on the grounds that new evidence not available when the applications were approved, evaluated together with the evidence available at the time of approval, shows that nitro-

furazone is not shown to be safe for use under either the approved or currently labeled conditions of use. Holders of approved NADA's have until September 16, 1976 to submit requests for a hearing in accordance with § 514.200 (21 CFR 514.-200).

In FR Doc. 76–23620 appearing elsewhere in this issue of the FEDERAL REGISTER, the Director is issuing a notice of proposed rulemaking to revoke the appropriate provisions of sections affected by the proposed withdrawal.

Nitrofurazone (NF–7) is a member of a class of chemicals called "nitrofurans," which are used at low levels in animal feed as antibacterial and antiprotozoan agents to increase resistance to disease, thereby assisting growth. Nitrofurans also have prescribed therapeutic uses. In addition to nitrofurazone (NF–7), which is the subject of this notice, there are three other nitrofurans that are used in food-producing animals and are or have been subject to agency action: nihydrazone (NF–64) and furaltadone (NF–260), which are subjects of companion notices in this issue of the FEDERAL REGISTER; and furazolidone (NF–180), which was the subject of notices in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906, 19907). A fifth nitrofuran, furamazone (NF–84), is not at this time the subject of contemplated agency action for withdrawal.

Nitrofurazone (NF–7), approved in 1948, was the first nitrofuran approved by FDA for use in food-producing animals. It is currently approved for use in mastitis products for dairy cattle (dry cow treatment only); for the treatment of genital tract infections in large female animals; for prevention and treatment of surface bacterial infections (all animals); as a medication in feed for swine for the treatment of infectious necrotic enteritis caused by *Salmonella choleraesuis;* for chickens and turkeys for the prevention and control of cecal and intestinal coccidiosis; and for chickens for the prevention of pullorum.

The original applications were approved without a requirement that the drug treatment be discontinued for a specified period of time before the slaughter of the animals. However, two of the sponsors, Norwich Pharmacal Co., Division of Morton-Norwich Products, Inc., and Hess & Clark, currently a Division of Rhodia, Inc., voluntarily revised the labels in 1971 to require that swine, turkeys, and chickens be withdrawn from nitrofurazone (NF–7) 5 days before slaughter.

The Food and Drug Administration issued a notice of opportunity for hearing, published in the FEDERAL REGISTER of March 31, 1971 (36 FR 5927), proposing to withdraw approval of NADA's for nitrofurazone (NF–7) on grounds that:

> Information available to the Commissioner establishes that the drugs, when administered to laboratory animals, have been shown to produce tumors. The drugs are, therefore, not considered to be safe for use in the absence of appropriately sensitive methods of analysis to establish their absence in food derived from treated animals.

Similar notices were published for nihydrazone (NF–64) in the FEDERAL REGISTER of March 31, 1971 (36 FR 5926) and for a hearing. Norwich assured FDA that done (NF–260) on August 4, 1971 (36 FR 14343). The history leading to the publication of these 1971 notices is discussed in the May 13, 1976 notice for furazolidone (NF–180).

Norwich and Hess & Clark responded to the March 31, 1971 notice concerning nitrofurazone (NF–7) by filing requests for a hearing. Norwich assured FDA that it had adequate methods of analysis to determine residues and adequate data to show that under the currently labeled conditions of use, the drugs were safe. In addition, Norwich set forth a hypothesis that nitrofurans were not primary tumorigens but stimulated spontaneous tumor growth by disrupting the normal hormone balance.

In response to the March 31, 1971 notice, Pharm-House, Inc. submitted a method for the determination of nitrofurazone (NF–7) in milk, which it indicated could detect nitrofurazone at levels down to 2 parts per billion (ppb).

Norwich has continued to submit data pertaining to the use of nitrofurazone (NF–7) in food-producing animals. The Food and Drug Administration has determined that new evidence, evaluated together with the evidence available when the approvals were granted, fails to demonstrate that either the approved or currently labeled uses of nitrofurazone are shown to be safe. The Director is withdrawing the March 31, 1971 notice of opportunity for hearing concerning nitrofurazone (NF–7), and is issuing this new notice, which presents in detail all of the evidence now available to him and the basis on which he proposes to withdraw approval of all uses of nitrofurazone in food-producing animals in accordance with section 512(e)(1)(B) of the act.

Section 512(e)(1)(B) of the act requires that FDA withdraw approval of an NADA when "new evidence * * * evaluated together with the evidence available * * * when the application was approved, shows that such drug is not shown to be safe * * *." Under this provision, the new evidence and the evidence submitted at the time the application was approved must be evaluated to determine whether all of the requirements for safety contained in section 512 of the act continue to be fulfilled.

THE DETERMINATION OF "SAFETY" IN SECTION 512

Section 512 of the act requires that the use(s) of a new drug in food-producing animals must be supported by adequate data supplied by the sponsor in applications that include, among other things, demonstration that the drug use will not result in unsafe residues in human food.

Under section 512(b) of the act, whenever a drug use may result in residues of the drug in food, an application must include not only full reports of investigations to show that the use of the drug is safe, but also a description of practicable methods for monitoring food to assure there are no unsafe residues in human food attributable to the drug use, and demonstration that the conditions of use are adequate to assure there are no unsafe residues.

Under section 512(d)(2) of the act, FDA is required, in the evaluation of the supporting safety data, to consider, among other things:

1. The probable consumption of such drug and of any substance formed in or on food because of the use of such drug (i.e., probable human consumption of residues, including the parent drug and metabolites).

2. The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, i.e, toxicological effects of the compounds comprising the residues.

3. Safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data (i.e., establishing "safe" levels of residues using appropriate safety factors to extrapolate animal data on cumulative effects to humans).

Under section 512(d)(1)(H) of the act, additional requirements must be met if the drug is a carcinogen.

The determination of safety within the meaning of section 512 of the act for a drug whose use may result in residues in the edible products of the treated animal, whether or not the drug is a carcinogen, requires a multistep process. These steps form an orderly procedure by which information is derived to satisfy each of the three considerations stated above.

Step 1. Assessment of the total residues in edible products and the depletion of those residues with time following cessation of drug treatment in order to determine probable human consumption (section 512(b)(1) and (d)(2)(A) of the act).

Step 2. Assessment of information about the residues to determine the appropriate testing in laboratory animals required to estimate the cumulative effects of human exposure to the residues (section 512(b)(1) and (d)(2)(A) of the act).

Step 3. Acquisition of dose-response data in test animals to determine the cumulative effects of dietary exposure to the residue compounds from which the maximum acceptable concentration of residues in food can be established using appropriate safety factors to assure that human exposure to residues in the total diet does not exceed a level deemed safe (section 512(b)(1) and (d)(2)(B) and (C) of the act). In the case of a carcinogenic drug, a conservative statistical extrapolation of the tumor data is used to estimate a level of residue exposure that could be considered insignificant and poses essentially no risk of cancer and operationally defines "no residue" for purposes of computing the residue assay requirements under section 512(d)(1)(H) of the act.

Step 4. Acquisition of information about the residues to (1) determine the tissue (called the target tissue) from which residues require the longest time to deplete to safe levels and which, therefore, must be monitored by the regulatory assay (step 5), and (2) determine the compound (called the marker) that is to be measured in the regulatory assay so that by its measurement there is assurance that no unsafe residues occur from the use of the drug (section 512(b)(7) of the act).

Step 5. Development of a practicable method of analysis that can measure the marker in the target tissue at a concentration that assures that total residues in the daily diet of humans do not exceed the level established in step 3 as safe (section 512(b)(7) of the act).

Step 6. Demonstration that practical conditions of use can be prescribed on the label of the product to assure there will be no unsafe residues in the food products from treated animals (section 512(b)(8) and (d)(2)(D) of the act).

Each of the steps involves principles that are essential for a determination of food safety and compliance with the requirements of the act to assure there are no unsafe residues in human food from the animal drug use. Each step builds upon the preceding step. Therefore, failure to accomplish any one of the six steps in whole or in part for any drug will ordinarily preclude a sponsor's fulfilling its obligation under the act to determine probable consumption of residues and cumulative effects of exposure, and to establish safe conditions of use with appropriate regulatory methods of analysis to control residues when deemed necessary.

New evidence concerning nitrofurazone (NF–7) not available when the applications were approved includes, among other things, a demonstration that nitrofurazone induces mammary tumors in female rats. The Director has evaluated all the data now available, including the new data received since 1948 when the uses for nitrofurazone (NF–7) were first approved, and the data available to FDA at the time of approval, and has concluded that the approval of NADA's for nitrofurazone (NF–7) must be withdrawn under section 512(e)(1)(B) of the act because:

1. Adequate investigations have not been provided to show that the uses of nitrofurazone are safe, as required by section 512(b)(1) of the act. Adequate information has not been provided on the probable consumption of residues, and the cumulative effects of exposure have not been determined by appropriate tests, as required by section 512(d)(2)(A) and (B) of the act. Therefore, "safe" levels of residue cannot be determined using appropriate safety factors, as required by section 512(d)(2)(C) of the act.

2. Adequate, reliable, and practicable methods of analysis are not available for monitoring food to assure there are no unsafe residues in edible tissues and milk that are attributable to the use of nitrofurazone, as required by section 512(b)(7) of the act.

3. Practical conditions of use cannot be specified in the labeling to assure there are no unsafe residues attributable to the use of nitrofurazone, as required by section 512(b)(8) and (d)(2)(D) of the act.

The data on which these conclusions are based are presented in the succeeding sections of this notice. The Director first describes all the relevant new evidence bearing on the determination of safety for the uses of nitrofurazone. Then he evaluates all the evidence before him using the six-step procedure necessary to satisfy a human safety determination for the use of nitrofurazone (NF–7) and to meet the considerations required in section 512 of the act.

I. New Evidence

In In October 1966 and in January 1967, Norwich submitted reports of the effect in rats of feeding diets containing nitrofurans for 45 weeks. These studies included tests on nitrofurazone (NF–7) and furazolidone (NF–180). In these studies it was shown that both nitrofurazone (NF–7) and furazolidone (NF–180) induced mammary tumors of similar type in female rats.

Subsequently, more extensive, longer term testing of furazolidone (NF–180) was conducted, but further testing of the carcinogenic potential of nitrofurazone (NF–7) has not been undertaken. The more extensive testing of furazolidone (NF–180), as described in the May 13, 1976 Federal Register, shows that the drug induces cancer in both rats and mice and that the tumors and cancers were not limited to the mammary gland or the endocrine tissues of female rats.

The Director is including in this notice information available on the toxicological properties of furazolidone (NF–180) as well as introfurazone (NF–7) because of the structural similarities of the drugs and their similar biological properties, which have been observed in the limited comparative data available. The new evidence showing that furazolidone (NF–180) is a carcinogen has a significant bearing on the Director's conclusions that the uses of nitrofurazone (NF–7) are not shown to be safe.

Although it is appropriate to consider data on furazolidone (NF–180) to judge the adequacy of existing data to support the safe use of nitrofurazone (NF–7) in food-producing animals, these data are not a substitute for data on nitrofurazone (NF–7) that are required by the statute. Basic data are required for each drug, recognizing that slight differences in chemical structure can result in significant differences in metabolism, residues, and toxicity. Although comparative data or the biochemical and toxicological properties of related drugs may be useful and appropriate in making decisions about the degree of testing required for each drug to show there is no probable hazard, these data cannot be used as a substitute for the basic information necessary on each drug to determine the probable exposure to residues and cumulative effects of exposure.

A. *Carcinogenic Potential of Nitrofurazone.* Norwich submitted data in October 1966 and January 1967 on the cumulative effects in rats of feeding diets containing nitrofurazone (NF–7) for 45 weeks ("Effects of Long Term Feeding of Various Nitrofurans," October 13, 1966 and January 4, 1967, Project No. 440.07, submitted to FDA as part of a June 2, 1967 Drug Experience Report). These studies include testing in female Sprague-Dawley (Holtzman strain) rats and testing in both male and female Carworth Farms (CFE strain) rats.

1. The Sprague-Dawley Female Rat Study: Seventy female Sprague-Dawley rats (Holtzman strain) were equally divided into two groups that were fed nitrofurazone at about 0.1 percent (55 milligrams per kilogram (mg/kg) body weight per day) and about 0.05 percent (28 mg/kg body weight per day) respectively in their diet for 45 weeks, followed by maintenance on an unmedicated diet for an additional 8 weeks before sacrifice. A comparable control group of female rats was maintained on a nitrofurazone-free diet for 53 weeks. At termination of the study the animals were autopsied, and tissues were examined for histopathological lessions.

The most prominent drug-related effect was the induction of tumors in the mammary glands of the female rats. Although rats develop mammary tumors spontaneously as they age, the incidence of spontaneous mammary tumors in rats just over 1 year old, depending upon the strain of rat used, can be quite low. The nitrofurazone-treated female rats had an increased number of mammary tumors, particularly the number of fibroadenomas, as compared with the control rats. The development of tumors included the finding of some mammary adenocarcinoma (cancer).

Norwich reported that no mammary tumors of any type were observed in the 33 control rats examined. It reported from hispopathological examination that a total of 19 mammary tumors were observed in 13 of the 30 rats examined that were fed nitrofurazone at 0.1 percent in the diet. In the 0.05 percent dose group a total of 18 mammary tumors were found by Norwich in 12 of the 33 rats examined for histopathology. Norwich did not report any of adenocarcinoma in either the 0.1 percent or 0.05 percent dose groups.

An Ad Hoc Committee was established to review the pathology data on all the nitrofurans tested in the Sprague-Dawley rat study and the Carworth Farms rat study. One member of the Ad Hoc Committee was the director of the Eppley Institute for Research in Cancer, University of Nebraska. He and his associate pathologists reviewed the pathology slides of the mammary tissues from the nitrofurazone-treated rats provided by Norwich and submitted a detailed report to FDA. They did not review all the mammary gland slides from the control rats.

Each of the reviewed slides had a rat identification number, and there were several slides for each rat. However, there was no information on the number of tumors in each rat. Therefore, it was not possible, in many cases, for the pathologists to determine which slides represented different tumors in the same rat and which were different sections of a single tumor.

The Eppley patholigists concluded from their review of the 0.1 percent dose group rats that 14 of the 30 nitrofurazone-treated female rats examined had mammary tumors that were predominantly fibroadenomas and that 4 of these rats had mammary adenocarcinoma.

From their examination of the 0.05 percent nitrofurazone dose group, they found mammary tumors in 12 out of the 33 rats examined. This included the finding of mammary adenocarcinoma in one rat. The remainder of the tumors in this dose group were fibroadenomas.

Because the Norwich report did not indicate which rats had tumors, it is not possible from the data available to determine if the tumors reported by the Eppley pathologists were from the same rats in which Norwich had reported tumors. The Eppley pathologists reported mammary adenocarcinoma in the nitrofurazone-treated rats, whereas the Norwich report shows no nitrofurazone-treated rats had mammary adenocarcinoma. However, because the Eppley pathologists did not review all the mammary gland slides from the control rats, a comparative incidence of mammary cancer cannot be determined from the reports.

A pathologist from the Bureau of Foods of FDA, who was not a member of the Ad Hoc Committee, later reviewed the pathology slides of the mammary tumors from the nitrofurazone-treated rats in which the Eppley pathologists had reported mammary tumors. From his examination of the histopathological preparations provided, he reported for the 0.1 percent dose group, 15 slides of mammary fibroadenoma from 10 rats and 4 slides of mammary adenocarcinoma from 3 rats. The mammary adenocarcinomas were diagnosed in the same three rats in which the Eppley pathologists had diagnosed mammary adenocarcinoma. The Bureau of Foods pathologist did not have any slides from the fourth rat in which the Eppley pathologist had found adenocarcinoma. In the 0.05 percent dose group, the Bureau of Foods pathologist reported histopathological preparations of mammary tumors from 12 rats. These included 5 slides of adenoma, 13 slides of fibroadenoma, and 1 slide of adenocarcinoma. The mammary adenocarcinoma was in the same rat in which the Eppley pathologists had diagnosed mammary adenocarcinoma.

The Bureau of Foods pathologist also did not have information indicating which slides were multiple sections of single tumors or which represented different tumors. He did have information on the rat identification number for each set of slides. Because the Bureau of Foods pathologist did not review all the slides in the study, tumor incidence and the comparison of incidence with the control rats cannot be determined from his report. However, his report supports the Eppley pathologists' findings that mammary tumors were found in at least 13 of the rats in the 0.1 percent nitrofurazone-treated group and in at least 12 of the rats in the 0.05 percent nitrofurazone-treated group. It also confirms that mammary adenocarcinoma was found in at least three rats in the 0.1 percent nitrofurazone-treated group and in one rat in the 0.05 percent nitrofurazone-treated group.

2. The Carworth Farms Rat Study: Nitrofurazone (NF–7) was fed to 20 male and 20 female Carworth Farms (CFE strain) rats at about 0.1 percent in the diet (50 mg/kg body weight per day) for 45 weeks, followed by maintenance on an unmedicated diet for an additional 7 weeks before sacrifice. A comparable control group of rats was maintained on a nitrofurazone-free diet for 52 weeks. At termination of the study the animals were autopsied, and the tissues were examined for the histopathological lesions.

As in the previous Sprague-Dawley rat study, the most prominent drug-related effect seen was the induction of tumors in the mammary glands of the female rats. This included an increase in the number of mammary fibroadenomas and the finding of some adenocarcinomas.

Norwich reported that no tumors were observed in the 15 female control and 18 male control rats examined. Norwich reported from histopathological examination that 11 out of 19 nitrofurazone-treated female rats examined had a total of 28 mammary tumors. No mammary tumors were reported in the male rats treated with nitrofurazone. Norwich reported 3 mammary adenocarcinomas among the 28 mammary tumors found in the nitrofurazone-treated female rats but did not specify whether these adenocarcinomas were seen in 3 different rats or whether some of these were multiple tumors in the same rat.

The Eppley pathologists reviewed the slides of the mammary tissues from the 19 nitrofurazone-treated rats provided by Norwich. They also concluded that 11 of the nitrofurazone-treated female rats had mammary tumors. However, from the slides reviewed they found only one rat with mammary adenocarcinomas. It is not known if the Eppley pathologists had all the slides that Norwich had diagnosed as mammary adenocarcinoma.

Slides of the mammary tumors reported by the Eppley pathologists were later reviewed by the Bureau of Foods pathologist. He reported mammary tumors in each of the 11 female rats. From his examination of the histopathological preparations provided, he reported 9 slides of mammary adenoma, 1 slide of mammary fibroma, 19 slides of mammary fibroadenoma, and 1 slide of mammary adenocarcinoma. The adenocarcinoma was in the same rat in which the Eppley pathologist had reported a mammary adenocarcinoma.

Because Norwich did not report the number of rats in which mammary adenocarcinoma was found, and because the Eppley and Bureau of Foods reviewing pathologists did not receive mammary tissue slides from control rats, and because the Bureau of Foods pathologist did not review slides from all of the treated rats, and because there is some question about whether the Eppley pathologists received all the mammary tissue slides of the treated rats, the incidence of mammary cancer cannot be determined from the available reports. However, the Eppley and Bureau of Foods reviewing pathologists did concur in the finding of mammary tumors in 11 rats and mammary adenocarcinoma in at least 1 nitrofurazone-treated female rat from the study.

Food and Drug Administration scientists recognize that there are uncertainties and limitations in the examination of tumors to determine if they have malignant potential. For example, in the early stages of a mammary tumor growth, the mass may be chiefly adenomatous. As the growth continues, the supporting white fibrous connective may also begin to proliferate, resulting in a fibroadenoma. Later the adenomatous part of the neoplastic mass may entirely disappear, leaving a fibroma. Finally, a part of the adenoma or fibroadenoma may develop malignant tendencies and that portion may then become an adenocarcinoma. All four tumor types, i.e., adenoma, fibroadenoma, fibroma, and adenocarcinoma may be present in the same tumor mass. A small focus of adenocarcinoma in the early stage of a malignant tumor may be overlooked in the tumor growth unless adequate multiple sections of the tumor are made.

Also, unless great care is exercised in the evaluation of the spread of an adenocarcinoma of the mammary gland, the metastasis along the lymphatic routes passing through, under, or near other mammary glands may be considered to be separate primary adenocaricinomas rather than a single primary growth with multiple metastases.

The reports from Norwich indicate that nitrofurazone (NF–7) caused an induction of mammary tumors in female rats just over 1 year old and that there is an indication of an increase in the number of mammary adenocarcinomas compared with control rats.

Erturk et al. (*Cancer Research*, 30:1409–1412, 1970) transplanted mammary fibroadenomas from female Holtzman rats orally treated with nitrofurazone into male and female newborn Holtzman rats. They reported increased anaplasia pleomorphism and mitotic activity in the rats into which the tumors had been transplanted. One of the tumors developed into an adenocarcinoma. The transplantability of rat mammary fibroadenomas and their conversion to malignant tumors has been considered by some eminent pathologists as one criterion of cancer (H. L. Stewart et al., "Atlas of Tumor Pathology," Sec. XII,

Fascicle 40, pp. 249–297, Washington, DC, Armed Forces Institute of Pathology, 1959).

Food and Drug Administration scientists conclude that the above studies show that nitrofurazone is tumorigenic in rats and that the data raise questions about the carcinogenic potential and potency of nitrofurazone. They conclude that none of the studies is adequate to assess the cumulative effects of exposure to nitrofurazone and its carcinogenic potential and potency because the studies were not of sufficient duration, and the number of animals used was not sufficient. In the Sprague-Dawley rat study only female animals were used; so it is not possible to determine whether nitrofurazone might have produced effects in the male rats. In the Carworth Farms rat study, the number of males was too small to determine with any confidence that nitrofurazone did not have an adverse effect. In both studies, drug treatment was for only 45 weeks. In spite of the weaknesses in the reports available, it is evident that a 45-week treatment was sufficient to induce tumors in female rats, and that some of these tumors were mammary cancers. The dose level, frequency, and duration of exposure to a compound are related not only to whether or not cancer is induced, but also to the latency period before the expression of cancer. Therefore, the 45-week treatment with nitrofurazone is not considered a sufficient period of exposure to determine adequately the cancer potential or potency.

The Director concludes that the available data provide sufficient cause for concern that nitrofurazone may be a carcinogen and that adequate lifetime testing in appropriate animal species is required to evaluate its carcinogenic potential and potency. The Director concludes that because nitrofurazone is a tumorigen, dose-response data in lifetime studies, using several dose levels, are necessary to determine the information required to assess the cumulative effects of exposure and to establish conditions of safe use. Although the demonstration of cancer induction may be made on the basis of testing at only one dose level, and it may be possible from the results of this testing to conclude that a drug requires regulation under the provisions of section 512(d)(1)(H) of the act, dose-response data are necessary to provide information from which FDA can establish the operational definition of "no residue" for purposes of determining the required conditions for the regulatory assay for residues of a carcinogenic drug. Regardless of whether adequate testing were to show that nitrofurazone induced cancer or induced only benign tumors, dose-response information would be required to establish the condition of safe use.

The Norwich data from these studies were available at the time FDA issued the March 31, 1971 FEDERAL REGISTER notice of opportunity for hearing on the proposed withdrawal of approvals for nitrofurazone (NF–7). In response to the March 31, 1971 notice, Norwich stated that all four nitrofurans (NF–7, NF–64, NF–180, and NF–260) cause an early development of mammary tumors that were of the type normally found in aging rats, and it postulated that the nitrofurans caused these tumors only at high levels of exposure in the female rats because of disruption in the hormonal system. Norwich presented data purporting to show that the hormonal disruption resulting in the tumors involved a process not applicable to humans, and that the proposed methods of analysis for control of residues were more than adequate to assure that levels of residues were below any level that might adversely affect humans.

The Norwich hormonal hypothesis is described in detail in the May 13, 1976 FEDERAL REGISTER notice on a furazolidone (NF–180). The supporting information provided by Norwich for the hypothesis was primarily limited to data on furazolidone (NF–180) and some very limited comparative data on nitrofurazone (NF–7).

B. *Comparative Data on Nitrofurazone and Furazolidone.* Norwich has provided data on furazolidone (NF–180) from the Sprague-Dawley female rat study and the Carworth Farms rat study. It has also supplied data on testing on furazolidone (NF–180) in three chronic rat studies and one mouse study; the tests are described in the May 13, 1976 FEDERAL REGISTER notice. The data have a bearing on the Director's proposed action in this notice for nitrofurazone (NF–7) and his decision to reject the Norwich hormonal hypothesis for nitrofurazone (NF–7) and furazolidone (NF–180). They also have a bearing on his decision to reject the sponsors' claims that adequate studies have been provided for nitrofurazone (NF–7) to support a determination that the drug uses are shown to be safe.

In the Sprague-Dawley female rat study and Carworth Farms rat study, furazolidone (NF–180) was also tested in the protocols using a dietary level of about 0.1 percent.

In the first study, Norwich reported that 14 of the furazolidone-treated Sprague-Dawley female rats out of 32 rats examined had mammary tumors. Norwich reported a total of 37 mammary tumors, including 5 mammary adenocarcinomas, but did not designate in how many rats or in which rats the adenocarcinomas were found. The Eppley pathologists reviewed the mammary tissue slides from the 32 furazolidone (NF–180)-treated female rats and reported mammary tumors in 14 of the rats. The Bureau of Foods pathologist, who later examined only the slides from the 14 rats reported to have mammary tumors by the Eppley pathologists, confirmed the presence of mammary tumors in the 14 rats. Both the Eppley and Bureau of Foods pathologists reported only one mammary adenocarcinoma and one mammary squamous cell carcinoma, each in a different rat, from the slides they had examined of the furazolidone (NF–180)-treated rats. From these results it appears that both furazolidone (NF–180) and nitrofurazone (NF–7) at 0.1 percent in the diet had about the same effect on the incidence of rats that developed mammary tumors. However, Norwich reported that furazolidone (NF–180) caused a greater increase in the number of multiple mammary tumors that developed. From the reviewing pathologists' reports it appears that there were slightly more female rats treated with nitrofurazone (NF–7) that developed mammary adenocarcinomas that were found in the rats treated with furazolidone (NF–180). The results reported by Norwich contradict this finding on malignancies.

In the Carworth Farms rat study, 15 of the furazolidone (NF–180)-treated female rats out of 17 examined were reported by Norwich as having mammary tumors. In comparison, Norwich had reported that 11 of the nitrofurazone (NF–7)-treated female rats out of 19 examined had mammary tumors. In the furazolidone (NF–180) study the total number of tumors reported by Norwich in the furazolidone (NF–180)-treated female rats was greater than twice the number found for the nitrofurazone (NF–7)-treated female rats. Norwich reported finding two mammary adenocarcinomas in the furazolidone (NF–180)-treated female rats, but it did not specify whether these were in one or two rats. The Eppley pathologists also reported finding two mammary adenocarcinomas in two rats, and these same findings were made by the Bureau of Foods pathologist who reviewed only the slides from rats in which tumors were reported by the Eppley pathologists. In addition, the Bureau of Foods pathologist reported mammary adenocarcinoma of low-grade malignancy in two additional rats. Tumors from these two additional rats had been diagnosed as fibroadenoma by the Eppley pathologists. The numer of mammary malignancies reported for rats treated with nitrofurazone (NF–7) and furazolidone (NF–180) are comparatively small in both cases, and no meaningful conclusions can be drawn about the relative carcinogenic potentials of the two drugs. It is evident from the reviewing pathologists' reports that the predominant number of tumors found in the furazolidone (NF–180)-treated female rats were fibroadenomas, as was also seen in the nitrofurazone (NF–7)-treated rats.

Based on these comparative data, the Director concludes that furazolidone (NF–180) and nitrofurazone (NF–7) qualitatively exhibit similar tumorigenic effects in female rats. Because the studies are not adequate to assess the cumulative effects of exposure and carcinogenic potential and potency, the data are not sufficient for a precise comparison of the tumorigenic potencies. The Director, therefore, concludes that although the limited data give some indication that nitrofurazone (NF–7) may be a less potent tumorigen than furazolidone (NF–180), adequate testing of nitrofurazone (NF–7) in lifetime studies in appropriate animal species with the development of dose-response data from the administration of nitrofurazone at

several dose levels would be required to determine adequately the carcinogenic potential of nitrofurazone (NF–7).

More definitive studies of the carcinogenic potential of furazolidone (NF–180) in male and female rats and mice provided by Norwich are described in the May 13, 1976 FEDERAL REGISTER notice. A summary of tl.. findings from the three chronic rat studies and the mouse study include the following:

1. Furazolidone induced malignancies in both rats and mice.

2. Furazolidone also induced nonmalignant tumors.

3. In most cases, the induced malignant and nonmalignant tumors were found at the same sites.

4. There is some evidence that the induction of benign tumors is related to the induction of, or progression to, malignancies as a function of dose.

5. There are marked sex differences in the tumor responses in the rats. There are also some commonalities in the tumor sites of the male and female rats.

6. Mammary tumors were the predominant effect in the female rats.

7. Nonmammary tumors were induced in the Sprague-Dawley male rats, with no one type singularly significant. In the Fisher rats, however, several specific nonmammary tumors were induced in both male and female rats.

8. The major target site for tumors in the mouse was the lung. There was no evidence of a significant difference between male and female mice in tumor response, and there were no tumorigenic effects in the endocrine tissues.

9. The induction of tumors involved not only increased incidence of animals with tumors but also an increased number of tumors per animal.

The Director has rejected the data supplied by Norwich to support the hormonal hypothesis for furazolidone (NF–180). A discussion of these data and his basis for rejection are also presented in the May 13, 1976 FEDERAL REGISTER notice. The Director also rejects the Norwich reply to the 1971 FEDERAL REGISTER notice on nitrofurazone (NF–7) attempting to explain the tumorigenic effects of nitrofurazone primarily on the basis of the furazolidone (NF–180) data relative to the hormonal hypothesis. The Director finds that the new evidence provided by the more extensive chronic testing data for furazolidone (NF–180), which shows that tumors were induced in both male and female rats and mice and were not limited to tumors of the mammary gland or the endocrine tissues, is inconsistent with the hormonal hypothesis.

Therefore, the Director concludes that the comparative data available on furazolidone (NF–180) and nitrofurazone (NF–7) in the Sprague-Dawley female rat study and the Carworth Farms rat study, together with the data on the four chronic studies of furazolidone (NF–180) in rats and mice, indicate that adequate testing of nitrofurazone (NF–7) has not been provided to assess the cumulative effects of exposure necessary for a determination of safety.

II. USES OF NITROFURAZONE ARE NOT SHOWN TO BE SAFE

To assess the safety of residues using criteria described in section 512(b) of the act and elaborated on in section 512(d)(2) of the act requires a multistep process that must take into account consideration of the metabolism of the drug, determination of the resulting residues, including parent drug and the metabolites, depletion of those residues with time after drug treatment, and the cumulative effect of human ingestion of the residues. The six basic steps involved in this evaluation process have been described previously in this notice.

A. *The Amount of Total Residue in the Edible Products and the Depletion of Residues with Time Has Not Been Determined (Step 1).* When a drug is administered to an animal, the drug may be altered by the animal into a variety of compounds called metabolites. The process of alteration may be such that little residue of the parent drug remains in the animal tissue, but the amount of metabolites may be substantial. Therefore, the total residue with which FDA is concerned includes both the parent drug and the metabolites.

The nature and amount of each of the residues depend in part upon the metabolism in a particular species. Because there are species differences in metabolism, it is necessary to determine metabolism and residues in each of the species for which the drug is used. Therefore, § 514.1(b)(7)(i) (21 CFR 514.1(b)(7)(i)) includes metabolism and residue depletion studies among those kinds of studies that are used to determine residues.

Exposure to nitrofurazone in the diet induced mammary tumors in female rats. It is not known whether the parent drug was the active agent or whether the responses were due to one or more active metabolites produced as a result of ingestion of the parent drug by the rats. Such lack of knowledge is not unique to nitrofurazone; it is typical of many tumorigenic and carcinogenic agents that the mechanism of the induction of tumors or the identification of the active agent is not known. Therefore, when considering the safety of food from nitrofurazone-treated animals, all drug-related residues to which humans may be exposed must be assumed to be potentially carcinogenic unless convincing evidence is presented to the contrary. Such evidence consists of not only the identification of the residues that are claimed to be safe, but also adequate toxicological studies showing that the levels of each of the residues claimed to be safe are in fact safe. All residues not identified or not shown to be safe must be considered potentially carcinogenic and must be required to be below a level of measurement that can be considered insignificant and to pose essentially no risk of cancer in humans.

The use of chemical assays to determine initially the total residues would require knowledge about what residues occur (parent drug and metabolites) and would require the availability of adequate methods of analysis to measure each one of the residues at the level of interest in the edible tissues. Therefore, this chemical approach is usually not feasible. Instead, a radiolabeled parent drug is used to provide a practical and adequate approach to the initial measurement of total residues in the edible tissues. In this approach, the drug is synthesized with a radioisotope so that when the drug is administered to the test animal according to label directions, all resulting residues of potential interest can be measured in the edible products. This is accomplished by counting the radioactivity in the tissues and converting these measurements to an estimation of the amount of residue expressed as parent drug equivalents.

No data have been provided by the sponsors to measure total residues in edible tissues and in milk from nitrofurazone-treated animals. Similarly no data have been provided to characterize the residues occurring in the edible products. It has been shown that nitrofurazone is found as a residue in edible tissues after drug treatment, as will be described below in step 6 (paragraph F. of this section), but it has not been shown what proportion of the total residue is the parent drug.

Although no data of any type have been supplied on the metabolism of nitrofurazone in any of the animals of intended use, some limited information has been provided on nitrofurazone in published studies of the absorption, distribution, and metabolism of nitrofurazone, primarily in rats:

1. Paul, M. F. et al., "Studies on Distribution and Excretion of Certain Nitrofurans," Antibiotics and Chemotherapy, 10:287–302, 1960. The authors reported that only 4.6 percent of an administered dose of nitrofurazone was recovered as unchanged nitrofurazone in rat urine, and 0.5 percent in feces. From the report it is evident that nitrofurazone is absorbed and rapidly metabolized before elimination.

2. Paul, H. E. et al., "Metabolic Degradation of Nitrofurans," Journal of Medicinal and Pharmaceutical Chemistry, 2:563, 1960. The report described in vitro studies where nitrofurazone was added to rat tissue homogenates. After a period of incubation, extracts were analyzed by ultraviolet (uv) spectroscopy. The resulting UV spectra were compared with (1) spectra from nitrofurazone that had been subjected to chemical reduction of the nitro-group to an amine, and (2) nitrofurazone that had been subjected to action by certain reductive enzyme systems. The authors report that the three uv spectra were similar, indicating that nitrofurazone metabolism in the rat appears to include a reductive pathway.

Data from these two studies reinforce the Director's conclusion that consideration must be given to metabolism in the animal of intended drug use to assess the residues and their significance as contaminants in food.

Data on the metabolism of another nitrofuran, nihydrazone (NF-64), in chickens have been submitted by Norwich. However, these data cannot be accepted as a substitute for metabolism data on nitrofurazone in chickens or the other animals for which the drug is approved because the metabolism of each compound may differ in each of the animal species.

Because no relevant data have been submitted on the metabolism and total residue depletion of nitrofurazone, the Director concludes that he cannot determine the amount of total residue and its depletion with time in the edible products for any of the approved uses of nitrofurazone. Therefore, the first step necessary to estimate probable consumption of residues, which is a required consideration of section 512(d)(2)(A) of the act, has not been fulfilled.

B. *Sufficient Information Has Not Been Provided about the Residues to Determine the Appropriate Testing Required in Laboratory Animals to Estimate the Cumulative Effects of Human Exposure to the Residues (Step 2).* The composition of a drug's residue may vary from the extremes of less than 1 percent parent drug and more than 99 percent metabolites to less than 1 percent metabolites and more than 99 percent parent drug, though the latter case would be rare. The Food and Drug Administration must assess the toxicity of the total residue because this is what man will be exposed to in food. This assessment would be based ideally on the identification of each of the metabolites in the residue, their synthesis, and subsequent testing of the parent drug and all the metabolites for the cumulative effects of exposure. However, this approach is usually impractical.

Various approaches are available to limit the number of residue compounds for which toxicity testing is required to provide a sufficiently conservative estimate of the toxicity of the total residue. However, Norwich has not presented any quantitative or qualitative information about the total residues of nitrofurazone in the edible tissues or milk.

Therefore, the Director concludes that not only is the toxicological testing provided for nitrofurazone inadequate, but he is unable to determine whether testing of metabolites in addition to the parent drug is required to determine the safe level of human exposure to residues in food. Step 2 has not been fulfilled; therefore, the requirements for step 3 cannot be fully determined.

C. *Adequate Dose-Response Data in Test Animals to Determine the Cumulative Effects of Dietary Exposure to the Residue Compounds Has Not Been Provided; Therefore, the Maximum Acceptable Concentration of Residues in Food Cannot Be Established Using Appropriate Safety Factors to Assure that Human Exposure to Residues in the Total Diet Does Not Exceed a Level Deemed Safe (Step 3).* As discussed under section I of this notice, the Director has concluded that adequate testing of the parent drug, nitrofurazone, has not been provided. Also, under steps 1 and 2 (paragraphs A and B of this section), the Director concluded that adequate information has not been provided about the residues to determine if toxicity testing of residue compounds in addition to the parent drug is required to estimate conservatively the cumulative effects of exposure to the residues.

The Director concludes that without such essential information about the residues and adequate toxicity testing data, he cannot, in light of the new evidence, determine if nitrofurazone requires regulation as a carcinogenic animal drug or, alternatively, to reasonably estimate a maximum acceptable level of residue in food that can be deemed safe. Therefore, he concludes that adequate information has not been provided to assess the cumulative effects of exposure and to determine the appropriate safety factors required in section 512(d)(2)(B) and (C) of the act.

D. *Sufficient Information about the Residues Has Not Been Provided to Establish the Conditions Necessary for the Analytical Method Used to Control Residues (Step 4).* The evaluation of an analytical method for residues first requires a determination of the tissues to be analyzed, the compound to be measured, and the lower limit of measurement that must be achieved to control total residues adequately. Only then, after selection of these parameters, is it meaningful to consider whether the method proposed by the sponsor meets other characteristic necessary for a practical reliable method.

1. Determination of the target tissue: The most practical approach to monitoring and controlling residues in the field is dependent on the selection of that edible tissue in which residues require the longest time to deplete to a "safe concentration." Therefore, by monitoring this tissue to assure that residues are below a "safe concentration," it can be assured that all residues in the carcass are below "safe concentrations." In lieu of this determination (identification of the target tissue), all edible tissues, including milk where applicable, must be monitored. This would place an additional burden on public funds for monitoring.

The target tissue is readily identified if the requirements of step 1 of the evaluation process are met. Norwich has failed to meet these requirements for any of the approved uses of nitrofurazone.

2. Determination of the compound (marker) which can be measured by the analytical method to assure control of total residues: Because the radiolabeled drug approach used initially to estimate total residues is not applicable to regulatory use, an alternative approach must be developed to assure control of total residues after drug approval. This is achieved by selecting an appropriate residue compound, which may be the parent drug or one or more metabolites, in such a way that its measurement serves as a valid indicator that when the marker compound is below a certain level in the target tissue, all residues in edible tissues are at safe levels. This step is esential to determine if the method of analysis for regulatory use is adequate. To determine a valid marker, adequate information, e.g., information derived from conducting an adequate metabolism study, is required that relates the proportionate amount of each of the residues to the total residue and their change in quantitative relationships with time. The marker must be a known proportion of the total residue when the total residue depletes to the "safe concentration" in the target tissue. It also must be structurally identified so that an adequate and specific method of analysis can be developed for its determination.

The regulatory method proposed by Norwich to control residues uses the parent drug, nitrofurazone, as a marker in each of the major edible tissues. Norwich has failed to submit substantiating evidence to show that the measurement of nitrofurazone is adequate to control total residues of potential concern or, alternatively, to show that all other residues are safe and do not need to be controlled.

3. Determination of the lower limit of measurement required for the analytical method: Establishment of the lower limit of measurement required for the assay begins with the availability of adequate toxicological testing to determine the cumulative effects of exposure. As described in section I of this notice and in steps 2 and 3 of this section, the sponsors have not provided adequate testing. Therefore, an estimate of the acceptable level of exposure to total residues in food cannot be determined.

Even if adequate testing data were available to estimate the acceptable level of exposure to total residues in food, Norwich has not provided adequate information about a marker compound to determine the lower limit of measurement required for the assay.

As previously stated, Norwich has proposed that the measurement of nitrofurazone is adequate to assure control of residues, but it has not provided any information to show whether nitrofurazone may be, for example, 80 percent of the total residue or 10 percent of the total residue. Therefore, it is not possible to determine at what concentration the marker must be measured to assure that total residues are at a "safe concentration."

After making the adjustment for the percent of total residue that the marker represents, one further adjustment is necessary to determine the lower limit of measurement required for the assay. This last adjustment takes into account the degree to which the method of analysis recovers the residue from the sample. Minimum standards for recovery for the acceptance of the method take into account that 100 percent recovery is rarely achieved and that a combined evaluation of the precision and accuracy for measurement of the marker must be considered.

Norwich is aware of the principles just described for the selection of a target tissue, marker compound, and the adjustments required to establish condi-

tions for the assay; this is evidenced by Norwich's citation of a paper prepared by two FDA scientists in Norwich's submission for furazolidone (NF–180) to FDA on November 11, 1975. The cited paper by M. K. Perez and N. E. Weber, entitled "Requirements for Metabolic Studies—Impact on Food Safety Regulation" was presented at the Gordon Research Conference on Drug Metabolism, June 23–27, 1975.

The Director concludes that he cannot make an assessment of the toxicity, including the carcinogenic potential and potency, of nitrofurazone without adequate testing data; he cannot conclude that nitrofurazone serves as a valid marker for control of total residues of toxicological interest; and therefore he cannot without adequate supporting data determine the conditions necessary for the analytical method used to control residues. The requirements of step 4 have not been fulfilled. He concludes that the new evidence on nitrofurazone (NF–7) and furazolidone (NF–180) leads to a determination that the methods of analysis for residues of nitrofurazone (NF–7) are not shown to be adequate.

E. *Practicable Methods of Analysis are Not Available to Assure that Total Residues in the Daily Diet of Humans Do Not Exceed a Level Deemed Safe (Step 5).* Section 514.1(b)(7) (21 CFR 514.1 (b)(7)) requires the sponsor of a new animal drug application to provide a practicable method of analysis to be used for the control of residues of its product. A "practicable" method is defined by FDA as one that reliably measures the compound throughout all residue levels of interest, and also is sufficiently rapidly and reasonable in terms of the expertise and equipment required to be applicable for use in the surveillance and control of residues. "Reliability" is a combination of accuracy, precision, and specificity. Accuracy and precision are quantitative terms. "Accuracy" is the measure of deviation from the true value, and "precision" refers to the variability of measurement in replications either by one analyst or within a laboratory or between laboratories. A method may provide reliable measurement if the measurements are not too variable even though it measures less than or more than 100 percent of the true value. Therefore, accuracy and precision must be considered together.

"Specificity" is a qualitative term. The measurements obtained by the method must reflect only the compound of interest. Because the method will be used on samples from animals for which exposure history is unknown, the techniques used in the method must be adequate to assure not only the integrity of the measurements, but also the identity of the residue to the exclusion of other interfering substances. Therefore, when the quantitative measurements are made by techniques that are not inherently specific, a confirmatory test is required as part of the official method to assure the identity of the residue.

The submitted methodology for nitrofurazone is based on chromatographic separation and fluorometric determination; both are nonspecific techniques. The uses of nitrofurazone were approved before that time when regulatory methods of analysis for residues were required. In 1960, a method of analysis for tissues capable of measuring nitrofurazone as low as 1 part per million (ppm) was published in Analytical Chemistry, 32(12):1676–1678. In 1962, FDA was provided with a method of analysis for nitrofurazone in milk; the method was claimed to be capable of measuring nitrofurazone as low as 0.01 ppm. This method was subsequently published in the Journal of Agricultural and Food Chemistry, 12:121, 1964. About the same time, revised methodology for tissue residues was also submitted to FDA; the revised methodology was claimed to be capable of measuring nitrofurazone as low as 0.1 ppm in tissue.

None of these methods have been subjected to validation trials by FDA. The data submitted in support of these methods only include studies of the recovery of nitrofurazone from samples to which known amounts of the drug have been added, i.e., spiked samples. No evidence has been submitted to show that the methods will satisfactorily recover nitrofurazone when the residue is naturally incurred through drug treatment, i.e., dosed samples.

After FDA received reports that nitrofurans had induced tumors in female rats, the drug sponsors were advised in 1969 and officially informed in a conference held January 4, 1971, that the residue methods were no longer deemed adequate. They were told that methods capable of measuring at least 2 ppb of the drug in edible tissues and at least 0.2 ppb of the drug in milk were required. In response to the notices of opportunity for hearing, Norwich and other sponsors submitted newly developed methods of analysis.

For the measurement of tissue residues, Norwich concentrated primarily on the method for furazolidone (NF–180) in the belief that this method could be readily adopted for the measurement of tissue residues for the other nitrofurans.

A discussion of the results on the evaluation of the furazolidone (NF–180) method for tissue analysis (including swine liver, kidney, muscle and fat and poultry liver, kidney, muscle and skin with adhering fat) is presented in the May 13, 1976 FEDERAL REGISTER notice for furazolidone. In that notice the Director concluded that the methods for edible tissue were not shown to be adequate.

Although the drug sponsors have submitted far more information to support the adequacy of the methods of analysis for furazolidone (NF–180) than they have submitted on methods of analysis for nitrofurazone, the sponsors have in the intervening years submitted some progress reports on the development of analytical methods for nitrofurazone.

In 1971, three different progress reports were submitted on the analysis of nitrofurazone in chicken tissues.

1. Project No. 475–17 Interim Report, "Chemical Method for Determination of Concentrations of Nitrofurazone in Chicken Liver at 2 ppb." Submitted to FDA with cover letter dated April 29, 1971.

The method presented was based on an ultraviolet densitometric measurement similar to the original method submitted for furazolidone (NF–180), which was rejected by FDA after a desk review of the supporting data. In the nitrofurazone submission, no recovery data were submitted. The results of analysis of five control chicken liver samples were submitted and compared to results obtained on three samples, each fortified with 2 ppb and 4 ppb of nitrofurazone. The measured responses for the samples fortified at the same level were quite variable, though it appeared that the method could perhaps distinguish between fortified and nonfortified samples. In a conference on May 4, 1971, Norwich was advised that the data were too meager for reasonable evaluation.

2. By letter dated May 17, 1971, Norwich provided data on the recovery of nitrofurazone from chicken liver, muscle, and skin-with-fat samples. The same ultraviolet densitometric method described in study 1 above was used. Norwich reported the following recoveries and standard deviations from tissues fortified with 2 ppb of nitrofurazone: liver (49±15%, muscle (47±14%), and skin-with-fat (39±5%). These recoveries were presumably based on the use of an internal standard where corrections were made for aliquot losses and losses in partitioning between solvents; so, they appear higher than the actual recoveries. The firm submitted data for samples fortified with nitrofurazone at 2 ppb, 4 ppb, and 6 ppb. These comparative data showed that the method could not reliably distinguish between the presence of 2 ppb and 4 ppb of nitrofurazone in liver tissue. Also, the single skin-with-fat sample fortified with 6 ppb nitrofurazone produced a lower reading than the one sample fortified with 4 ppb of nitrofurazone.

3. On September 17, 1971, Norwich submitted data on the analysis of chicken kidney for nitrofurazone using the same ultraviolet densitometric method used in studies 1 and 2 described above. Data were provided on peak areas, but sufficient data were not provided to calculate recoveries. The analytical response for the control tissues was as high as 66 percent of the response obtained with tissues fortified with 2 ppb of nitrofurazone.

After 1971, Norwich apparently abandoned the ultraviolet densitometric approach and concentrated on the method of analysis for furazolidone (NF–180) that was subjected to a method trial by FDA and USDA in 1972. They also explored the use of new instrumentation (programmed multiple development thin layer chromatography (PMD–TLC)) and mechanization of spotting thin layer chromatography plates.

By letter dated September 6, 1974, Norwich submitted a status report to FDA on the analysis of nitrofurazone in chicken and swine tissue using the PMD–TLC method. This report included the results of analyses of samples of chicken mus-

cle, kidney, and skin-with-fat and swine muscle, fat, liver, and kidney fortified at 2 ppb, 4 ppb, and 6 ppb with nitrofurazone. No data were presented on the analysis of chicken liver. Recoveries for the samples fortified with 2 ppb of nitrofurazone were calculated by FDA as follows: chicken muscle (112–141%), chicken kidney (84–103%), chicken skin-with-fat (46–76% with the exclusion of one of the four samples where there was an interfering fluorescent band), swine liver (108–142%), swine muscle (82–127%), swine kidney (81–117%), and swine fat (67–116% with the exclusion of one of four samples as an outlier).

Due to the within-laboratory variability in the results, FDA chemists rejected the data as not adequate to warrant interlaboratory validation of the method. It appeared unlikely that the method, if subjected to validation trials, would prove reliable for measurement of nitrofurazone at 2 ppb. Also, as stated previously, until adequate data are presented as described in steps 1 through 4 of the safety evaluation process, the conditions required of a regulatory assay cannot be determined and, therefore, a validation trial is of no value at this stage.

No supporting data have been presented on a method of analysis for edible carcass tissue of food animals other than chickens and swine for which nitrofurazone is approved.

In response to the March 31, 1971 notice of opportunity for hearing on nitrofurazone, Pharm-House Inc. submitted a method of analysis for nitrofurazone in milk; it claimed the method could detect nitrofurazone as low as 2 ppb. The method was based on colorimetric determination of a phenylydrazone derivative of nitrofuzazone. This method was based on essentially the same derivatization technique and measurement as the method submitted by Norwich in 1962, but the Pharm-House method used a different chromatographic cleanup of the extract and concentration of the colored analyte before the colorimetric determination of the nitrofurazone derivative. No recovery data were submitted and a satisfactory standard curve was not presented. Control milk samples showed a response 50 percent of that measured for samples fortified with 2 ppb of nitrofurazone. Only two samples at each fortification level were reported; that is an insufficient number. From the data submitted it is doubtful that the method could provide reliable measurement of nitrofurazone at 2 ppb even if this level were found adequate.

None of the submitted methods of analysis for nitrofurazone in edible carcass tissue or milk are inherently specific, and no confirmatory tests have been provided by the sponsors that could be used to confirm the identity of any residue found by the proposed assay methods.

The Director concludes that the sponsors have not shown that adequate practicable methods of analysis for residues of nitrofurazone in edible carcass tissue and milk are available. Appropriate data have not been provided to determine if nitrofurazone can be used as a marker to control total residues in edible products, nor to determine the lower limit of measurement required for a method to assure that total residues do not exceed safe levels. The Director concludes that the methods proposed by the sponsors for the determination of nitrofurazone are not quantitative and are not adequately specific at the levels of measurement that are likely to be necessary based on the tumorigenic property of the drug. Therefore, the methods proposed are not quantitatively or qualitatively reliable practicable methods for regulatory use, even if it were established that measurement of nitrofurazone was adequate to control total residues. Therefore, step 5 and the requirements of section 512 (b) (7) of the act have not been met.

F. *Practical Conditions of Use Cannot be Prescribed on the Label of Products to Assure Safe Use (Step 6)*. Section 512 (b) (8) of the act requires that conditions of use assure that there are no unsafe residues, and section 512(d) (2) (D) of the act adds a further requirement that these conditions be such that they are "reasonably certain to be followed in practice."

It is required by FDA that residue depletion studies be conducted for each drug use under simulated field use conditions to develop data for establishing the withdrawal period. A withdrawal period is the time following drug treatment when, because of residues, a treated animal cannot be slaughtered for food and its milk must be discarded. A withdrawal period must be sufficiently long to assure adequate residue depletion, but it cannot be so long that it is impractical and unlikely to be followed in practice. An adequate analytical method for residues, preferably the same method that will be approved for regulatory use, must be used to measure the residues in the depletion studies.

Only two reports have been submitted by the sponsors of nitrofurazone on residue depletion, and both studies measured only the presence of the parent drug nitrofurazone:

1. Final Report Problem 466.03.23, Phase II and 466.27.23, "Tissue Residues in Swine from Furacin Water Mix," April 19, 1967, NADA 9–415, Vol. 3. From cover letter to FDA, dated January 8, 1971.

Swine were administered nitrofurazone at 0.011 percent in drinking water for 14 days. No nitrofurazone was detected in the edible tissues (liver, kidney, fat, or muscle) at zero day's withdrawal by a chemical method of analysis that Norwich claimed was capable of detecting nitrofurazone as low as 0.1 ppb.

2. Dr. J. L. Mertz's Memorandum to Dr. J. P. Heotis, "Tissue Residue Withdrawal Studies for Nitrofurazone (Amifur) in Chickens Fed Nitrofurazone at 150 Grams Per Ton of Feed for 14 Days," November 8, 1971, NADA 9–415, Vol. 3.

Chickens were fed nitrofurazone at 150 grams per ton in feed for 14 days. Animals were slaughtered at 3, 4, and 5 days after withdrawal from medication. Edible tissues were examined using the TLC-ultraviolet based methodology, which the sponsor claimed could detect nitrofurazone as low as 2 ppb. However, FDA had not accepted this method because of the variability in the recovery data submitted. Only kidney samples were analyzed after 3 days' withdrawal. Samples of kidney, liver, muscle, and skin with fat were analyzed at 4 and 5 days' withdrawal. One of four kidney samples was reported to contain 2 ppb of nitrofurazone at 3 days' withdrawal. One of two kidney samples was reported to contain nitrofurazone above 2 ppb after 5 days' withdrawal. All other samples analyzed at the various withdrawal times were reported to contain no detectable nitrofurazone.

No residue depletion data have been provided for the other food-producing animals for which the use of nitrofurazone is approved, i.e., poultry other than chickens and large animals other than swine.

Nitrofurazone was originally approved for the treatment of mastitis in 1949, including both lactating and dry cow treatment. However, in 1963, the sponsor revised the labeling to limit its use to dry cow treatment only. No residue depletion studies have been submitted to demonstrate whether this dry cow treatment results in residues in milk after the treated animals freshen or whether the treatment would result in residues in the edible carcass tissues that would be of concern in the event the animal was culled from the dairy herd for slaughter.

The Director concludes that withdrawal periods are likely to be necessary for the safe use of nitrofurazone. The currently labeled withdrawal period for chickens, turkeys, and swine voluntarily used now by the sponsors is 5 days. The Director concludes that data to support this withdrawal period or any practical withdrawal period for any of the uses have not been provided because:

a. No data for any of the uses have been submitted on the amount of total residue (parent drug and metabolites) after drug treatment and the depletion with time of total residues of concern.

b. No data have been provided to show that only the parent drug compound is of concern in evaluating the safety of the residue.

c. No data have been provided to show whether the measurement of nitrofurazone in edible products can be used to control total residues and, if so, at what level its measurement is required to assure that all residues are below concentrations deemed safe.

d. The residue depletion studies submitted for chickens and swine are not shown to be adequate even if nitrofurazone could be shown to be an adequate marker for total residues. In the swine study the method of analysis would not be sufficiently sensitive based on the known tumorigenic properties of the drug. Similarly, the method use in the chicken study, even if it could be shown that nitrofurazone measurement at 2 ppb was adequately sensitive, is not acceptable because the supporting data on the

method are not adequate to assure the reliability of results.

e. No depletion data have been submitted for uses of nitrofurazone in poultry other than chickens and in large animals other than swine, or for safe use of nitrofurazone as a dry cow treatment for mastitis.

The requirements of step 6 and section 512(b)(8) and (d)(2)(D) of the act have not been fulfilled.

Therefore, the Director is hereby withdrawing the notice of opportunity for hearing issued March 31, 1971, proposing to withdraw approval of NADA's providing for the use of nitrofurazone (NF–7) in food-producing animals. Under section 512(e)(1)(B) of the act (21 U.S.C. 360b(e)(1)(B))., the Director proposes to withdraw approval of certain existing NADA's providing for the use of nitrofurazone in food-producing animals on the grounds that such use violates section 512 of the act in that such use has not been shown to be safe.

This notice applies to all outstanding NADA's for the use of nitrofurazone in food-producing animals. All such applications known to FDA are listed below by NADA number and by each applicant's name and last known address in FDA records. Copies of this notice are being forwarded by registered or certified mail to each of the known applicants. Notice to other applicants or holders of NADA's whose identity is not known to FDA is given by this publication.

6–395, 7–801, 8–324, 8–410, 8–529, 8–784, 10–741, Hess & Clark, Division of Rhodia, Inc., 7th and Orange St., Ashland, OH 44805.
6–475, 8–129, 9–415, Eaton Laboratories, Division of Morton-Norwich Products, Inc., P.O. Box 191, Norwich, NY 13815.
6–649, E. F. Drew & Co., Farm Feed Division, Boonton, NH 07005.
9–013, Nopco Chemical Co., 60 Park Place, Newark, NJ 07102.

Any holder of an approved application that elects to request an opportunity for hearing pursuant to section 512(e)(1) of the act and § 514.200 of Chapter I of Title 21 of the Code of Federal Regulations must file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, a written appearance requesting such hearing by September 16, 1976, giving the reasons why approval of the application should not be withdrawn, and providing a well-organized and full-factual analysis of the scientific and other investigational data such holder is prepared to prove in suppport of its opposition to the Director's proposal. A request for hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is one or more genuine and substantial issue(s) of fact requiring a hearing. Responses to this notice and copies of published literature cited in this notice may be seen at the office of the Hearing Clerk, Food and Drug Administration, during regular business hours, Monday through Friday.

If a hearing is requested and is justified by any holder's response to this notice of opportunity for hearing, the issues will be defined, an Administrative Law Judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

Any hearing on withdrawal of approval of the foregoing NADA's will be open to the public. If, however, the Director finds that portions of the applications that serve as a basis for such a hearing contain information concerning a method or process that is entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.29) (recodification published in the FEDERAL REGISTER of June 16, 1976 (41 FR 24262)).

A discussion of the economic and environmental impact of this action is set forth in the notice of proposed rule making on nitrofurazone published elsewhere in this issue of the FEDERAL REGISTER.

It is hereby certified that the economic and inflation effects of this proposal have been carefully evaluated in accordance with Executive Order 11821.

Dated: August 6, 1976.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc.76-23622 Filed 8-10-76;11:19 am]

[Docket No. 76N-0233]

HESS & CLARK, ET AL.

Nihydrazone (NF–64); Opportunity for Hearing on Proposal To Withdraw Approval of Certain New Animal Drug Applications

The Director of the Bureau of Veterinary Medicine of the Food and Drug Administration (FDA) is issuing a notice of opportunity for hearing on a proposal to withdraw approval of approved new animal drug applications (NADA's) Nos. 13–195 and 13–200 for the use of nihydrazone (NF–64) in food-producing animals in accordance with section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(1)(B)) (hereinafter, "the act") on the grounds that new evidence not available when the applications were approved, evaluated together with the evidence available at the time of approval, shows that nihydrazone is not shown to be safe for use under either the approved or currently labeled conditions of use. Holders of approved NADA's have until September 16, 1976 to submit requests for a hearing in accordance with § 514.200 (21 CFR 514.200).

In FR Doc. 76–23620, appearing elsewhere in this issue of the FEDERAL REGISTER, the Director is issuing a notice of proposed rule making to revoke the appropriate provisions of sections affected by the proposed withdrawal.

Nihydrazone (NF–64) is a member of a class of chemicals called "nitrofurans," which are used at low levels in animal feed as antibacterial and antiprotozoan agents to increase resistance to disease, thereby assisting growth. Nitrofurans also have prescribed therapeutic uses. In addition to nihydrazone (NF–64), which is the subject of this notice, there are three other nitrofurans that are used in food-producing animals and are or have been subject to agency action: nitrofurazone (NF–7) and furaltadone (NF–260), which are subjects of companion notice in this issue of the FEDERAL REGISTER; and furazolidone (NF–180), which was the subject of notices in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906–19907). A fifth nitrofuran, furamazone (NF–84), is not at this time the subject of contemplated agency action for withdrawal.

Nihydrazone (NF–64) was first approved in 1963. It is currently approved for use in medicated broiler and replacement chicken feeds for the prevention of chronic respiratory disease (air sac infection), pullorum disease, fowl typhoid, paratyphoid (salmonellosis), histomoniasis (blackhead) and coccidiosis caused by *Eimeria tenella, E. necatrix, E. maxima,* and *E. brunetti.*

The original applications were approved without a requirement that the drug treatment be discontinued for a specified period of time before slaughter of the animals. However the sponsors, Norwich Pharmacal Co., Division of Morton-Norwich Products, Inc., and Hess & Clark, currently a Division of Rhodia, Inc., voluntarily revised the labels in January 1971 to require that chickens be withdrawn from nihydrazone (NF–64) 4 days before slaughter.

The Food and Drug Administration issued a notice of opportunity for hearing published in the FEDERAL REGISTER of March 31, 1971 (36 FR 5927) proposing to withdraw approval of NADA's for nihydrazone (NF–64) on grounds that:

> Information available to the Commissioner establishes that the drugs, when administered to laboratory animals, have been shown to produce tumors. The drugs are, therefore, not considered to be safe for use in the absence of appropriately sensitive methods of analysis to establish their absence in food derived from treated animals.

Similar notices were published for nitrofurazone (NF–7) in the FEDERAL REGISTER of March 31, 1971 (36 FR 5926) and for furazolidone (NF–180) and furaltadone (NF–260) on August 4, 1971 (36 FR 14343). The history leading to the publication of these 1971 notices is discussed in the May 13, 1976 notice for furazolidone (NF–180).

Norwich and Hess & Clark responded to the March 31, 1971 notice concerning nihydrazone (NF–64) by filing requests for a hearing. Norwich assured FDA that it had adequate methods of analysis to determine residues and adequate data to show that under the currently labeled conditions of use the drugs were safe. In addition, Norwich set forth a hypothesis that nitrofurans were not primary

tumorgens but stimulated spontaneous tumor growth by disrupting the normal hormone balance.

Norwich has continued to submit data pertaining to the use of nihydrazone (NF–64) in food-producing animals. The Food and Drug Administration has determined that the new evidence, evaluated together with the evidence available when the approvals were granted, fails to demonstrate that either the approved or currently labeled uses of nihydrazone are shown to be safe. The Director is withdrawing the March 31, 1971 notice of opportunity for hearing concerning nihydrazone (NF–64), and is issuing this new notice, which presents in detail all the evidence now available to him, and the basis on which he proposes to withdraw approval of all uses of nihydrazone (NF–64) in food-producing animals in accordance with section 512(e)(1)(B) of the act.

Section 512(e)(1)(B) of the act requires that FDA withdraw approval of an NADA when "new evidence * * * evaluated together with the evidence available * * * when the application was approved, shows that such drug is not shown to be safe * * *." Under this provision, the new evidence and the evidence submitted at the time the application was approved must be evaluated to determine whether all of the requirements for safety contained in section 512 of the act continue to be fulfilled.

The Determination of "Safety" in Section 512

Section 512 of the act requires that the use(s) of a new drug in food-producing animals must be supported by adequate data supplied by the sponsor in applications that include, among other things, demonstration that the drug's use will not result in unsafe residues in human food.

Under section 512(b) of the act, whenever a drug's use may result in residues of the drug in food, an application must include not only full reports of investigations to show that the use of the drug is safe, but also a description of practicable methods for monitoring food to assure there are no unsafe residues in human food attributable to the drug's use, and demonstration that the conditions of use are adequate to assure there are no unsafe residues.

Under section 512(d)(2) of the act, FDA is required, in the evaluation of the supporting safety data, to consider, among other things, the following:

1. The probable consumption of such drug and of any substance formed in or on food because of the use of such drug (i.e., probable human consumption of residues, including the parent drug and metabolites).

2. The cumulative effect of such drug on man or animals, taking into account any chemically or pharmacologically related substance (i.e., toxicological effects of the compounds comprising the residues).

3. Safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data (i.e., establishing "safe" levels of residues using appropriate safety factors to extrapolate animal data on cumulative effects to humans).

Under section 512(d)(1)(H) of the act, additional requirements must be met if the drug is a carcinogen.

The determination of safety within the meaning of section 512 of the act for a drug whose use may result in residues in the edible products of the treated animal, whether or not the drug is a carcinogen, requires a multistep process. These steps form an orderly procedure by which information is derived to satisfy each of the three considerations stated above.

Step 1. Assessment of the total residues in edible products and the depletion of those residues with time following cessation of drug treatment in order to determine probable human consumption (section 512(b)(1) and (d)(2)(A) of the act).

Step 2. Assessment of information about the residues to determine the appropriate testing in laboratory animals required to estimate the cumulative effects of human exposure to the residues (section 512(b)(1) and (d)(2)(A) of the act).

Step 3. Acquisition of dose-response data in test animals to determine the cumulative effects of dietary exposure to the residue compounds from which the maximum acceptable concentration of residues in food can be established using appropriate safety factors to assure that human exposure to residues in the total diet does not exceed a level deemed safe (section 512(b)(1) and (d)(2)(B) and (C) of the act.) In the case of a carcinogenic drug, a conservative statistical extrapolation of the tumor data is used to estimate a level of residue exposure that could be considered insignificant and poses essentially no risk of cancer and operationally defines "no residue" for purposes of computing the residue assay requirements under section 512(d)(1)(H) of the act.

Step 4. Acquisition of information about the residues to (1) determine the tissue (called the target tissue) from which residues require the longest time to deplete to safe levels and which, therefore, must be monitored by the regulatory assay (step 5), and (2) determine the compound (called marker) that is to be measured in the regulatory assay so that by its measurement there is assurance that no unsafe resides occur from the use of the drug (section 512(b)(7) of the act).

Step 5. Development of a practicable method of analysis that can measure the marker in the target tissue at a concentration that assures that total residues in the daily diet of humans do not exceed the level established in step 3 as safe (section 512(b)(7) of the act).

Step 6. Demonstration that practical conditions of use can be prescribed on the label of the product to assure there will be no unsafe residues in the food products from treated animals (section 512(b)(8) and (d)(2)(D) of the act).

Each of the steps involves principles that are essential for a determination of food safety and compliance with the requirements of the act to assure there are no unsafe residues in human food from the animal drug use. Each step builds upon the preceding step. Therefore, failure to accomplishment any one of the six steps in whole or in part for any drug ordinarily will preclude a sponsor's fulfilling its obligation under the act to determine probable consumption of residues and cumulative effects of exposure, and to establish safe conditions of use with appropriate regulatory methods of analysis to control residues when deemed necessary.

New evidence concerning nihydrazone (NF–64) not available when the applications were approved includes, among other things, a demonstration that nihydrazone induces mammary tumors in female rats. The Director has evaluated all the data now available, including the new data received since 1963 when uses for nihydrazone were first approved and the data available to FDA at the time of approval, and has concluded that the approval of NADA's for nihydrazone must be withdrawn under section 512(e)(1)(B) of the act because:

1. Adequate investigations have not been provided to show that the uses of nihydrazone are safe, as required by section 512(b)(1) of the act. Adequate information has not been provided on the probable consumption of residues, and the cumulative effects of exposure have not been determined by appropriate tests, as required by section 512(d)(2)(A) and (B) of the act. Therefore, "safe" levels of residue cannot be determined using appropriate safety factors, as required by section 512(d)(2)(C) of the act.

2. Adequate, reliable, and practicable methods of analysis are not available for monitoring food to assure there are no unsafe residues in edible tissues that are attributable to the use of nihydrazone, as required by section 512(b)(7) of the act.

3. Practical conditions of use cannot be specified in the labeling to assure there are no unsafe residues attributable to the use of nihydrazone, as required by section 512(b)(8) and (d)(2)(D) of the act.

The data on which these conclusions are based are presented in the succeeding sections of this notice. The Director first describes all the relevant new evidence bearing on the determination of safety for the uses of nihydrazone. Then he evaluates all the evidence before him using the six-step procedure necessary to satisfy a human safety determination for the use of nihydrazone (NF–64) and to meet the considerations required in section 512 of the act.

I. New Evidence

In October 1966 and in January 1967, Norwich submitted reports of the effect in rats of feeding diets containing nitrofurans for 45 weeks. These studies included tests on nihydrazone (NF–64) and furazolidone (NF–180). In these studies it was shown that both nihydrazone (NF–64) and furazolidone (NF–180) in-

duced mammary tumors of similar type in female rats.

Subsequently, more extensive, longer term testing of furazolidone (NF–180) was conducted, but further testing of the carcinogenic potential of nihydrazone (NF–64) has not been undertaken. The more extensive testing of furazolidone (NF–180), as described in the May 13, 1976 FEDERAL REGISTER, shows that the drug induces cancer in both rats and mice and that the tumors and cancers were not limited to the mammary gland or the endocrine tissues of female rats.

The Director is including in this notice information available on the toxicological properties of furazolidone (NF–180) as well as nihydrazone (NF–64) because of the structural similarities of the drugs and their similar biological properties, which have been observed in the limited comparative data available. The new evidence showing that furazolidone (NF–180) is a carcinogen has a significant bearing on the Director's conclusions that the uses of nihydrazone (NF–64) are not shown to be safe.

Although it is appropriate to consider data on furazolidone (NF–180) to judge the adequacy of existing data to support the safe use of nihydrazone (NF–64) in food-producing animals, these data are not a substitute for data on nihydrazone (NF–64) that are required by the statute. Basic data are required for each drug, recognizing that slight differences in chemical structure can result in significant differences in metabolism, residues, and toxicity. Although comparative data on the biochemical and toxicological properties of related drugs may be useful and appropriate in making decisions about the degree of testing required for each drug to show there is no probable hazard, these data cannot be used as a substitute for the basic information necessary on each drug to determine the probable exposure to residues and cumulative effects of exposure.

A. *Carcinogenic Potential of Nihydrazone.* Norwich submitted data in October 1966 and January 1967 on the cumulative effects in rats of feeding diets containing nihydrazone (NF–64) for 45 weeks ("Effects of Long Term Feeding of Various Nitrofurans, October 13, 1966 and January 4, 1967, Project No. 440.07, submitted to FDA as part of a June 2, 1967 drug experience report). These studies include data on testing in female Sprague-Dawley (Holtzman strain) rats and testing in both male and female Carworth Farms (CFE strain) rats.

1. The Sprague-Dawley Female Rat Study: Thirty-five female Sprague-Dawley rats (Holtzman strain) were fed nihydrazone at about 0.06 percent (34 milligrams per kilogram (mg/kg) body weight per day) in their diet for 45 weeks, followed by maintenance on an unmedicated diet for an additional 8 weeks before sacrifice. A comparable control group of female rats was maintained on a nihydrazone-free diet for 53 weeks. At termination of the study the animals were autopsied, and tissues were examined for histopathological lesions.

The most prominent drug-related effect was the induction of tumors in the mammary glands of the female rats. Although rats develop mammary tumors spontaneously as they age, the incidence of spontaneous mammary tumors in rats just over 1 year old, depending upon the strain of rat used, can be quite loww. The nihydrazone-treated female rats had an increased number of mammary tumors, particularly the number of fibroadenomas, as compared with the control rats. The development of tumors included the finding of some mammary adenocarcinoma (cancer).

Norwich reported that no mammary tumors of any type were observed in the 33 control rats examined. It reported from histopathological examination that a total of 11 mammary tumors were found in 9 of the 32 nihydrazone-treated female rats examined. Two of the mammary tumors were reported by Norwich as adenocarcinomas. Norwich did not designate whether these cancers were found in one or two rats.

An Ad Hoc Committee was established to review the pathology data on all the nitrofurans tested in the Sprague-Dawley rat study and the Carworth Farms rat study. One member of the Ad Hoc Committee was the director of the Eppley Institute for Research in Cancer, University of Nebraska. He and his associate pathologists reviewed the pathology slides of the mammary tissues from 32 of the nihydrazone-treated rats provided by Norwich; they submitted a detailed report to FDA. They did not review all the mammry gland slides from the control rats.

Each of the reviewed slides had a rat identification number, and there were several slides for each rat. However, there was no information on the number of tumors in each rat. Therefore, it was not possible, in many cases, for the pathologists to determine which slides represented different tumors in the same rat and which were different sections of a single tumor.

The Eppley pathologists concluded from their review of the nihydrazone-treated female rats that nine of the rats had mammary tumors that were predominantly fibroadenomas and that three of these rats had mammary adenocarcinoma.

Because the Norwich report did not indicate which rats had tumors, it is not possible from the data available to determine if the tumors reported by the Eppley pathologists were from the same rats in which Norwich had reported tumors. The Eppley pathologists reported mammary adenocarcinoma in three of the nihydrazone-treated rats, whereas the Norwich report only indicates the finding of two mammary adenocarcinomas and does not indicate the number of rats with cancer. However, because the Epply pathologists did not review all the mammary gland slides from the control rats, a comparative incidence of mammary cancer cannot be determined from the reports.

A pathologist from the Bureau of Foods of FDA, who was not a member of the Ad Hoc Committee, later reviewed the pathology slides of the mammary tumors from the nihydrazone-treated rats in which the Eppley pathologists had reported mammary tumors. From his examination of the histopathological preparations provided, he reported nine slides of mammary fibroadenoma from nine rats and three slides of mammary adenocarcinoma from two rats. The mammary adenocarcinomas were diagnosed in the same two rats in which the Eppley pathologists had diagnosed mammary adenocarcinoma. However, the Bureau of Foods pathologist diagnosed a fibroadenoma in the third rat, which has been reported by the Eppley pathologsts to have an adenocarcinoma.

The Bureau of Foods pathologist also did not have information indicating which slides were multiple sections of single tumors or which represented different tumors. He did have information on the rat identification number for each set of slides. Because the Bureau of Foods pathologist did not review all the slides in the study, tumor incidence and the comparison of incidence with the control rats cannot be determined from his report. However, his report supports the Eppley pathologists' findings that mammary tumors were found in at least nine of the rats treated with nihydrazone and confirms that mammary adenocarcinoma was found in at least two of the nihydrazone-treated rats.

2. The Carworth Farms Rat Study: Nihydrazone (NF–64) was fed to 20 male and 20 female Carworth Farms (CFE strain) rats at about 0.06 percent in the diet (27 to 32mg/kg body weight per day) for 45 weeks, followed by maintenance on an unmedicated diet for an additional 7 weeks before sacrifice. A comparable control group of rats was maintained on a nihydrazone-free diet for 52 weeks. At termination of the study the animals were autopsied, and the tissues were examined for histopathological lesions.

As in the previous Sprague-Dawley rat study, the most prominent drug-related effect seen was the induction of tumors in the mammary glands of female rats. This included an increase in the number of mammary fibroadenomas and the finding of one rat with mammary adenocarcinoma.

Norwich reported that no tumors were observed in the 15 female control and 18 male control rats examined. Norwich reported from histopathological examination that 7 out of 20 nihydrazone-treated female rats examined had a total of 9 mammary tumors. It reported 1 male rat out of 18 nihydrazone-treated male rats as having a tumor mass. However, it is not known what diagnosis was made from the histopathology for this male rat. Norwich also reported that no mammary adenocarcinomas were found in the nihydrazone-treated female rats.

The Eppley pathologists reviewed the slides of the mammary tissues from the 20 nihydrazone-treated female rats provided by Norwich. They also concluded that seven of the treated female rats had mammary tumors, and they reported that

one of these tumors was a mammary adenocarcinoma.

Slides of the mammary tumors in the nihydrazone-treated female rats reported by the Eppley pathologists were later reviewed by the Bureau of Foods pathologist. He reported mammary tumors in each of the seven female rats. From his examination of the histopathological preparations provided, he reported eight slides of mammary fibroadenoma and one slide of mammary adenocarcinoma. The adenocarcinoma was in the same rat in which the Eppley pathologists had reported a mammary adenocarcinoma.

Food and Drug Administration scientists recognize the there are uncertainties and limitations in the examination of tumors to determine if they have potential for malignancy. For example, in the early stages of a mammary tumor growth, the mass may be chiefly adenomatous. As the growth continues, the supporting white fibrous connective tissue may also begin to proliferate, resulting in a fibroadenoma. Later, the adenomatous part of the neoplastic mass may entirely disappear, leaving a fibroma. Finally, a part of the adenoma of fibroadenoma may develop malignant tendencies, and that portion may then become an adenocarcinoma. All four tumor types, i.e., adenoma, fibroadenoma, fibroma, and adenocarcinoma may be present in the same tumor mass. A small focus of adenocarcinoma in the early stage of a malignant tumor may be overlooked in the tumor growth unless adequate multiple sections of the tumor are made.

Also, unless great care is exercised in the evaluation of the spread of an adenocarcinoma of the mammary gland, the metastasis along the lymphatic routes passing through, under, or near other mammary glands may be considered to be separate primary adenocarcinomas rather than a single primary growth with multiple metastases.

The reports from Norwich indicate that nihydrazone (NF–64) caused an induction of mammary tumors in female rats just over 1 year old and that there is an indication of an increase in the number of mammary adenocarcinomas compared with control rats.

Food and Drug Administration scientists conclude that both studies show that nihydrazone is tumorigenic in rats and that the data rose questions about the carcinogenic potential and poency of nihydrazone. They conclude that neither of the studies is adequate to assess the cumulative effects of exposure to nihydrazone and its carcinogenic potential and potency because the studies were not of sufficient duration and the number of animals used was not sufficient. In the Sprague-Dawley rat study only female animals were used; so it is not possible to determine whether nihydrazone might have produced effects in the male rats. In the Carworth Farms rat study, the number of males was too small to determine with any confidence that nihydrazone did not have an adverse effect. In both studies, drug-treatment was for only 45 weeks and included only one dose level. In spite of the weaknesses in the reports available, it is evident that a 45-week treatment was sufficient to induce tumors in female rates, and that some of these tumors were mammary cancers. The dose level, frequency, and duration of exposure to a compound are related not only to whether or not cancer is induced but also to the latency period before the expression of cancer. Therefore, the 45-week treatment with nihydrazone is not considered a sufficient period of exposure to determine adequately the cancer potential or potency.

The Director concludes that the available data provide sufficient cause for concern that nihydrazone may be a carcinogen and that adequate life-time testing in appropriate animal species is required to evaluate its carcinogenic potential and potency. The Director concludes that because nihydrazone is a tumorigen, dose-response data in lifetime studies, using several dose levels, are necessary to develop the information required to assess the cumulative effects of exposure and to establish conditions of safe use. Although the demonstration of cancer induction may be made on the basis of testing at only one dose level, it may be possible from the results of this testing to conclude that a drug requires regulation under the provisions of section 512(d)(1)(H) of the act, dose-response data are necessary to provide information from which FDA can establish the operational definition of "no residue" for purposes of determining the required conditions for the regulatory assay for residues of a carcinogenic drug. Regardless of whetheer adequate testing were to show that nihydrazone induced cancer or induced only benign tumors, dose-response information would be required to establish the conditions of safe use.

The Norwich data from these two studies were available at the time FDA issued the March 31, 1971 FEDERAL REGISTER notice of opportunity for hearing on the proposed withdrawal of approvals for nihydrazone (NF–64). In response to the March 1971 notice, Norwich stated that all four nitrofurans (NF–64, NF–7, NF–180, and NF–260) caused an early development of mammary tumors that were of the type normally found in aging rats, and it postulated that the nitrofurans caused these tumors only at high levels of exposure in the female rats because of disruption in the hormonal system. Norwich presented data purporting to show that the hormonal disruption that produced the tumors involved a process not applicable to humans, and that the proposed methods of analysis for control of residues were more than adequate to assure that levels of residues were below any level which might adversely affect humans.

The Norwich hormonal hypothesis is described in detail in the May 13, 1976, FEDERAL REGISTER notice on furazolidone (NF–180). The supporting information provided by Norwich for the hypothesis was primarily limited to data on furazolidone (NF–180) and some very limited comparatative data on nitrofurazone (NF–5). No data were presented on nihydrazone related to a hormonal mechanism of action.

B. *Comparative Data on Nihydrazone and Furazolidone.* Norwich has provided data on furazolidone (NF–180) from the Sprague-Dawley female rat study and the Carworth Farms rat study It has also supplied data on testing of furazolidone (NF–180) in three chronic rat studies and one mouse study; the tests are described in the May 13, 1976 FEDERAL REGISTER notice. The data have a bearing on the Director's proposed action in this notice for nihydrazone (NF–64) and his decision to reject the Norwich hormonal hypothesis for nihydrazone (NF–64) and furazolidone (NF–180). They also have a bearing on his decision to reject the sponsor's claims that adequate studies have been provided for nihydrazone (NF–64) to support a determination that the drug uses are shown to be safe.

In the Sprague-Dawley female rat study and Carworth Farms rat study, furazolidone (NF–180) was also tested in the protocols; it was tested using a dietary level of about 0.1 percent as compared to the nihydrazone (NF–64) dietary level, which was about 0.06 percent.

In the first study, Norwich reported that 14 of the furazolidone-treated female Sprague-Dawley rats out of 32 rats examined had mammary tumors. The total number of rats with tumors reported by Norwich was roughly twice the number of female rats with tumors reported for the nihydrazone-treated rats. However, the tumor multiplicities reflected in the total number of tumors for the furazolidone (NF–180)-treated female rats were better than three times the number of total tumors found in the nihydrazone-treated rates. Norwich reported five adenocarcinomas in the mammary glands of the furazolidone-treated rats and did not specify in how many rats or in which rats these were found. The Eppley pathologists reviewed the mammary tissue slides from 32 furazolidone-treated female rats and reported tumors in 14 of the rats. The Bureau of Foods pathologist later reviewed slides of the mammary tumors from the 14 rats and reported tumors in all of these rats. Both the Eppley and Bureau of Foods pathologists reported only one mammary adenocarcinoma and one mammary squamous cell carcinoma, each in a different rat. from the slides of the furazolidone-treated rats they had examined. In comparison with these furazolidone-treated rats, the Eppley pathologist found mammary adenocarcinoma in three nihydrazone-treated rats, and the Bureau of Foods pathologist confirmed the cancer diagnosis of the Eppley pathologist in two of the three rats.

In the Carworth Farms rat study, 15 of the furazolidone-treated female rats out of 17 examined were reported by Norwich as having mammary tumors. In com-

parison, Norwich had reported that 7 of the nihydrazone (NF–64)-treated female rats out of 20 examined had mammary tumors. The total number of mammary tumors reported by Norwich in the furazolidone (NF–180)-treated female rats was seven times the total number of mammary tumors that it had reported for the nihydrazone (NF–64)-treated female rats.

Based on these comparative data, the Director concludes that furazolidone (NF–180) and nihydrazone (NF–64) qualitatively exhibit similar tumorigenic effects in female rats. Because the dose levels of the two drugs were not the same (nihydrazone at about 0.06 percent in the diet and furazolidone at about 0.1 percent in the diet), and because the studies are not adequate to assess the cumulative effects of exposure and carcinogenic potential and potency, the data are not sufficient for a precise comparison of the tumorigenic potencies. The Director therefore concludes that although the limited data give some indication that nihydrazone may be a less potent tumorigen than furazolidone, adequate testing of nihydrazone in lifetime studies in appropriate animal species with the development of dose-response data from the administration of nihydrazone at several dose levels is required to determine adequately the carcinogenic potential and potency of nihydrazone.

More definitive studies of the carcinogenic potential of furazolidone (NF–180) in male and female rats and mice provided by Norwich are described in the May 13, 1976 FEDERAL REGISTER notice. A summary of the findings from the three chronic rat studies and the mouse study include the following:

1. Furazolidone induced malignanices in both rats and mice.

2. Furazolidone also induced nonmalignant tumors.

3. In most cases, the induced malignant and nonmalignant tumors were found at the same sites.

4. There is some evidence that the induction of benign tumors is related to the induction of, or progression to, malignancies as a function of dose.

5. There are marked sex differences in the tumor responses in the rats. There are also some commonalities in the tumor sites of the male and female rats.

6. Mammary tumors were the predominant effect in the female rats.

7. Nonmammary tumors were induced in the Sprague-Dawley male rats, with no one type singularly significant. In the Fisher rats, however, several specific nonmammary tumors were induced in both male and female rats.

8. The major target site for tumors in the mouse was the lung. There was no evidence of a significant difference between male and female mice in tumor response, and there were no tumorigenic effects in the endocrine tissues.

9. The induction of tumors involved not only increased incidence of animals with tumors but also an increased number of tumors per animal.

The Director has rejected the data supplied by Norwich to support the hormonal hypothesis for furazolidone (NF–180). A discussion of these data and his basis for rejection are also presented in the May 13, 1976 FEDERAL REGISTER notice. The Director also rejects the Norwich reply to the 1971 FEDERAL REGISTER notice on nihydrazone (NF–64), which attempted to explain the tumorigenic effects of nihydrazone primarily on the basis of the furazolidone (NF–180) data relative to the hormonal hypothesis. The Director finds that the new evidence provided by the more extensive chronic testing data for furazolidone (NF–180), which shows that tumors were induced in both male and female rats and mice and were not limited to tumors of the mammary gland or endocrine tissues, is inconsistent with the hormonal hypothesis.

Therefore, the Director concludes that the comparative data available on furazolidone (NF–180) and nihydrazone (NF–64) in the Sprague-Dawley female rat study and the Carworth Farms rat study, together with the data on the four chronic studies of furazolidone (NF–180) in rats and mice, indicate that adequate testing of nihydrazone (NF–64) has not been provided to assess the cumulative effects of exposure necessary for a determination of safety.

II. USES OF NIHYDRAZONE ARE NOT SHOWN TO BE SAFE

To assess the safety of residues using criteria described in section 512(b) of the act and elaborated on in section 512(d)(2) of the act requires a multistep process that must take into account consideration of the metabolism of the drug, determination of the resulting residues, including parent drug and the metabolites, the depletion of those residues with time after drug treatment, and the cumulative effect of human ingestion of the residues. The six basic steps involved in this evaluation process have been previously described above.

A. *The Amount of Total Residue in the Edible Products and the Depletion of Residues with Time must be Determined (Step 1).* When a drug is administered to an animal, the drug may be altered by the animal into a variety of compounds called metabolites. The process of alteration may be such that little residue of the parent drug remains in the animal tissue, but the amount of metabolites may be substantial. Therefore, the total residue with which FDA is concerned includes both the parent drug and the metabolites.

The nature and amount of each of the residues depend in part upon the metabolism in a particular species. Because there are species differences in metabolism, it is necessary to determine metabolism and residues in each of the species for which the drug is used. Therefore, § 514.1(b)(7)(i) (21 CFR 514.1(b)(7)(i)) includes metabolism and residue depletion studies among those kinds of studies that are used to determine residues.

Exposure to nihydrazone in the diet-induced mammary tumors in female rats. It is not known whether the parent drug was the active agent or whether the responses were due to one or more active metabolites produced as a result of ingestion of the parent drug by the rats. Such lack of knowledge is not unique to nihydrazone; it is typical of many tumorigenic and carcinogenic agents that the mechanism of the induction of tumors or the identification of the active agent is not known. Therefore, when considering the safety of food from nihydrazone-treated animals, all drug-related residues to which humans may be exposed must be assumed to be potentially carcinogenic unless convincing evidence is presented to the contrary. Such evidence consists of not only the identification of the residues that are claimed to be safe but also adequate toxicological studies showing that the levels of each of the residues claimed to be safe are in fact safe. All residues not identified or not shown to be safe must be considered potentially carcinogenic and must be required to be below a level of measurement that can be considered insignificant and to pose essentially no risk of cancer in humans.

The use of chemical assays to determine initially the total residues would require knowledge about what residues occur (parent drug and metabolites) and would require the availability of adequate methods of analysis to measure at the level of interest each one of the residues in the edible tissues. Therefore, this chemical approach is usually not feasible. Instead, a radiolabeled parent drug is used to provide a practical and adequate approach to the initial measurement of total residues in the edible tissues. In this approach, the drug is synthesized with a radioisotope so that when the drug is administered to the test animal according to label directions, all resulting residues of potential interest can be measured in the edible products. This is accomplished by counting the radioactivity in the tissues and converting these measurements to an estimation of the amount of residue expressed as parent drug equivalents.

By using radiolabeled nihydrazone administered to chickens, Norwich has measured total radioactivity in the tissues. Norwich has provided these data, which include the study of residue deposition in edible tissues as a function of the length of time of drug administration and the depletion of residues with time after cessation of drug treatment. Comparative data were presented with a carbon-14 label (^{14}C) on the first carbon in the side chain at the 2-position of the furan ring (formyl label) and a ^{14}C label on the carbonyl carbon of the side chain (acetyl label). Both the nitrofuran part and the hydrazine part of the molecule are of toxicological interest. These studies show that under the approved conditions of use for nihydrazone, residues in edible tissues of chickens, as reflected by measurement of the radioactivity expressed as nihydrazone equivalents, are in the parts per million (ppm) range. Evidence is provided to show that the parent drug, nihydrazone, appears to be only a small fraction of the total radioactivity in the tissue. Other data are presented

to further define the metabolic pathways of nihydrazone.

First, the studies on tissue residues in chickens are discussed. These also include balance studies to account for the percent of administered dose eliminated and that retained in the tissues. Second, the studies relating to the metabolic pathways are discussed. These include studies of urinary metabolites in chickens, rats, and rabbits, as well as synthetic studies, bearing on the questions. The discussion in this second part is organized to present, in turn, evidence for (1) a reductive pathway, (2) a hydrolytic pathway, (3) a pathway involving formation of "415" metabolite, and (4) a discussion of possible ring cleavage.

1. *^{14}C-Nihydrazone studies in chickens.* a. Food and Drug Research Laboratories (FDRL), under contract to Norwich, presented a report dated November 27, 1959, which was submitted in NADA 13–200, Vol. 3. In these studies, white Leghorn cockerels from the hatchery were maintained on niyhdrazone-medicated feed to a weight of 200 grams (20 to 22 days on medication). ^{14}C-nihydrazone (formyl label) was then administered twice daily to three of the cockerels at a daily dose of 4 mg/day. The birds were sacrificed after 2, 4, and 9 days on treatment with the radiolabeled drug.

Norwich stated that the result of the balance study, to account for the percent of administered dose eliminated versus that retained, showed the chick attained body equilibrium with respect to the drug after 2 days and before the fourth day of dosing, and further showed no evidence of residue accumulation in any specific tissue. Food and Drug Administration scientists conclude that with only one bird examined after each feeding period, animal variation in tissue residue levels cannot be determined. Therefore, definitive evidence is not presented to determine if residues are accumulating after 4 days of repeated dosing. However, in the following two examples, it appears that there is an indication of accumulation. The residue levels in the leg muscle for the three birds after 2, 4, and 9 days' dosing, reported as nihydrazone equivalents, were 3.92, 5.79, and 7.01 ppm, respectively. Corresponding values for liver were 9.68, 10.61, and 13.42 ppm. Residues in blood, head, leg muscle, fat, and residual carcass after 9 days on radioactive drug treatment were reported at about 7 ppm and were all greater than the 4-day values. In the reported balance study, recovery of the radioactivity as percent of total dose administered for treatment periods of 2, 4, and 9 days, respectively were: expired carbon dioxide ($^{14}CO_2$) (11.5, 4.3, and 10.9 percent); urine and feces not separated (80.6, 71.5, and 85.0 percent), and tissues (12.1, 6.0, and 5.9 percent). These data will be compared with a later study also utilizing the formyl label (section II.A.1.d. of this notice) and a study utilizing the acetyl label (section II.A.1.b.).

b. Nuclear Science and Engineering Corp. (NSEC), also conducted a study for Norwich, titled "Chicken Residue of ^{14}C-nihydrazone", NSEC No. 50–11–9098, December 4, 1959, submitted in NADA 13–200, Vol. 3. In the NSEC study, 1-day-old white Leghorn chicks were maintained on nihydrazone-medicated feed for 4 weeks before the administration of radiolabeled drug. ^{14}C-nihydrazone (acetyl label) was given twice daily at a dose of 4 mg/day to three birds. The birds were treated with the radiolabeled drug for either 2, 4, or 8 days, and then were withdrawn from medication for 1 day before sacrifice. Recoveries of radioactivity as percent of total dose for the treatment periods of 2, 4, and 8 days, were as follows: expired $^{14}CO_2$ (46.8, 57.4, and 60.9 percent); urine and feces not separated (33.6, 37.9, and 47.6 percent); and tissue (11.78, 7.92, and 10.2 percent). It is apparent from the results on expired $^{14}CO_2$ in the NSEC study that the radioactive carbon derived from the acetyl label is removed from molecular species of toxicological interest and that the radioactivity in the tissue will include incorporation of ^{14}C into endogenous substances that are not of toxicological interest. For this reason, the NSEC study does not answer the questions about the total drug-related residues in tissues of interest and their depletion with time. The results from the formyl label studies discussed in the preceding paragraph also indicate some expired $^{14}CO_2$, but to a lesser extent (4.3 percent to 11.5 percent).

c. Further studies were conducted by J. A. Buzzard et al. and were submitted by Norwich (Special Report Problem No. 360.3, September 1, 1961, NADA 13–200, Vol. 3). In these studies, male and female chicks were administered nihydrazone ad libitum in the feed at 0.0138 percent for 3 weeks. One group was then given ^{14}C-nihydrazone, labeled in the formyl position, and another group was given ^{14}C-nihydrazone labeled in the acetyl position. Radiolabeled drug was given for 4 days; Norwich claimed that previous studies showed that 4 days was the time required for tissue saturation and equilibration. One male and one female chick from each group were sacrified for analysis after radiolabeled drug treatment for 1, 3, or 4 days; there was no withdrawal from treatment before sacrifice.

In the formyl-labeled studies, the maximum levels of radioactive residue after dosing from 1 to 4 days, expressed as nihydrazone equivalents, were approximately 2 to 3 ppm in thigh, breast, and leg muscle; and about 8 ppm in liver and kidney. Fat was only analyzed on day 1 and was 1.35 ppm nihydrazone equivalent. With the acetyl label, the maximum level of radioactive residue after dosing for 1 to 4 days was much higher. For example, maximum values of 6.8 ppm in thigh muscle, 35 ppm in kidney, 15.6 ppm in liver, and 91.3 ppm in fat, expressed as nihydrazone equivalents, were reported. Data were also presented on the depletion of residues after 3 weeks' treatment with 0.0138 percent nihydrazone in feed followed by 4 days of radiolabeled drug treatment and subsequent withdrawal from medication. The formyl-label-treated chicks were analyzed after sequential sacrifices up to 5 days postmedication, and the acetyl-label-treated chicks were analyzed after sequential sacrifices up to 16 days postmedication. One male and one female chick were analyzed from each group at each withdrawal time up to 5 days withdrawal. After 5 days withdrawal, the formyl-label-treated chick had the following residue levels, expressed as nihydrazone equivalents: 0.79 ppm and 0.96 ppm in muscle tissues, 0.70 ppm and 0.86 ppm in fat, 1.27 ppm and 1.64 ppm in kidney, and 1.36 ppm and 1.64 ppm in liver. Liver and kidney showed biphasic disappearance curves indicating a pool of rapidly disappearing metabolites with a biological half-life, calculated by Norwich to be about 0.7 day. The pool of slower-depleting components in the various tissues was reported to have a biological half-life ranging from 3.2 days in liver to 4.9 days in breast muscle. Fat was not examined. Results demonstrating a biphasic nature for the depletion of residues from use of the acetyl label were also presented. A biological half-life for the rapidly depleting pool is reported at about 0.8 to 1.6 days. The biological half-life of the slower-depleting pool was reported as 4.1 days for fat, about 5 days in kidney and liver, and 7.2 to 11.7 days for muscle tissues. Norwich did not explain how it derived the biological half-lives for the rapidly depleting pools.

With the acetyl label, initial residues were much higher than with the formyl label. After 16 days withdrawal, the level of radioactivity in tissues was in the same range as that seen after only 5 days withdrawal with the formyl label.

Further studies were presented in this report to show the effect of longer-term administration of radiolabeled drug on the residues measured. Norwich claimed from the previous studies that dosing with the labeled drug for 4 days was sufficient to assure saturation of tissues with radiolabeled drug residues after pretreatment with unlabeled drug. Three 21-day-old male Leghorn birds, not pretreated with nihydrazone, were given the formyl label drug in feed for 8, 16, or 32 days, after which each bird was withdrawn from treatment for 4 days before sacrifice and measurement of residues. The data combined with the 4-day treatment data from the previous study show that the amount of residue in liver, kidney, fat and thigh, breast, and muscle tissue, expressed as nihydrazone equivalents, continued to increase with increasing length of treament. For example, muscle residues were reported as 0.79, 1.35, 1.78, and 2.17 ppm for the 4-, 8-, 16-, and 32-day treatment, respectively, each followed by a 4-day withdrawal from medication. A similar study with the acetyl label, where drug treatment was given for 8, 16, 24, or 32 days followed by 4 days withdrawal, also indicated an increase in residues with prolonged treatment. However, the pattern seen in the tissues in this study deviates for the kidney and fat tissue in particular. Food and Drug Administration scientists agree in part with Norwich that this deviation probably results from loss of labeled acetate from nihydrazone. This would result in the

incorporation of ^{14}C derived from acetate into endogenous substances. This is consistent with the showing of a much higher $^{14}CO_2$ expiration with the acetyl label compared to the formyl label as previously discussed. It is also consistent with the higher level of radioactivity, especially in fat, for the acetyl versus the formyl-label-treated birds. Acetate is a biochemical precursor of fatty acids, and therefore a higher incorporation of radiolabel into endogenous fatty acids would be expected. Norwich references work by Weinhouse et al. (Journal of Biological Chemistry, 166: 691, 1946) and Elliott et al. (Journal of Biological Chemistry, 186: 477, 1950) to support that kidney in general is a high acetate metabolizing organ, and therefore, as with fat, the high apparent residue levels in kidney may result from the incorporation of radiolabeled acetate into endogenous substances.

Food and Drug Administration scientists agree that kidney is a high acetate metabolizing organ; however, liver also has strong acetate metabolizing capability, and in comparison to kidney, liver has a much more versatile anabolic (synthetic) capability. Therefore, the argument of Norwich that the disproportionate amount of kidney residues results from the labeled acetate is not supported in view of the data for liver and common knowledge of liver metabolism.

d. Norwich has provided an additional report using the formyl label to study residues in chickens. Buzzard et al., in Special Report Problem, No. 370.3, September 1, 1961, reported a radioactivity recovery study in the chicken. One chicken was fed a diet containing nihydrazone at 0.0138 percent for 5 weeks before the administration of ^{14}C-nihydrazone (formyl label) for 8 days. The bird was then withdrawn from medication for 4 days before sacrifice. Recovery of radioactivity as percent of the total dose administered was reported as follows: expired $^{14}CO_2$ (2.52 percent), urine and feces (100.45 percent), and tissues (2.17 percent). Residues in the tissues, expressed as nihydrazone equivalents, ranged from a low of 0.5 ppm in the crop and its contents, to 1 to 2 ppm in muscle tissues, 4.0 ppm is liver, and 4.2 ppm in kidney. The results of this experiment show a lower level of expired $^{14}CO_2$ compared to the results of the FDRL study with the formyl label previously described, where about 11 percent of the total dose was accounted for as $^{14}CO_2$ for two of the three birds examined. In the Food and Drug Research Laboratories study (cited previously in this notice, under section II.A.1.a.), some high values during the early collection period were questioned; investigators felt they might possibly be due to fermentation of droppings during collection.

The report continues with data that Norwich claims demonstrate that the ^{14}C-nihydrazone (formyl label) results in the incorporation of carbon-14 into serum proteins, glucose from liver glycogen, glutathione from erythrocytes, glutamic acid isolated from erythrocyte glutathione, and glutamic acid, serine, tyrosine, aspartic acid, and phenylalanine from blood hydrolysates. These results are based on presumptive identification. After acid hydrolysis of the tissues, ion exchange column chromatography was used to separate the amino acids, and identification was based on column retention time compared to standards. From the evidence of expired $^{14}CO_2$ (although only a small percentage of the total dose), it may be expected that the formyl label also would result in a small amount of incorporation of ^{14}C into endogenous substances. The data presented by Norwich do not provide any estimate of the proportion of the total radioactive residues that result from such incorporation. Therefore, the total drug residues of toxicological concern cannot be determined. As one example, Norwich reported that erythrocytes contained 74 percent of the radioactivity in the blood. The extraction of 1 milliliter of erythrocytes yielded 1.4 milligrams of glutathione with a radioactive count of 10,466 disintegration per minute per milligram (dpm/mg). After hydrolysis and chromatography to separate glycine, cystine, and glutamic acid, it was reported that the radioactivity was associated with glutamic acid representing a radioactive count of 560 dpm, which is only a minor part of the total radioactivity in the isolated glutathione fraction (about 14,600 dpm). Bar graphs were presented for the various amino acid fractions from hydrolyzed blood protein with which radioactivity was associated. The largest component was not identified with the endogenous substances examined.

Food and Drug Administration scientists cannot use such data to determine what amount of radioactive residue has to be subtracted from the total residue in edible tissue to yield that portion that is of remaining toxicological interest. Furthermore, although much of the radioactivity appeared to chromatograph with retention times similar to the amino acid standards, many substances, even including some of the standards, cochromatograph. Therefore, to presume identification of an endogenous substance solely by column retention time is not considered reliable because it is possible that drug-related metabolites may also chromatograph in the system described. Furthermore, it is possible that some of the nihydrazone metabolite residues may be "bound" in some manner with macromolecular structures and at least in part may be contributing to some of the results seen in the data of this study.

The Director concludes from the studies with the acetyl label that this label does not provide any meaningful answers to the question of drug-related residues of toxicological concern. It appears that the acetyl label may not remain associated with the hydrazine part of the molecule that is of toxicological interest, and would likewise not provide an adequate label for following the fate of the nitrofuran part. The Director concludes that the formyl label more reasonably provides an estimate of the total drug-related residues of interest. Studies, which will be discussed later, indicate that one pathway for nihydrazone metabolism includes breaking the carbon nitrogen double bond in the side chain giving rise to furan derivatives as well as hydrazine derivatives. The latter would not be followed with the formyl label. However, this hydrolytic pathway appears to be significant in the rat and rabbit but is apparently not operant in the chicken, possibly due to different gastrointestinal tract acidity.

The Director further concludes that substantial levels of radioactive residue are shown in the edible tissues of chickens. The Director acknowledges that the formyl label data also indicate that some ^{14}C incorporation into endogenous substances may occur, based on the small amount of expired $^{14}CO_2$. The Director concludes that Norwich's data on this point are presumptive qualitative information without quantitative accountability. Therefore, the Director concludes that even if he agreed that the evidence supports the presence of labeled ^{14}C in the endogenous substances, he is not able to determine what amount of residue may be subtracted from the total residue as demonstrated to be safe; therefore, he cannot estimate the amount of total drug-related residues of interest from the data presented. Because of the evidence suggesting a carcinogenic potential for the drug, even low levels of nihydrazone-related metabolites are significant.

As will be discussed in the second part of section II.A of this notice, there is reason to believe that major portions of the residue are likely to be drug-related metabolites of toxicological concern.

e. Norwich has presented some data on the amount of parent drug residue, i.e., nihydrazone residue, that occurs in chicken tissue. These data are described in detail in section II. F. of this notice. In one study, broiler chickens were treated for 5 days with nihydrazone in their ration at 100 grams/ton. A ^{14}C-nihydrazone (formyl label) was used, and the levels of nihydrazone, parent drug only, were measured by using a reverse isotope dilution technique following the 5-day treatment and for 5 subsequent days of withdrawal. The maximum concentration of nihydrazone at 0-day withdrawal was in skin with adhering fat at a level of 37 parts per billion (ppb), which depleted to a level of 2 ppb after 3 days withdrawal.

Subsequently, other studies in chickens were conducted using chemical assays to measure residues that Norwich claimed were specific for nihydrazone and could detect residues as low as 2 ppb. The method of analysis used was similar to the one subjected to validation trials for furazolidone (NF-180); the method was not shown to be reliable. Data from these studies, which involved longer periods of treatment of the birds with nihydrazone, indicated that the levels of parent drug, nihydrazone, in edible tissues are in the parts-per-billion range. It is therefore apparent that nihydrazone represents only a very small fraction of the total residue in the tissues when com-

pared to the findings from the radiolabeled drug studies.

The Director concludes that Norwich has not provided adequate identification of the residues in edible tissue to provide convincing evidence that the substantial levels of residues reflected by the radioactivity measurements are safe. However, Norwich has provided other data on the metabolism of nitrofurans. From studies of the nature of metabolites in rabbit, rat, and chicken urine and from synthetic studies, Norwich has shown that several pathways may be operant. These data are germane to the Director's conclusion that adequate information has not been provided about the residues in edible tissues of treated animals to conclude that such residues are safe.

2. *Metabolic pathways.* Norwich has provided some data on the chromatographic analysis of urine from chickens dose with ^{14}C-nihydrazone that indicates that several metabolic pathways are involved. They present evidence to show that in the urine, about 5 percent of the administered dose is excreted as nihydrazone, a similar amount as 5-acetamido-2-furaldehyde acetylhydrazone, about 16 to 17 percent as a compound designated as "415" because the ultraviolet (uv) spectra shows an absorption maximum at 415 nanometers and several other unidentified compounds that had been chromatographically separated. These data will be discussed along with other relevant studies in the following paragraphs.

a. *The reductive pathway.* Norwich has provided several references of work by others that show evidence of the reduction of a number of nitrofurans by various body tissues and bacteria. Beckett and Robinson (Journal of Medical and Pharmaceutical Chemistry, 1:155, 1959) postulated that hydrazone derivatives of nitrofurans of the B Type (—CH=N—N)(R)COR) are unstable and that furan ring cleavage occurs upon reduction because they cannot be stablized by hydrogen bonding. These same authors (ibid. p. 135) demonstrated the stability of Type A hydrazone derivatives of nitrofurans(—CH=N—N(H)COR) upon reduction to their amino analogs. They suggest that the NH group alpha to the Schiff's base may be essential for stability of these amino compounds. Beckett and Robinson used bacterial systems, as well as alcohol solutions (highly protonic) for the reductions. Elbetino et al. ("Reduction of Nitrofurans I. Aminofuran," Eaton Laboratories, report submitted in NADA 13-200, Vol. 3) reported on the catalytic reduction of a number of 2-substituted 5-nitrofurans to the corresponding aminofurans, including the reduction of nihydrazone. They avoided the use of exclusively protonic solutions for the reduction. Based on their findings, these authors found that the reduction did not necessarily result in ring cleavage, particularly for the Type B nitrofurans. They found that the 5-nitrofuran compounds could be catalytically reduced and that the amino analogs were easily acetylated. The acetylated amino derivatives were more stable in aqueous solution than the corresponding amino compounds.

They reported the catalytic reduction of nihydrazone to 5-amio-2-furaldehyde acethylhydrazone, which, after reaction with acetic anhydride in the presence of pyridine, produced 5-acetamino-2-furaldehyde acetylhydrazone. This compound had infrared and uv spectra and a paper chromatography retardation factor (R_f) value identical to that of a nihydrazone metabolite found in rabbit urine by Olivard et al. of Eaton Laboratories (discussed below), which was subsequently confirmed as to identity. Elbetino et al. reported that the 5-amiofuran derivative of nihydrazone and other Type A nitrofurans produced through the catalytic reduction were relatively unstable compared to the Type B nitrofurans studies. In contrast to Beckett and Robinson, they postulated a hydrogen-bonded form that might be more susceptible to furan ring cleavage.

Olivard et al. ("Metabolism of 5-nitro-2-furaldehyde acetylhydrazone," NADA 13-200, Vol. 3) reported the presence if 5-acetamido-2-furaldehyde acetylhydrazone and evidence for 5-amino-2-furaldehyde acetylhydrazone in the urine of rabbits that had been given nihydrazone by stomach tube at a dose of 100 mg/kg body weight/day for 5 days.

The 2,4-dinitrophenylhydrazone derivative of 5-acetamido-2-furaldehyde was isolated from the urine of the nihydrazone-treated rabbits after the addition to the urine of 2,4-dinitrophenylhydrazine in hydrochloric acid, and subsequent extraction with ethyl acetate followed by chromatography on alumina. The isolated derivative was identical with an authentic sample by melting point, absorption maxima in neutral and alkaline solutions, infrared-spectra, and R_f values on paper chromatograms. Elemental analysis supported the empirical formula. Additional evidence for the existence of the 5-acetamido-2-furaldehyde acetylhydrazone in urine was shown by the demonstration of ^{14}C in the R_f area corresponding to the authentic sample when ^{14}C nihydrazone (acetyl label) was administered. Thus it was demonstrated that the carbon-nitrogen double bond in the side chain remains intact, at least in part, in the rabbit. Although neither the 5-acetamido nor 5-diacetamido compounds, synthetically produced or isolated from the urine, could be recrystallized to satisfactory purity for elemental analysis, evidence of the identity of the isolated products from the urine is reasonably assured by the spectral data and paper chromatography R_f values. The "diacetyl" derivative was actually a triacetyl compound when including the acetyl group attached to hydrazine. The infrared spectra, however, did not distinguish whether the diacetamido occurs in association with the hydrazine part or the 5-amino part of the molecule. Fresh rabbit urine indicated only traces of nihydrazone and the 5-amino analog; however, the urine of chickens that had been dosed orally with 100 mg/kg body weight/day of nihydrazone showed essentially equal quantities of nihydrazone, 5-acetamido and the 5-amino metabolites.

In a series of studies, Buzzard et al. reported on the chromatographic study of urine from rats dosed with ^{14}C-nihydrazone as well as urine from chickens dosed with ^{14}C-nihydrazone (Problem No. 370.3, September 1, 1960, June 15, 1961, and September 1, 1961, NADA 13-200, Vol. 3).

The studies all show paper chromatographic evidence for the presence of the acetamido nihydrazone derivative in urine. The paper chromatographic profiles of urine are discussed here and will be referred to in succeeding discussions of the different metabolic pathways and species differences and are relevant to the Director's conclusions in section II.B. of this notice.

In this first study, one rat was dosed with 20 milligrams of ^{14}C-nihydrazone (formyl label) and one rat was dosed with 20 milligrams of ^{14}C-nihydrazone (acetyl label). The urine was first analyzed by paper chromatography using *n*-butanol: 95 percent ethanol: 0.5 *N* ammonium hydroxide in a 4:1:1: system (butanol system). Both labels yielded qualitatively similar chromatographs. From one label, presumably the formyl label, the authors found that 14 percent of the urine radioactivity was 5-acetamido-2-furaldehyde acetylhydrazone, 35 to 40 percent was the "415" metabolite that will be discussed later, 6 to 8 percent was an unknown acidic compound (R_f 0.3) and 30 to 40 percent remained at the origin.

Further paper chromatography of the urine samples was carried out in an SDA (specially denatured alcohol) 30: tris buffer system (SDA 30: 0.5M tris-(hydroxymethyl)-aminomethane in a 4:1 ratio). This system provided improved separation of the more polar materials that remained at the origin in the butanol system.

Comparative data for the rats given the acetyl-labeled nihydrazone indicated that only 6 percent of the urine radioactivity was the 5-acetamido-2-furaldehyde acetylhydrazone, 20 percent was the "415" metabolite, and there was no evidence for the unknown acidic compound at R_f 0.3 in the butanol system. Only a trace of nihydrazone was found. After chromatography in the SDA 30: tris buffer system, 14 percent of the activity was attributed to R_f 0.33 compounds, 10 percent to R_f 0.45 compounds, and 21 percent to R_f 0.70 compounds. Two other minor peaks represented about 12 percent of the urine radioactivity. No explanation is given for the apparent differences in results when the formyl label was used. Deficiencies in the use of the acetyl label, which have been previously discussed, would be expected to confound the relative proporitions of residues separated in the chromatographic systems.

Subsequent data were reported using the same chromatographic systems for the urine from a fasted 200-gram chicken given a 28.6-milligram dose of ^{14}C-nihydrazone (formyl label). Fifteen urine samples separated from feces were collected over a 31-hour period. The maxi-

mum excretion of radioactivity occurred between 2 to 5 hours after dosing. After 31 hours, 40 percent of the administered dose had been recovered in either urine or expired $^{14}CO_2$.

Sufficient raw data were not presented to show what percent of total excreted radioactivity may be assigned to each component chromatographically separated. However, from the data presented for two early collections of urine, it appeared that the nihydrazone and the 5-acetamido derivative were each about 4 to 6 percent of the total radioactivity, and the "415" compounds were about 16 to 17 percent of the total radioactivity in the respective samples. About 60 percent of the radioactivity remained at the origin in the butanol system previously described (1.25 to 2-hour collection sample), and about 10 percent of the radioactivity at R_f 0.35 in the butanol system was designated as an unknown acidic compound. By using the SDA 30: tris buffer system, the origin activity in the butanol system was separated into at least three major metabolites with R_f 0.33 (8.7 percent), R_f 0.45 (10.7 percent), and R_f 0.70 (34.2 percent). The 3 to 4.25-hour collection sample was analyzed for these data. The R_f 0.70 zone in this system also contained the unknown acidic compound with R_f 0.35 in the butanol system. The unidentified compound at R_f 0.35 in the butanol system was not acetylhydrazine, 5-nitrofuric acid, nor the endogenous substance, α-ketoglutaric acid.

The Director concludes that these data conclusively demonstrate a reductive pathway in chickens, rats, and rabbits as shown by the presence of the acetamido derivative of nihydrazone. Hence, the reduced compounds are not necessarily subject to hydrolysis of the carbon nitrogen double bond of the side chain or to ring cleavage, as will be discussed later. The reduced compounds are shown to be partially eliminated as the reduced intact drug. The Director concludes that the potential presence of reduced nihydrazone analogs and derivatives in edible chicken tissues may well be of major toxicological significance because there is reason to believe such compounds may be biologically active when ingested.

b. *Hydrolytic pathway.* A review of the literature on hydrazine derivatives indicates two usual pathways of metabolism in mammalian species. One is *N*-acetylation and the other is a hydrolytic pathway breaking the carbon-nitrogen double bond of hydrazones. By the hydrolytic pathway, nihydrazone would be metabolized to 5-nitro-2-furaldehyde and acetylhydrazide. These pathways influence toxicity. The *N*-acetylation appears to be a detoxification pathway. Monacetyl hydrazide appears consistently to have toxic properties that may approach those of hydrazine. However, 1,2-diacetylhydrazide produces fewer or diminished toxic reactions. Conversely, for the hydrazone derivatives, the toxicity is generally greater in those species where a hydrolytic cleavage of the carbon-nitrogen double bond occurs.

Free hydrazine and various hydrazine derivatives have been reported as carcinogenic in mice, rats, or hamsters (*Biancifiori Tumori* 60:429, 1974 and *Cancer Research*, 35:3693, 1975). The monoacetyl and diacetyl metabolites of hydrazine have not been tested for their carcinogenic potential.

Norwich presented work by McKennis et al. (Journal of Pharmacology and Experimental Therapeutics, 126:109–116, 1959) that included a discussion of previous work by others on the metabolism of certain hydrazines. McKennis et al. have shown that hydrazine and monoacetyl hydrazide on interperitoneal injection to rabbits are both metabolized to 1,2 diacetylhydrazide.

Olivard et al., in a previously referenced work on the metabolism of nihydrazone in the rabbit, reported that following oral administration of nihydrazone, the urine collected contained 5-nitrofuroic acid based on the paper chromatographic R_f value and spectral data, and also contained 1,2-diacetylhydrazide. The 1,2-diacetylhydrazide was identified by R_f value and Ehrlich reagent with subsequent column purification, crystallization, and demonstration of the identity by infrared spectra, R_f value, melting point, and mixed melting point (no depression) with authentic standard. The authors stated that no 1,2-diacetylhydrazide, acetylhydrazide, or 5-nitrofuroic acid was found in urine by paper chromatography if the rabbits were given nihydrazone interperitoneally. Similarly, they found no evidence by paper chromatography of 1,2-diacetylhydrazide, acetylhydrazide, or 5-nitrofuroic acid in the urine from a chicken given nihydrazone orally. The authors suggest that the hydrolysis of the carbon-nitrogen-double-bond linkage of the side chain is related to the liability of nihydrazone under conditions of acidity comparable to those in the mammalian stomach, and that it is unlikely to occur under the weakly acidic conditions of the gastrointestinal tract of the chicken.

It was shown by studies with chickens using the ^{14}C-nihydrazone (acetyl label) discussed in the first part of section II.A. of this notice, that a large amount of $^{14}CO_2$ was recovered in expired air as opposed to a much smaller amount of $^{14}CO_2$ recovered when the formyl label was used. Therefore, it would appear from this evidence and considering the evidence presented in the above studies by Olivard et al. that another type of hydrolysis may occur in the chicken. It appears that in the chicken, deacetylation might be a major hydrolytic pathway that was not discussed in the data presented by Norwich. Some compounds are known to be *N*-deacetylated in poultry, as evidenced by reports by S. A. Peoples and G. L. Westberg, Federation Proceeding, 34:227, 1975, and R. H. Nimmo-Smith, Biochemical Journal, 75: 284, 1960. The formation of deacetylated nihydrazone or its corresponding reduced analogs or derivatives in the chicken may result in tissue residues. Such residues might then be subject to hydroylsis in the gastrointestinal tract of man, involving breaking the carbon-nitrogen double bond, giving rise to hydrazine as well as potentially toxic nitrofuran metabolites.

The data presented by Norwich on nihydrazone show that a hydrolysis, breaking the carbon-nitrogen double bond of the side chain, is operant in the mammalian systems but does not appear to be operant in the chicken.

The Director concludes that hydrolytic pathways of two types may occur. The first type, deacetylation, has been indicated in the chicken by the large amount of expired $^{14}CO_2$ when the ^{14}C-nihydrazone (acetyl label) was orally administered compared to use of the formyl label. Although N-acetylation is generally the usual pathway for hydrazine metabolism is mammalian species, there is evidence for deacetylation of some drugs in poultry. The second type of hydrolysis, involving breaking the carbon-nitrogen double bond, has been shown in the rabbit. However, this hydrolysis does not appear to be operant in the chicken; this observation is based on the lack of evidence for 5-nitrofuroic acid, and mono- or diacetyl hydrazide as urinary metabolites. The Director concludes that deacetylated nihydrazone, and its reduced analogs or derivatives are of concern as potential tissue residues in chickens. Studies have not been presented by the sponsors of nihydrazone to show that the substantial levels of radioactive residues in chicken tissues are not due to the presence of such compounds. The Director further concludes that deacetylated nihydrazone derivates, if present in chicken tissues, upon ingestion by man would likely be subject to hydrolysis, breaking the carbon-nitrogen double bond, as indicated by the evidence for this pathway in mammalian species. This probability presents serious questions about man's potential exposure to free hydrazine, which is a demonstrated carcinogen, in addition to exposure to other potentially toxic derivatives of the 5-nitrofuran part of nihydrazone.

c. *Pathway involving formation of "415" metabolites.* A metabolite yielding a uv absorption maximum of 415 nanometers was found in rat, rabbit, dog, monkey, and chicken urine after dosing with nihydrazone according to the report by Olivard et al., previously referenced. The "415" metabolite did not appear to result from either the simple hydrolysis of the carbon-nitrogen double bond or from the reductive pathway, yet both a nitro group and a carbon-nitrogen double bond are apparently necessary for the formation of the "415" metabolite. Administration of "415" metabolite to the rat did not yield reduced nitrofurans nor did dosing with the reduced nitrofurans yield "415." The infrared spectra of "415" metabolite indicated a carboxyl anion, two carbonyl groups, a carbon double bond with no furan, nitro or aromatic group. The spectroscopist indicated there was a probability for the presence of OH and NH, but not much CH.

The compound with mild acid treatment instantly was converted to one with

an R_f of 0.5 in the butanol paper chromatographic system previously described and had an absorption maximum of 400 nanometers. It is in turn gradually destroyed by 2.3N hydrochloric acid at 70° C. Chromatographs of the hydrolyzate showed no ninhydrin positive zones, as would be expected for amino acids. Preparation of the 2,4-dinitrophenylhydrazine derivative of "415," as indicated by the infrared spectra, gave a compound showing only one absorption peak in the carbonyl region in contrast to the 2 carbonyl peaks seen in the infrared spectrum of "415." The "415" metabolite can apparently be made photochemically from 5-nitro-2-furaldehyde diacetate and coupling with acetone acetylhydrazone. It is believed that the "415" compound retains the carbon-nitrogen double bond of the side chain and thus would include the hydrazine part of the molecule. Buzzerd and Olivard proposed that the "415" compound may be related to the Stenhouse dyes formed from aniline and furfural. However, all attempts by the sponsors to identify the "415" metabolite, which appears to be the major residue component in the urine of animals dosed with nihydrazone, have been unsuccessful.

The Director concludes that a pathway involving formation of "415" metabolite is operant in chickens and mammalian species, and the evidence indicates this metabolite is drug related and not an endogenous substance. Its potential presence as a tissue residue and a part of the total radioactive residue seen in chicken tissue has not been resolved.

d. *Furan ring cleavage.* Buzzard, Hoetis and Klein (Problem No. 370.3, October 1, 1961, NADA 13-200, Vol. 3) showed that by alkali-catalyzed hydrolysis of ethyl-5-amino-2-furoate, followed by acid hydrolysis of the products of the ring opening reaction, α-ketoglutaric acid was formed, identified as the 2,4-dinitrophenyl hydrazone derivative) as well as β-formyl propionic acid. A mechanism for the reaction was proposed. Since attempts to prepare 5-amino-2-furoic acid were not successful, it could not be shown whether nihydrazone would react similarly. Based on the observed chemical activity of the model furan studied, Norwich hypothesized that the slower depleting pool of residues in chickens dosed with nihydrazone arose from a similar degradation of nihydrazone through formation of α-ketoglutaric acid. The work of Buzzard et al., discussed in section II.A.1.d. of this notice, which presents presumptive evidence for the incorporation of ^{14}C into endogenous substances in chicken tissues, in the opinion of Norwich, adds further support to the hypothesis.

There is no evidence to show that the chemical reaction of the model furan giving rise to α-ketoglutaric acid is a reaction that would occur in the chicken. Investigation of the "415" metabolite in urine also gave some evidence that ring cleavage may be involved. However, as previously discussed, "415" is not an endogenous substance.

Even if α-ketoglutaric acid were one of the products of nihydrazone metabolism, there is question about what part of the radioactive residues in chicken tissues would be attributable to this hypothetical pathway. As discussed in section II.A.1.d. of this notice, the evidence provided by Buzzard et al. for the identification of the radioactive residues in chicken tissues as endogenous substances is presumptive and does not provide quantitative accountability.

Therefore, the Director does not accept the evidence provided by Norwich as sufficient to show that the residues persisting in chicken tissues after a short withdrawal period are the result of nihydrazone metabolism to endogenous substances through ring cleavage and formation of α-ketoglutaric acid. Norwich has provided evidence in animals that ring cleavage of nihydrazone may occur in the formation of "415" metabolite that is not an endogenous substance. Norwich has not provided conclusive evidence that ring cleavage of nihydrazone occurs in chickens to produce the formation of α-ketoglutaric acid. Even if this pathway did occur, no quantitative accountability of residues identified as endogenous substances has been provided. Furthermore, a pathway by which nihydrazone would be degraded to α-ketogolutaric acid would require hydrolysis of the carbon-nitrogen double bond. Therefore, the fate of the hydrazine part of the molecule would also have to be accounted for. Studies provided by Norwich indicate that this hydrolysis is not prevalent in the chicken. Therefore, the Director concludes that a pathway involving furan ring cleavage does not necessarily lead to metabolities that may be presumed safe without supporting evidence.

In summary, the Director concludes that each of the studies presented in this part adds to knowledge of the metabolism of nihydrazone, but the studies do not satisfactorily answer the significant questions about the safety of the residues. There is a demonstration of a reductive pathway leading to the formation of compounds of toxicological concern. There is also evidence of a possible deacetylation pathway in the chicken that leads to the potential for compounds which, as residues, if ingested by mammalian species may result in exposure to free hydrazine, which is a carcinogen, and other potentially toxic nitrofuran analogs and derivatives. There is further demonstration of a major pathway involving formation of "415" metabolite; it appears to result from ring cleavage but with the hydrazine part of nihydrazone intact. From all of these factors and the lack of information on tissue residues arising from these proposed pathways of metabolism, the Director concludes that the substantial levels of radioactive residues in chicken tissue even after a 4- or 5-day withdrawal period are not shown to be safe. There is no conclusive evidence that nihydrazone is degraded to α-ketoglutaric acid in the chicken. Nor is there concurrent accountability for the hydrazine part of nihydrazone in this proposed pathway. Even if the identification of some radioactive residues in chickens as endogenous substances, based on column chromatography, were accepted, quantitative accountability for these residues is lacking. Therefore, the Norwich contention that nihydrazone residues in chicken tissue, following the currently labeled conditions of use, are endogenous substances and therefore safe, cannot be accepted by the Director.

B. *Sufficient Information Has Not Been Provided about the Residues to Determine the Appropriate Testing Required in Laboratory Animals to Estimate the Cumulative Effects of Human Exposure to the Residues (Step 2).* Norwich has demonstrated that very little of the residue in edible tissues is nihydrazone and most of the residues are metabolites.

The Food and Drug Administration must assess the toxicity of the total residue because this is what man will be exposed to in food. This assessment would be based ideally on the identification of each of the metabolites in the residue, their synthesis, and subsequent testing of the parent drug and all the metabolites for the cumulative effects of exposure. However, this approach is usually impractical.

Recognizing this, FDA makes judgmental assessments from certain types of data about the residue and metabolism. A determination is made about assumptions that can be accepted from the toxicity testing of the parent drug. Because the test animal metabolizes the drug, the resulting dose-response effects represent to some degree the cumulative effects of exposure to each of the biologically active substances produced by the test animal.

Norwich has provided some comparative metabolic data in the rat and chicken through chromatographic analysis of the urine collected after treatment with labeled drug. These data show certain qualitative similarities between the two species. Both the chicken and rat appear to excrete "415" metabolites and 5-acetamido-2-furaldehyde acetylhydrazone; this indicates that both the reductive pathway and the pathway leading to formation of the "415" metabolite are involved in both species. The proportion of the total radioactivity in urine for each of the compounds appears to be somewhat higher for the rat than for the chicken. Only trace quantities of nihydrazone are reported in rat urine, whereas nihydrazone was about 5 percent of the total radioactivity in early collection samples of chicken urine, roughly equal to the amount of 5-acetamido-2-furaldehyde acetylhydrazone excreted in urine. It was also reported that an acidic compound with an R_f at about 0.3 in the butanol chromatographic system represented about 10 percent of the radioactivity in chicken urine. This compound was also reported in the urine of the rat treated with the formyl label, but the compound was not seen with the acetyl label. Substantial quantities of unknown compounds were seen in both rat and chicken urine which remained at the

origin in the butanol system and were further separated in the SDA 30: tris buffer system, indicating that these materials represented more polar metabolites.

One major difference is apparent in the chicken versus mammalian species. This involves the hydrolytic pathways previously discussed. Deacetylation is an apparent major pathway in the chicken, and there is no evidence for a hydrolytic pathway in the chicken that involves breaking the carbon-nitrogen double bond. Conversely, there is evidence that a hydrolytic pathway with breaking of the carbon-nitrogen double bond is operant in the mammalian species, and that the resulting hydrazide is acetylated. The scientific literature suggests that deacetylation in mammalian species is not a significant pathway.

Although the sponsors have not provided information characterizing the tissue residues, it may be assumed that at least some of the metabolites found in chicken urine may also be present as tissue residues. The "415" metabolite and at least some of the reduced nitrofurans appear as urinary metabolites in the chicken as well as in mammalian species. Therefore, in testing nihydrazone in the rat, some exposure of the rat to these metabolites would have occurred. However, chicken tissue may contain deacetylated metabolites of nihydrazone. Testing of nihydrazone in the rat is unlikely to have provided exposure to deacetylated nihydrazone or deacetylated derivatives of nihydrazone formed through other pathways operant in the chicken. Both the nitrofuran part of nihydrazone as well as the hydrazide part of nihydrazone may be involved with tumorigenesis. In general, acetylation appears to be a detoxification pathway for hydrazines. Therefore, there is some reason to believe that deacetylated nihydrazone metabolites may be more toxic than nihydrazone when ingested by mammalian species.

In order to make an adequate assessment of the extent to which testing of nihydrazone can be used to evaluate the safety of residues, sufficient information about the residues in chickens is required in addition to comparative metabolic data in the test species. Because the nature of the residues in chicken tissues is not known, there are unanswered questions about potential residues, including those residues that may give rise to exposure to free hydrazine when ingested. Therefore, the Director concludes that not only is the toxicological testing provided for nihydrazone inadequate, but he is unable to determine whether testing of metabolites in addition to the parent drug is required to determine the safe level of human exposure to residues in food. Step 2 has not been fulfilled; therefore, the requirements for step 3 cannot be fully determined.

C. *Adequate Dose-Response Data in Test Animals to Determine the Cumulative Effects of Dietary Exposure to the Residue Compounds Has Not Been Provided; Therefore, the Maximum Acceptable Concentration of Residues in Food Cannot be Established Using Appropriate Safety Factors to Assure That Human Exposure to Residues in the Total Diet Does Not Exceed a Level Deemed Safe (Step 3).* As discussed under section I of this notice, the Director has concluded that adequate testing of the parent drug, nihydrazone, has not been provided. Also, under steps 1 and 2, discussed in section II. A. and B. of this section, the Director concluded that adequate information has not been provided about the residues to determine if toxicity testing of residue compounds in addition to the parent drug is required to estimate conservatively the cumulative effects of exposure to the residues.

The Director concludes that without such essential information about the residues and adequate toxicity testing data, he cannot, in light of the new evidence, determine if nihydrazone requires regulation as a carcinogenic animal drug or, alternatively, to reasonably estimate a maximum acceptable level of residue in food that can be deemed safe. Therefore, he concludes that adequate information has not been provided to assess the cumulative effects of exposure and to determine the appropriate safety factors required under section 512(d)(2)(B) and (C) of the act.

D. *Sufficient Information about the Residues Has Not Been Provided to Establish the Conditions Necessary for the Analytical Method Used to Control Residues (Step 4).* The evaluation of an analytical method for residues first requires a determination of the tissues to be analyzed, the compound to be measured, and the lower limit of mesurement that must be achieved to control total residues adequately. Only then, after selection of these parameters, is it meaningful to consider whether the method proposed by the sponsor meets other characteristics necessary for a practicable reliable method.

1. Determination of the target issue: The most practical approach to monitoring and controlling residues in the field is dependent on the selection of that edible tissue in which residues require the longest time to deplete to a "safe concentration." Therefore, by monitoring this tissue to assure that residues are below a "safe concentration," it can be assured that all residues in the carcass are below "safe concentrations." In lieu of this determination (identification of the target tissue), all edible tissues, including milk where applicable, must be monitored. This would place an additional burden on public funds for monitoring.

The target tissue is readily identified if the requirements of step 1 of the evaluation process are met. Although Norwich has presented data on the total residues, as measured by radioactivity and expressed as nihydrazone equivalents, these data show substantial amounts of residues and do not show depletion to levels that might be presumed safe, considering that nihydrazone is a tumorigen and may be a carcinogen. From the radiotracer studies it would appear that liver or kidney may be the target tissue. On the other hand, data on the measurement of parent drug, nihydrazone, indicate that skin with adhering fat shows residues at the highest level for the longest time for this residue component. Because adequate data have not been provided to determine when total drug residues of toxicological interest are reduced to levels that can be presumed safe, and depletion characteristics of the component residues are not provided relative to the total residues down to an established safe level, it is not possible to make an assignment of the target tissue.

2. Determination of the compound (marker) that can be measured by the analytical method to assure control of total residues: Because the radiolabeled drug approach used initially to estimate total residues is not applicable to regulatory use, an alternative approach must be developed to assure control of total residues after drug approval. This is achieved by selecting an appropriate residue compound, which may be the parent drug or one or more metabolites, in such a way that its measurement serves as a valid indicator that when the marker compound is below a certain level in the target tissue, all residues in edible tissues are at safe levels. This step is essential to determine if the method of analysis for regulatory use is adequate. To determine a valid marker, adequate information, e.g., information derived from conducting an adequate metabolism study, is required to relate the proportionate amount of each of the residues to the total residue and their change in quantitative relationships with time. The marker must be a known proportion of the total residue when the total residue depletes to the "safe concentration" in the target tissue. It also must be structurally identified so that an adequate and specific method of analysis can be developed for its determination.

The regulatory method proposed by Norwich to control residues uses the parent drug, nihydrazone, as a marker in each of the major edible tissues. Norwich has failed to submit substantiating evidence to show that the measurement of nihydrazone is adequate to control total residues of potential concern or, alternatively, to show that all other residues are safe and do not need to be controlled.

3. Determination of the lower limit of measurement required for the analytical method: Establishment of the lower limit of measurement required for the assay begins with the availability of adequate toxicological testing to determine the cumulative effects of exposure. As described in section I of this notice, the sponsors have not provided adequate toxicological testing of nihydrazone. Also, as described in steps 1 and 2 in section II.A. and B. of this notice, the sponsors have not provided adequate information about the substantial levels of residue shown by radiotracer studies to show if portions of the residue can be removed from toxicological concern, and to adequately define the residues of interest to determine if testing of any of

the metabolites in addition to the parent drug, nihydrazone, is required for a determination of safety. Therefore, lacking this essential information, the Director concludes that he is unable to make an appropriate estimate of the acceptable level of exposure to total residues of interest in food.

Even if adequate testing were available to estimate the acceptable level of exposure to total residues in food, Norwich has not provided adequate information about a marker compound to determine the lower limit of measurement required for the assay.

As previously stated, Norwich has proposed that the measurement of nihydrazone is adequate to assure control of residues. The proportional relationship of the amount of nihydrazone to the amount of total residues indicates that nihydrazone is even less than 1 percent of the total residue during the early periods of withdrawal. It is therefore unlikely that nihydrazone can be used as a suitable marker unless it were shown that the major portion of the residue, reflected by the radioactivity measurements, can be qualitatively and quantitatively defined to show that these residues are of no toxicological interest. And if the residues cannot be shown to be of no toxicological interest, the lower limit of measurement that would have to be placed on nihydrazone to assure no significant residues from the use of this tumorigenic and potentially carcinogenic drug would probably be beyond technological achievement.

When a "safe concentration is assigned for the total residue of interest, and a suitable marker is selected and its proportional relationship to the total residue at the "safe concentration" is known, one further adjustment is necessary to determine the lower limit of measurement required for the assay. This last adjustment takes into account the degree to which the method of analysis recovers the residue from the sample. Minimum standards for recovery for the acceptance of the method take into account that 100 percent recovery is rarely achieved and that a combined evaluation of the precision and accuracy for measurement of the marker must be considered.

Norwich is aware of the principles just described for the selection of a target tissue, marker compound, and the adjustments required to establish conditions for the assay; this is evidence by Norwich's citation of a paper prepared by two FDA scientists in a submission for furazolidone (NF–180) to FDA on November 11, 1975. The cited paper by M. K. Perez and N. E. Weber, entitled "Requirements for Metabolic Studies—Impact on Food Safety Regulation" was presented at the Gordon Research Conference on Drug Metabolism, June 23–27, 1975.

The Director concludes that he cannot make an assessment of the toxicity, including the carcinogenic potential and potency, of nihydrazone without adequate testing data; he cannot conclude that nihydrazone serves as a valid marker for control of total residues of toxicological interest; and therefore he cannot without adequate supporting data determine the conditions necessary for the analytical method used to control residues. The requirements of step 4 have not been fulfilled. He concludes that the new evidence on nihydrazone (F–64) and furazolidone (NF–180) leads to a determination that the methods of analysis for residues of nihydrazone (NF–64) are not shown to be adequate.

E. *Practicable Methods of Analysis are Not Available to Assure that Total Residues in the Daily Diet of Humans Do Not Exceed a Level Deemed Safe (Step 5).* Section 514.1(b)(7) (21 CFR 514.1(b)(7)) requires the sponsor of a new animal drug application to provide a practicable method of analysis to be used for the control of residues of its product. A "practicable" method is defined by FDA as one that reliably measures the compound throughout all residue levels of interest, and also is sufficiently rapid and reasonable in terms of the expertise and equipment required to be applicable for use in the surveillance and control of residues. "Reliability" is a combination of accuracy, precision, and specificity. Accuracy and precision are quantitative terms. "Accuracy" is the measure of deviation from the true value, and "precision refers to the variability of measurement in replications either by one analyst or within a laboratory or between laboratories. A method may provide reliable measurement if the measurements are not too variable even though it measures less than or more than 100 percent of the true value. Therefore, accuracy and precision must be considered together.

"Specificity is a qualitative term. The measurements obtained by the method must reflect only the compound of interest. Because the method will be used on samples from animals for which exposure history is unknown, the techniques used in the method must be adequate to assure not only the integrity of the measurements, but also the identity of the residue to the exclusion of other itnerfering substances. Therefore, when the quantitative measurements are made by techniques that are not inherently specific, a confirmatory test is required as part of the official method to assure the identity of the residue. The most recently submitted methodology for nihydrazone is based on chromatographic separation and fluorometric determination, which are both nonspecific techniques.

The uses of nihydrazone were approved prior to that time when regulatory methods of analysis for residues were required. In 1962, a method of analysis for tissues capable of measuring nihydrazone as low as 0.1 ppm was submitted in Food Additive Petition No. 665. The method is based on acid hydrolysis to break the carbon-nitrogen double bond, generating 5-nitro-2-furaldehyde and reaction with phenylhydrazone to form the 5-nitro-2-furfural phenylhydrazone derivative, which is measured colorimetrically.

This method was not subjected to validation trials by FDA because it predated this current FDA preclearance requirement. The data submitted in support of this method only included studies of the recovery of nihydrazone from samples to which known amounts of the drug had been added (spiked samples). Recoveries of about 50 percent were estimated by FDA for samples fortified at 0.1 ppm. No evidence has been submitted to show that the method will satisfactorily recover nihydrazone when the residue is naturally incurred through drug treatment (dosed samples) at a level of 0.1 ppm. Furthermore, the method is not specific.

After FDA received reports that nitrofurans had induced tumors in female rats, the drug sponsors were advised in 1969 and officially informed in a conference held January 4, 1971, that the residue methods were no longer deemed adequate. They were told that methods capable of measuring at least 2 ppb of the drug in edible tissues were required. In response to the notices of opportunity for hearing, Norwich submitted newly developed methods of analysis.

For the measurement of tissue residues, Norwich concentrated primarily on the method for furazolidone (NF–180) in the belief that this method could be readily adapted for the measurement of tissue residues for the other nitrofurans.

A discussion of the results on the evaluation of the furazolidone (NF–180) method for tissue analysis (including swine liver, kidney, muscle, and fat and poultry liver, kidney, muscle, and skin with adhering fat) is presented in the May 13, 1976 FEDERAL REGISTER notice for furazolidone. In that notice, the Director concluded that the methods for edible tissues were not shown to be adequate.

Although the drug sponsors have submitted far more information to support the adequacy of the methods of analysis for furazolidone (NF–180) than they have submitted on methods of analysis for nihydrazone, the sponsors have in the intervening years submitted some progress reports on the development of analytical methods for nihydrazone.

In 1971, three different progress reports were submitted on the analysis of nihydrazone in chicken tissues:

1. Project No. 476.17 Interim Report, "Chemical Method for the Determination of Concentrations of Nihydrazone in Chicken Liver at 2 ppb," submitted to FDA by cover letter dated June 30, 1971.

The method presented was based on a fluorometric-densitometry measurement similar to the method submitted for furazolidone (NF–180); the method was not shown to be reliable in the validation trial in 1973. Farrand integrator counts were provided for five control chicken liver samples and for chicken liver samples fortified with 2 ppb of nihydrazone. Norwich reported an approximate recovery of 40 percent using an external standard curve and making corrections for aliquot losses. Food and Drug Administration chemists estimated the actual recovery from these data to be about 28 percent. Individual recoveries for each

sample were not provided by Norwich. The sponsor was notified that these data were not acceptable.

2. By letter dated May 17, 1971, Norwich provided data on the recovery of nihydrazone from chicken liver, kidney, and mucle samples. The same fluorometric-densitometry method was used. Norwich reported the following recoveries and standard deviations from tissues fortified with 2 ppb of nihydrazone: liver (78±31 percent), with a range of 35 to 102 percent; kidney (85±26 percent), with range of 43 to 121 percent; and muscle (77±18 percent), with a range of 30 to 96 percent. These recoveries were corrected for aliquot losses and losses in partitioning between solvents. Therefore, they appear higher than the actual recoveries. The Food and Drug Administration has concluded that the results are too erratic and too low for an acceptable method of analysis.

3. On June 30, 1971, in a letter to the FDA hearing clerk, Norwich submitted an interim report on Project No. 476.17, June 29, 1971, "Chemical Method for the Determination of Nihydrazone in Chicken Skin with Fat at 2 ppb." This project used the same fluorometric-densitometry method used for the other two submissions. Data were presented for 7 control samples of skin with adhering fat and for 21 samples fortified with 2, 4, or 6 ppb of nihydrazone. No recovery data were provided and none could be calculated in the absence of a standard curve. The integrator counts were variable, and the result for one of the 4-ppb-fortified samples was below several of those reported for the 2-ppb-fortified samples. A similar overlap of values for the 4- and 6-ppb-fortified samples was observed. These data were rejected as inadequate. No further data have been supplied by the drug sponsors on methods of analysis for nihydrazone.

None of the submitted methods of analysis for nihydrazone, i.e., the colorimetric or fluorometric-densitometry methods, are inherently specific. No confirmatory tests have been provided by the sponsors that can be used to confirm the identity of any residue found by the proposed assay methods.

The Director concludes that the sponsors have not shown that adequate practicable methods of analysis for residues of nihydrazone in edible chicken tissue are available. Appropriate data have not been provided to determine if nihydrazone can be used as a marker to control total residues in edible products, nor to determine the lower limit of measurement required for a method to assure that total residues do not exceed safe levels. The Director concludes that the methods proposed by the sponsors for the determination of nihydrazone are not quantitative and are not adequately specific at the levels of measurement that are likely to be necessary, based on the tumorigenic property of the drug. Therefore, the methods proposed are not quantitatively or qualitatively reliable and practicable methods for regulatory use, even if it were established that measurement of nihydrazone at 2 ppb was adequate to control total residues of toxicological interest. Therefore, step 5 and the requirements of section 512(b)(7) of the act have not been met.

F. *Practical Conditions of Use Cannot be Prescribed on the Label of Products to Assure Safe Use (Step 6).* Section 512(b)(8) of the act requires that conditions of use assure there are no unsafe residues, and section 512(d)(2)(D) of the act adds a further requirement that these conditions be such that they are "reasonably certain to be followed in practice."

It is required by FDA that residue depletion studies be conducted for each drug use under simulated field use conditions to develop data for establishing the withdrawal period. A withdrawal period is the time following drug treatment when, because of residues, a treated animal cannot be slaughtered for food. A withdrawal period must be sufficiently long to assure adequate residue depletion, but it cannot be so long that it is impractical and unlikely to be followed in practice. An adequate analytical method for residues, preferably the same method that will be approved for regulatory use, must be used to measure the residues in the depletion studies.

Because Norwich has not provided adequate data to determine the requirements necessary for an analytical method to control total residues of toxicological concern, depletion studies under those conditions currently required by FDA for the establishment of an adequate withdrawal period cannot be designed. Norwich, through its radiotracer studies, has shown that substantial levels of residue, expressed as nihydrazone equivalents, are present in edible tissues following drug treatment and persisting through the longest periods of withdrawal (5 days with the formyl-labeled nihydrazone). Although radiolabeled studies may be used initially to estimate drug depletion, it is usually not practical to follow this approach for the final determination of the withdrawal period. The establishment of a withdrawal period requires consideration of animal-to-animal variability, thus requiring that larger numbers of animals be used for the determination of residues. Likewise, it is important to have data using the chemical method proposed for control of residues and to compare these results with the results from the radiotracer metabolism studies to evaluate the capability of the method satisfactorily to recover the residue when naturally incurred.

Norwich has failed to show through the radiotracer studies that a safe and practical withdrawal period can be established for the uses of nihydrazone. Radioactive residues, expressed as nihydrazone equivalents, are shown in the few animals examined to be at levels of 1 to 13 ppm in tissues after treatment with the ^{14}C-formyl-labeled nihydrazone. They are shown to persist in muscle tissue at levels just below 1 ppm and in other major edible tissues at levels from 1 to 2 ppm following treatment of birds on the approved level of drug for 3 weeks and subsequent dosing with the radiolabeled drug for 4 days and observation of a 5-day withdrawal period.

Norwich has provided data in 3 reports on the depletion of parent drug, nihydrazone, from edible tissues:

1. Problem No. 476.03, Final Report "NF-64 and Metabolite Residues," September 24, 1969, NADA 13-200V, Vol. 5. ^{14}C-Nihydrazone (formyl label) was given to broiler chickens in their ration at 100 grams per ton for 5 days. The birds were then maintained on unmedicated feed, and four birds were sacrificed each day thereafter, up to 5 days after withdrawal from medication. A reverse isotope dilution technique was used to determine parent drug, nihydrazone, in muscle, liver, kidney, and skin-with-fat tissues. Norwich claimed the reverse isotope procedure was capable of measuring nihydrazone as low as 2 ppb. At 0-day withdrawal the levels of nihydrazone were reported as follows: muscle (less than 2 ppb to 9 ppb), kidney (4 ppb to 23 ppb), skin with fat (3 ppb to 37 ppb), and liver (less than 2 ppb and 3 ppb). Norwich reported that no nihydrazone was detected at the other withdrawal times, except for skin with fat. One skin-with-fat sample out of four examined after 3 days withdrawal indicated 2 ppb of nihydrazone.

2. Research Report No. JMS 63:1, "Nihydrazone Residue Analysis of Tissues of Chickens Receiving Rations Containing 100 g Nihydrazone per Ton of Feed for Eight Months," August 27, 1963, NADA 13-200, Vol. 5, from letter of submission to FDA January 8, 1971. Edible tissues from five birds given nihydrazone in the feed at 100 grams per ton for 8 months were analyzed using a colorimetric procedure. Norwich claimed the colorimetric procedure could detect nihydrazone at levels as low as 0.1 ppm. Norwich reported that all tissues contained less than 0.1 ppm of nihydrazone at 0-day withdrawal. Positive values for one liver and one kidney sample were reported but were dismissed by Norwich as false positives because of the lack of the characteristic pink or red color generally observed for the 5-nitro-2-furfural phenylhydrazone derivative during column chromatography.

3. "Tissue Residue Withdrawal Studies for Nihydrazone (Sonifur) in Chickens Fed Nihydrazone at 100 Grams Per Ton of Feed for Eight Weeks," from a Memorandum from Dr. Mertz to Dr. Heotis, November 9, 1971, submitted to FDA by cover letter of November 10, 1971, NADA 13-200V, Vol. 5.

Edible tissues from chickens fed a ration containing nihydrazone at 100 grams per ton for 8 weeks were analyzed by the fluorometric-densitometry method described in section II.E. of this notice. Norwich claimed the fluorometric-densitometry method could measure nihydrazone as low as 2 ppb. Samples of liver, muscle, kidney, and skin with fat from birds sacrificed at 4 and 5 days after withdrawal from medication were examined. One out of eight liver samples after 5 days withdrawal was reported to contain nihydrazone at 2 ppb. One out of seven skin-with-fat samples examined after 5 days withdrawal from medication was reported to

contain nihydrazone above 2 ppb, and an additional sample was reported questionable.

The Director concludes that withdrawal periods are necessary for the safe use of nihydrazone. The currently labeled withdrawal period for chickens now voluntarily used by the sponsors is 4 days. The Director concludes that data to support this withdrawal period or any practical withdrawal period has not been provided because of the following reasons:

a. The data show that the levels of total residue, from the limited radiotracer studies available, are substantial and not shown to be safe.

b. The data on depletion of nihydrazone where larger numbers of birds were used are not adequate because no data have been provided to show whether the measurement of nihydrazone in edible products can be used to control total residues of toxicological concern and, if so, at what level its measurement is required to assure that all residues are below concentrations deemed safe.

c. The chemical methods used to determine the depletion of nihydrazone in chicken tissues are not shown to be adequate, even if nihydrazone could be shown to be an adequate marker for total residues. In the second study the method of analysis would not be sufficiently sensitive, based on the known tumorigenic properties of the drug. In the third study the method used, even if it could be shown that nihydrazone measurement at 2 ppb was adequately sensitive, is not aceptable because the supporting data on the method are not adequate to assure the reliability of results. Likewise, in the first study the results are so variable that a withdrawal period for the depletion of parent drug, nihydrazone, if nihydrazone were accepted as a marker at 2 ppb, could not be established with reasonable certainty, based on the numbers of animals used in view of data presented. The requirements of step 6 and section 512 (b) (8) and (d) (2) (D) of the act have not been fulfilled.

Therefore, the Director is hereby withdrawing the notice of opportunity for hearing issued March 31, 1971, proposing to withdraw approval of NADA's providing for the use of nihydrazone (NF–64) in food-producing animals. Under section 512(e) (1) (B) of the act (21 U.S.C. 360b(e) (1) (B), the Director proposes to withdraw approval of certain existing NADA's providing for the use of nihydrazone in food-producing animals on the grounds that such use violates section 512 of the act in that such use has not been shown to be safe.

This notice applies to all outstanding NADA's for the use of nihydrazone in food-producing animals. All such applications known to FDA are listed below by NADA number and by each applicant's name and last known address in FDA records. Copies of this notice are being forwarded by registered or certified mail to each of the known applicants. Notice to other applicants or holders of NADA's whose identity is not known to FDA is given by this publication.

13–195, Hess and Clark, Division of Rhodia, Inc., 7th and Orange St., Ashland, OH 44805.

13–200, Norwich Pharmacal Co., Division of Morton-Norwich Products, Inc., 13–27 Eaton Ave., Norwich, NY 13815.

Any holder of an approved application that elects to avail itself of an opportunity for hearing pursuant to section 512(e) (1) of the act and § 514.200 of Chapter I of Title 21 of the Code of Federal Regulations must file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, a written appearance requesting such hearing by September 16, 1976, giving the reasons why approval of the application should not be withdrawn, and providing a well-organized and full-factual analysis of the scientific and other investigational data such holder is prepared to prove in support of its opposition to the Director's proposal. A request for hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is one or more genuine and substantial issue(s) of fact requiring a hearing. Responses to this notice and copies of published literature cited in this notice may be seen in the office of the Hearing Clerk, Food and Drug Administration, during regular business hours, Monday through Friday.

If a hearing is requested and is justified by any holder's response to this notice of opportunity for hearing, the issues will be defined, an Administrative Law Judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

Any hearing on the withdrawal of approval of the foregoing NADA's will be open to the public. If, however, the Director finds that portions of the applications that serve as a basis for such a hearing contain information concerning a method or process that is entitled to protection as a trade secret, that part of the hearing will not be public, unless the respondent so specifies.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.29) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)).

A discussion of the economic and environmental impact of this action is set forth in the notice of proposed rulemaking on nihydrazone, which is published elsewhere in this issue of the FEDERAL REGISTER.

It is hereby certified that the economic and inflation effects of this proposal have been carefully evaluated in accordance with Executive Order 11821.

Dated: August 6, 1976.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc.76-23618 Filed 8-10-76;11:19 am]

federal register

TUESDAY, AUGUST 17, 1976



PART III:

DEPARTMENT OF DEFENSE

Department of the Army

■

ENVIRONMENTAL QUALITY

Facilities Engineering, Pest Control Services

DEPARTMENT OF DEFENSE

Department of the Army

[32 CFR Part 657]

ENVIRONMENTAL QUALITY

Facilities Engineering, Pest Control Services (AR 420–76)

Notice is hereby given that the Secretary of the Army, acting through the Chief of Engineers, is proposing a regulation to prescribe the policies, responsibilities and procedures for conducting pest control services on all Army installations and activities. The regulation implements Department of Defense Directive 4150.7 and the policies and procedures of 32 CFR 650, "Environmental Protection and Enhancement," and 40 CFR 165—"Regulations for the Acceptance of Certain Pesticides and Recommended Procedures for the Disposal and Storage of Pesticides and Pesticides Containers." The proposed regulation is being published pursuant to the following authorities: Executive Order 11870, Environmental Safeguards on Activities for Animal Damage Control on Federal Lands; Executive Order 11752, Prevention, Control and Abatement of Environmental Pollution at Federal Facilities; Pub. L. 92-516, Federal Environmental Pesticide Control Act of October 21, 1972; Pub. L. 93-205, Endangered Species Act of 1973. This regulation applies to: Installations and activities in use by the Regular Army, those held in inactive or standby condition for future active use by the Regular Army, and those in excess category; Federally operated installations and activities, or portions thereof, which are in full-time or intermittent use by the National Guard, or which are being held by the Department of the Army for use by the National Guard; Installations and activities, or portions thereof, which are in full-time or intermittent use by Army Reserve or ROTC. This regulation does not apply to: Installations and activities, or portions thereof, which have been licensed or transferred to the States, to the Commonwealth of Puerto Rico or to the Territory of the Virgin Islands for use by the National Guard; Civil Works functions of the Corps of Engineers; Facilities occupied by Army activities as tenants when responsibility for support is vested in another Government agency.

The proponent agency of this regulation is the Office of the Chief of Engineers. Prior to the adoption of this proposed regulation, consideration will be given to any comments, suggestions, or objections thereto which are submitted in writing to the Chief of Engineers, Forrestal Building, Washington, DC 20314, ATTEN: DAEN-FEB-N on or before September 16, 1976.

Dated: August 4, 1976.

W. O. Bachus,
Brigadier General, USA,
Director of Facilities Engineering.

This regulation provides general Department of the Army policy, and guidance in pest control services. Local limited supplementation of this regulation is permitted but not required. If supplements are issued, Army staff agencies and major Army commands will furnish one copy each to HQDA (DAEN-FEB) WASH DC 20314; other commands will furnish one copy each to the next higher headquarters. A Department of the Army pamphlet supplementing this regulation will be published that will provide detailed guidance to pest controllers on operational, procedural, reporting and record keeping requirements.

This regulation supersedes AR 420-76, 24 November 1971.

PART 657—FACILITIES ENGINEERING, PEST CONTROL SERVICES (AR 420–76)

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Subpart A—General

§ 657.1 Purpose.

This regulation provides policies, responsibilities and certain procedures for pest control activities at U.S. Army installations.

§ 657.2 Applicability.

The regulation applies to all Department of the Army installations and activities owned and/or controlled by the Department of the Army, including those in full-time or intermittent use by the ARNG and USAR.

§ 657.3 Explanation of terms.

The terms used herein are explained as follows:

(a) *Pests.* Those organisms which adversely affect the health of man and animals (except those living on or in man or animals); which attack military facilities, stored supplies or equipment; or which are otherwise undesirable by their presence.

(b) *Pesticides.* Substances or combinations of substances intended for preventing, destroying, repelling or mitigating pests.

(c) *Pest control services.* All actions taken to prevent or mitigate pest problems including surveillance, determining proper application procedures, and operational implementation of chemical, physical and biological control techniques.

(d) *Pesticide classification.* A categorization of pesticides, based on toxicity and use patterns, for general or restricted use by the U.S. Environmental Protection Agency (EPA).

(e) *Certification.* Recognition by the MACOM and/or a State certification agency that a pest control supervisor or operator has been trained and is qualified to use pesticides.

(f) *MACOM entomologist.* A professional entomologist serving on the headquarters engineer staff of the MACOMs or a subordinate command, as appropriate.

(g) *Operating personnel.* Trained pest control services personnel who are employed in the facilities engineering organization that have a valid Certificate of Competency, DD Form 1826.

(h) *Standard pesticides and equipment.* Only those pesticides and equipment listed in the Department of Defense (DOD) section of the Federal Supply Catalog (ref para 4c(1)) will normally be used in pest control operations.

(i) *Nonstandard pesticides and equipment.* All pesticides and equipment that are not listed as standard items in the DOD section of the Federal Supply Catalog.

§ 657.4 Objective.

Preventive measures will be continuously applied with the objective of:

(a) Maintaining an effective pest control program at each Army facility.

(b) Minimizing service calls on common household and nuisance pests.

Subpart B—Policies

§ 657.11 General.

Pest control operations will be developed and applied consistent with the policies stated below.

§ 657.12 Supervision.

Except as specifically exempted (see Section 657.22 below—Outleased property), pest control operations will be performed by trained and certified personnel or under the direct and continuing supervision of these personnel.

§ 657.13 Operations.

Surveillance and control operations will be conducted on a scheduled basis to:

(a) Determine effectiveness of preventive and corrective measures.

(b) Prevent development of excessive pest populations.

§ 657.14 Materials and equipment.

(a) Pesticides and equipment listed in the DOD section of the Federal Supply Catalogs and registered with EPA will be used in pest control operations. Microfiches of catalogs C6800IL and 3740/50IL are available from the Adjutant General, USA Publications Directorate, Supply Operations Branch, ATTN: DAAG-PAS-

T, Washington, DC 20314. Use of a pesticide other than those registered by EPA and approved for specific application in accordance with labeling is not authorized. Pesticides that have been suspended or finally canceled by EPA will not be used.

(b) MACOM entomologists will review and approve proposed projects prior to acquisition or application of:

(1) Nonstandard pesticides and pest control equipment.

(2) Standard pesticides with restricted use patterns as classified by EPA.

(c) Justification for the use of standard pesticides with restricted use patterns and nonstandard pesticides or equipment will be approved only when one or more of the following criteria are met:

(1) An emergency exists which requires local purchase.

(2) Comparable standard pesticides with general use patterns are not available.

(3) Resistance to standard pesticides has been verified by competent authority.

(d) Contract items. Alternate pesticides (standard or nonstandard) which do not meet applicable contract specifications will not be authorized without approval of the MACOM entomologist.

(e) Requisitions. (1) Requisitions for pesticides requiring entomological approval will be forwarded to the MACOM for review and written approval. Agencies or commands not having access to engineer entomological support may obtain requisition review service from HQDA (DAEN–FEB) WASH DC 20314. Pesticide requisitions must be accompanied by data indicating the target pest, description of the area to be treated, extent of the area to be treated, the rate of application, name and certification number of the applicator and the justification as outlined in § 657.14(c) above.

(2) The Cdr DARCOM, CINCUSA REUR, Cdr USARJ, and Cds USAEIGHT may delegate to subordinate commanders (excluding installation commanders) served by MACOM entomologists as much of their approval authority as they may desire.

(3) CONUS (includes Alaska and Hawaii). Upon written approval of the requisition by the MACOM entomologist, nonstandard pesticides may be purchased locally.

(4) Overseas. When written approval of the requisition is received, it will be submitted through the appropriate supply agency for CONUS procurement. The DA entomologist, DAEN–FEB will be available to furnish technical guidance to CONUS supply agencies regarding procurement of nonstandard pesticides and equipment.

(f) Equipment listings are contained in TM 5–632. Procurement criteria are listed in AR 420–17. Information concerning new developments in equipment is available from MACOM entomologists.

§ 657.15 Training and certification.

(a) All personnel responsible for determining the need for, the effectiveness of, or selection and application of pest control measures on Army real property must receive periodic training and examination. Training information (initial and refresher) is available from:

(1) U.S. Army Health Services Command, ATTN: HSA–INS, Ft. Sam Houston, TX 78234, for the use of insecticides and rodenticides.

(2) The Pesticide Applicator Training Coordinator located at the respective land grant agricultural colleges. All States must meet the requirements of the Federal Insecticide, Fungicide and Rodenticide Act by submitting their pesticide programs to EPA, including training and certification, for the approval of EPA by October 1977. The target date for EPA approval of all state plans is October 1977.

(b) A Certificate of Competency (DD Form 1826) will be issued to personnel who successfully meet the required competency levels and as recommended by the MACOM entomologist. Refresher training and re-certification will be required at 3-year intervals.

(c) On-the-job training of new hires and interns will be accomplished by supervisors and certified applicators. MACOM entomologists may assist in the training during technical visits.

§ 657.16 Environmental quality.

Pest control operations will be planned and conducted to minimize and/or eliminate adverse environmental effects. When environmental impact or assessments statements are required, draft documents and final environmental impact statements will be prepared and processed in a timely manner in accordance with AR 200–1.

§ 657.17 Nonappropriated fund activities.

The application of pesticides at nonappropriated fund activities shall be made only by or under the direct supervision of trained and certified personnel. Contracts for pest control at nonappropriated fund activities shall be governed by provisions of this regulation.

§ 657.18 Property leased to the Government.

(a) CONUS and overseas. (1) Lease instruments will be negotiated to delineate specifically the responsibilities of the Lessor and of the Lessee (Government) for accomplishing pest control operations. In foreign countries, these responsibilities will be predicated upon custom, condition, and practices of the country concerned as applicable. In CONUS responsibilities must be in accordance with applicable laws and regulations.

(2) Occupants will maintain the leased premises in a clean and sanitary condition in conformance with normal standards of good housekeeping.

(b) CONUS (includes Alaska and Hawaii). Where feasible, the lessor will:

(1) Furnish the leased housing in pest-infestation-free condition to the lessee and maintain the premises free of pest infestation (AR 420–71).

(2) Employ control measures and pesticides which conform to local health department regulations.

§ 657.19 Cooperation with other agencies.

(a) *General.* Specialists of other Federal agencies provide consultation service and assistance on problems of medical, agricultural, and environmental importance (e.g., disease and pest control, quarantine control, customs inspection, fish and wildlife protection, water protection) as requested. Requests for services of these specialists will be made by the installation commander to the appropriate MACOM commander. The agencies include the United States Department of Health, Education, and Welfare (Public Health Service); the United States Department of Agriculture (Plant Protection Division, Plant Quarantine Division, and Animal Health Division of the Agricultural Research Service); the United States Department of the Interior (Fish and Wildlife Service); the United States Treasury Department (Bureau of Customs); and the Environmental Protection Agency.

(b) *Coordination.* Installations will coordinate environmental assessments of outdoor applications of pesticides with appropriate departments and agencies in section § 657.19(a). This coordination will be requested through the MACOM to the appropriate agency. Requirements for Environmental Impact Assessments or Statements (EIA/EIS) for certain application of pesticides are provided in AR 200–1.

(c) *Notification.* Installations will notify MACOM commanders, or their designees, of proposed visits or surveys by representatives of the departments and agencies identified in section 657.19(a) when these visits or surveys relate to quarantine or to past or proposed pesticide applications.

§ 657.20 Quarantine.

(a) General. In accordance with AR 40–12, all echelons of command will give full cooperation to officials of governmental agencies responsible for quarantines of agricultural and public health significance.

(b) MACOM commanders, or their designees, will insure that areas to receive pesticide treatment are liimted to the minimum necessary to meet quarantine requirements.

(c) Installations will procure pesticides, equipment, and other materials necessary to comply with quarantine requirements.

§ 657.21 Aerial application of pesticides.

Will be accomplished in accordance with AR 40–574.

§ 657.22 Outleased property.

Outgrant holders must comply with all applicable pesticide and animal damage control laws, ordinances, specifications and rules set forth in the land use regulations referred to and part of the outgrant document. Prior to commencing any program for compliance which de-

viates from the land use regulation specifications, review and approval of details of said program must be obtained from the MACOM. Where possible, supplemental agreement to existing outgrants so renewed or amended, for any reason, shall make provision for compliance hereof.

§ 657.23 Contractual services for pest control.

(a) Determinations made on methods of performance (in-house versus contract) must adhere to the requirements of AR 235–5.

(b) Installations located in states that conduct pesticide training, regulation and certification programs approved by EPA will determine contract/in-house triennial review as outlined in para 3–3 AR 235–5.

(c) Installations located in states that do not have EPA approved programs may justify in-house performance under Exemption Code C (Table B–2, App. B, AR 235–5).

(d) MACOMS will approve the technical provisions of all proposed contracts. CINCUSAREUR, USARJ and Eighth Army may delegate this approval.

Subpart C—Responsibilities

§ 657.31 MACOM entomologist.

The entomologist serving on the engineer staff will provide direction, focus and technical supervision for pest control services on all real property within the MACOM jurisdiction. Included are:

(a) Advising on all aspects of pest control operations to include manpower requirements, operational needs, minimizing pesticidal environmental impact, training and certification of pest control personnel, and procedural requirements necessary to assure efficient pest control programs.

(b) Coordinating with other agencies to assure implementation of environmentally safe and efficient pest control programs.

(c) Coordinating with Army medical authorities in implementing their responsibilities as given in AR 40–5.

(d) Reviewing and providing written approval for the use of standard pesticides with restricted use patterns and all nonstandard pesticides prior to procurement.

(e) Conducting reviews of installation pest control programs and recommending to the facilities engineer those changes which would result in safer, more economical, and more efficient operations.

(f) Maintaining professional proficiency by attending professional meetings and keeping abreast of new developments reported in professional publications.

(g) Providing on-the-job training for installation pest control personnel in the selection, use, and maintenance of pest control equipment; in the selection, preparation, and application of pesticides; and in accurate reporting of usage of these materials.

(h) Maintaining surveillance and record of training and certification status of pesticide applicators.

(i) Recommending certification of those pest control personnel who have been found competent in accordance with FIFRA standards.

§ 657.32 Facilities engineers.

Installation facilities engineers will:

(a) Plan, supervise and manage pest control operations.

(b) Conduct preventive maintenance and surveillance inspections at timely intervals.

(c) Assure that pest control services personnel receive adequate training to achieve essential certification.

(d) Provide on-the-job training of pest control services personnel.

(e) Obtain and maintain adequate supplies of materials and equipment.

(f) Assure all pest control operations are accomplished safely.

(g) Determine the phases of pest control to be accomplished by contract based on existing policies. Included are:

(1) Preparation of necessary specifications and technical provisions of the contract document.

(2) Arranging for the purchasing and contracting (P&C) officer to obtain contractural services.

(3) Assuring that the contract operations are conducted in accordance with the specifications through direct and continuous inspection by a certified pest controller.

(h) Perform all recordkeeping and reporting requirements of this regulation.

(i) Inform heads of nonappropriated fund activities that applications of pesticides at these activities shall be made by certified personnel and where certification training is given.

(j) Assure that pest control services are conducted so as to minimize any adverse effects on the environment.

(k) Cooperate with the installation medical authority by:

(1) Furnishing and maintaining mosquito light traps.

(2) Performing essential pest control operations indicated by results of surveillance of medical and quarantine pests.

(3) Providing all essential requirements to meet health safety requirements criteria, including shops, equipment, and protective gear.

(l) Maintain records of operations (e.g., investigations, inspections; utilization of manpower, funds, and pesticides) to be used for analyzing efficiency and economy, and evaluating accomplishment, of pest control.

§ 657.33 Installation commanders.

Will be responsible for:

(a) Determining an installation's position and responsibilities in community-wide pest control activities regarding quarantines and epidemics.

(b) Maintaining liaison with MACOM's concerning pest surveys, and investigations proposed by other agencies.

(c) Establishing lessee responsibility for using pesticides on outgrants of military real property.

(d) Initiating requests for aerial spraying of pesticides as prescribed in AR 40–574.

§ 657.34 Surgeon General.

The medical authority (State Adjutant General for the National Guard Bureau) serving the installation is responsible for:

(a) Conducting surveillance of populations of pests involved in the health of the command and those involved in U.S. Department of Agriculture quarantine regulations, and furnishing the facilities engineer results of the surveillance activities.

(b) Conducting the installation pesticide monitoring program.

(c) Obtaining identification and susceptibility status of pests to pesticides as necessary and furnishing this information to facilities engineers to be incorporated into pest control operations.

(d) Establishing health and personnel safety criteria associated with pesticide operations.

§ 657.35 Building occupants.

Occupants of buildings, including Army family housing will:

(a) Apply good sanitation practices to prevent pest infestations.

(b) Apply only those pesticides approved for use by building occupants.

(c) Cooperate fully with installation pest control personnel in scheduling major pest control operations, to include preparation of areas to be treated.

Subpart D—Procedures

§ 657.41 Handling.

(a) Pesticides will be stored and mixed in an adequately ventilated and heated shop. Showers will be readily accessible to mixing facilities.

(b) Usable standard pesticides (in unopened containers) no longer needed will be reported as excess to the property disposal office.

(c) Pesticides in deteriorated containers will be transferred to lined containers that preclude chemical reactions. Labels will be properly affixed.

(d) Appropriate action will be taken to deactivate areas contaminated by pesticide spills.

(e) Vehicles with lockable storage suitable for safe transportation of pesticides, personnel and supplies will be assigned for control operations and will not be used for other purposes.

(f) Pesticides will not be transported in cabs of military vehicles or anywhere in privately owned vehicles.

(g) Pesticide contaminated clothing will not be home laundered.

(h) Inspection and inventory of stored pesticides will be made at appropriate intervals. Certified personnel, safety and fire protection officers will perform and record inspections in accordance with their criteria.

§ 657.42 Contract operations.

(a) Contracts for pest control services will be executed, when required, accord-

ing to existing procurement regulations and the following guidelines:

(1) The services are economically beneficial to the Government, or the annual operating cost of the service is less than $50,000 and certified contractors are available.

(2) Application by trained and certified facilities engineering personnel is not feasible because of remote location, project size, and/or manpower-time-equipment limitations.

(3) Single applications of fumigants for entire building or other large inclosure are required .

(4) Aerial or special equipment applications over large areas such as mosquito breeding areas are necessary.

(5) Extensive wood treatment projects such as groundline treatment of utility poles are proposed.

(6) Extensive termite control operations are required which facilities engineering personnel cannot accomplish with in-house resources.

(b) Technical requirements for all pest management contracts will be prepared by the facilities engineering office in cooperation with the installation medical authority. Project plans and specifications will be forwarded to the appropriate MACOM for approval before a request is submitted for procurement of the service from commercial sources. Information should be included on the status of the Environmental Protection Agency's approval of State Plans for training and certification of commercial applicators and/or Department of the Army criteria established pending EPA approval of State Plans.

(c) Technical provisions will specify only the pesticides approved by HQDA DAEN–FEB WASH DC and registered by EPA. The items provided for use by the contractor must be identified qualitatively and quantitatively.

(d) The contractor must submit proof that the supervisory personnel to be employed on the contract will:

(1) Meet the State certification standards that have been established in response to EPA's implementation of FIFRA, or competency requirements established by HQDA (DAEN–FEB) WASH DC for the pesticide(s) to be used in the contract for those states that do not meet FIFRA certification requirements.

(2) Be capable of providing safe working conditions for his personnel and installation occupants.

(e) Inspection of the contract will be performed by a representative of the contracting officer who has a current DA Certificate of Competency (DD Form 1826) in pesticide selection and application. Inspection will include but not be limited to:

(1) Onsite inspection, by the contracting officer of unopened pesticide containers to verify that the chemicals listed on the label meet contract specifications and can be applied in accordance with the registered use.

(2) Observation of the mixing and equipment operations, rate of application (volume versus area), recognition of environmental hazards, and safety precautions in order to verify competence equal to DA standards for pesticide applicators.

§ 657.43 Record and reporting requirements.

(a) Adequate records must be maintained of all pest control operations. The records will serve as reference for continuous monitoring and management of pest control operations and for the reporting, inspection and manpower requirements.

(b) DD Form 1532. The Pest Control Summary Report (Report Control Symbol DD–HL (AR 1080)) will be prepared on DD Form 1532 dated 1 July 1974. Each installation will submit the reports monthly to the appropriate MACOM; the US Army Environmental Hygiene Agency (USAEHA), Aberdeen Proving Ground, MD 21010; and to the appropriate medical entomologist at USAEHA Regional Divisions, within 15 days after the report period. This regulation does not change any other instructions or standard terminology previously furnished.

(c) Annual Pesticide Usage Report (RCS DD–H&E (A) 1124). This report must be submitted by 31 December each year for annual review by the Federal Working Group on Pest Management. The routine programmed uses of pesticides reported in the past are to be excluded from future reports. MACOM entomologists will review all programs submitted and forward only those involving use of new programs, procedures, methods, materials or any control measures of a controversial nature. Negative reports will be submitted by installations if programs are routine as described above.

[FR Doc.76–23983 Filed 8–16–76;8:45 am]

federal register

TUESDAY, AUGUST 17, 1976



PART IV:

FEDERAL COMMUNICATIONS COMMISSION

Nondiscrimination in the Employment Policies and Practices of Cable Television Applicants and Certificate Holders and Licensees of Cable Television Relay Stations

Notice of Proposed Rulemaking

FEDERAL COMMUNICATIONS COMMISSION

[Docket No. 20829; FCC 76-749]

[47 CFR Part 76]

CABLE TELEVISION APPLICANTS

Nondiscrimination in Employment Policies and Practices

In the matter of nondiscrimination in the employment policies and practices of cable television applicants and certificate holders and licensees of cable television relay stations.

1. Notice of proposed rule making is hereby given in the above-captioned matter, relating to the Commission's policies concerning nondiscrimination in the employment policies and practices of cable television applicants and certificate holders and Cable Television Relay Station (CARS) licensees subject to the provisions of Parts 76 and 78 of the Commission's Rules.

2. The Commission has conducted a thorough examination of its rules, policies and compliance review procedures as they relate to nondiscrimination in the employment policies and practices of cable television applicants and operators. Additionally, we have conducted a study of the FCC Form 395's (Annual Employment Reports) filed by cable systems in 1974, in an attempt to ascertain present employment levels of minorities and women in the cable industry. Our findings indicate that although our nondiscrimination rules are fairly comprehensive, there is a further need to describe and exemplify the measures which cable operators should undertake to promote the full realization of equal opportunity in employment for minorities and women. Our purposes in initiating this proceeding are, therefore, threefold:

First, to emphasize to cable and CARS operators and the public that equal employment opportunity (EEO) is an important aspect of our regulatory scheme for cable operations in the public interest;

Second, to clarify our policy that equal employment programs must be active and affirmative, not merely passive or nondiscriminatory; and

Third, to propose changes in our rules and procedures which will make enforcement more effective without unnecessarily increasing the record keeping and reporting burdens on cable certificate of compliance holders.

Background

3. In March 1972, we adopted rules prohibiting discriminatory employment practices by cable television operators and cable television relay station licensees analogous to those already adopted for broadcast and common carrier licensees.[1] These cable rules require submission of affirmative action programs, annual employment reports (FCC Form 395), and annual complaint reports. Discriminatory Employment Practices, FCC 72-275, 34 FCC 2d 186 (1972).

4. When cable EEO rules were first proposed, we stated that "the same considerations of public policy that apply to broadcast . . . facilities are applicable to community antenna television systems and community antenna relay stations . . . [and] . . . that the national policy against discrimination is applicable to all CATV systems and CAR stations, whether or not they are subject to the specific provisions of the Civil Rights Act." Notice of Proposed Rule Making in Docket 19246, FCC 71-455, 29 FCC 71-455, 29 FCC 2d 18, 19 (1971). See also *United States* v. *Southwestern Cable Company*, 392 U.S. 157 (1968); *United States* v. *Midwest Video*, 406 U.S. 649 (1972). And we reaffirmed that conclusion in Discriminatory Employment Practices, supra. In addition to recognizing the fact that the national policy of nondiscrimination in employment necessitated the development of EEO rules for cable television, we also noted the unique position of cable television as a potential outlet for minority expression. In paragraph 9 of Discriminatory Employment Practices, supra. at 190, we stated.

> Cable, by virtue of its multi-channel capacity, is uniquely capable of serving the special programming, and other communications needs of discriminated-against minority groups. But a company which is not an equal opportunity employer is less likely than it otherwise would be, to recognize and respond to those needs. In light of this fact, among others, it would certainly be improper for the Commission to countenance discriminatory practices by cable systems at the same time as it forbids such practices by broadcast . . facilities.[2]

Therefore, in view of the potential of cable as an outlet for minority expression, and in light of the Supreme Court's decision in *United States* v. *Southwestern Cable Co.*, supra. which indicated that the Communications Act confers on the Commission that jurisdiction over cable television "reasonably ancillary to the effective performance of the Commission's various responsibilities for the regulation of television broadcasting", id. at 178,[3] we determined that discriminatory employment practices on the part of cable operators call into question their continued ability to serve the public interest.

5. The FCC Form 395's recently analyzed contained information on full-time cable system employees for any one payroll period in January, February or March, 1974. Approximately 90 percent of all cable television employment units (with five or more employees) submitted reports. The analysis separated job categories into high salary and low salary positions, and according to managerial and technical functions of employees, e.g., officials and managers through laborers and unskilled workers. Additionally, persons were classified according to race, sex, and national origin. Our statistics showed that minority and female employment levels in the cable television industry were very low in relation to their numbers in society, and that minorities and females were disproportionately represented in the lower skilled and lower paying jobs. These statistics also suggest that, on the whole, existing equal employment opportunity programs are not sufficiently active and affirmative. Practices and procedures neutral on their face "cannot be maintained if they operate to freeze the status quo or perpetuate prior discriminatory employment practices." *Griggs* v. *Duke Power Co.*, 401 U.S. 424 (1971).

6. The foregoing considerations shape our present intent to seek comment as to whether cable applicants and operators should be required to develop updated affirmative action employment programs consistent with the new proposals to be set forth herein. The objective to be achieved is to insure that all cable applicants and operators are identifying and eliminating artifical barriers having discriminatory effects in their employment systems, and that, in time, minority groups and women will participate in each cable television work force in a reasonable relationship to their availability in the labor recruitment area generally.

The Commission's Authority

7. We note that a recent case involving the Federal Power Commission raises issues regarding the authority of federal agencies to promulgate EEO rules for their respective regulated industries. It has been previously recognized that the "public interest" mandate of a federal regulatory agency is not a broad license to promote the general welfare, and that such a mandate takes on specific content and meaning only when one carefully examines the purposes for which the agency was established. In keeping with this principle, the Supreme Court recently held that a general grant of authority to regulate an industry in the "public interest" does not authorize the regulation of employment discrimination per se, and that discriminatory practices may be considered only to the extent that such conduct is directly related to the agency's particular statutory responsibilities. *NAACP* v. *Federal Power Commission*, 44 U.S.L.W. 4659 (May 19, 1976). The court went on to note, however, that our regulations, including a specific reference to cable television regulations, can be justified insofar as they are "neces-

[1] Section 76.311 of the Commission's Rules applies to operators of cable television systems, both in that capacity and as licensees and permittees of CARS stations. See also Section 78.75.

[2] Although cable operators, unlike broadcasters, are under no affirmative duty to program in the public interest, the availability of multiple channels allows cable a great potential to offer diverse programming and community access. The Commission no longer requires any cable television operator to engage in origination cablecasting. FCC 74-1279, 49 FCC 2d 1090 (1974).

[3] In *United States* v. *Midwest Video Corp.*, *supra*, the Supreme Court affirmed the Commission's decision to go beyond mere protective measures and also regulate cable with a view to "promote the objectives for which the Commission had been assigned jurisdiction over broadcasting." 406 U.S. 649, 665. Among those objectives recognized by the Court are increasing the number of outlets for local self-expression and augmentnig the diversity of programs and types of services available to the public.

sary to enable the FCC to satisfy its obligation under the Communications Act . . . to ensure that its licensees' programming fairly reflects the tastes and viewpoints of minority groups." Id. at 4662, note 7. The Supreme Court affirmed the decision of the Court of Appeals, which held that the FPC has the "power to take into account, in the performance of its regulatory functions, including licensing and rate review, evidence that the regulatee is a demonstrated discriminator in its employment relations." 520 F. 2d at 435 (D.C. Circuit, 1975). As the Court of Appeals noted:

> A regulatee's performance in the area of equal employment oportunity may also be relevant to that company's efforts to secure a license renewal or other Commission authorization. It is conceivable that an applicant's record could be so riddled with discrimination—related legal difficulties, and its future so lacking in any promise of improvement on that score, that the Commission could validly conclude that for this reason it should not be permitted to be the recipient of franchise grants. 520 F. 2d at 444.

8. In light of the Supreme Court's opinion, we seek comment as to whether our proposed actions are within the Commission's "statutory authority to consider the consequences of employment discrimination in performing its mandated regulatory functions." *NAACP* v. *FPC, supra,* note 2.

Policy Clarification

9. As noted above, the Commission's rules embody two concepts: Nondiscrimination and affirmative action. Nondiscrimination applies to all persons. Thus, no person may be denied employment or related benefits on grounds of race, color, religion, national origin or sex. Affirmative action, however, requires more than mere employment neutrality. It calls upon cable operators and applicants to make additional efforts—to engage in a positive, continuing program of specific practices—to assure equal employment opportunity with regard to recruiting, hiring, training, promotion and other personnel actions.

10. In its simplest terms, therefore, an affirmative action plan is a set of specific and result oriented procedures in which cable operators and applicants undertake good faith efforts to assure that minorities and women are given equal and full consideration for job opportunities. The essential elements of such a program are embodied in Section 76.311 of our Rules. Section 76.311(a) provides, in substance, that each cable operator shall provide equal opportunity in employment to all qualified individuals, and that no person shall be discriminated against in employment because of race, color, religion, national origin or sex. A basic element, and the starting point for developing an effective employment program, therefore, is a reaffirmation of each cable operator's equal employment opportunity policy with respect to recruitment, evaluation, selection, promotion, compensation, training and termination. Therefore, each cable operator's program should set forth at the outset its policy and commitment with respect to the national goal of eliminating discrimination and fostering equal employment opportunity.

11. In developing a positive, continuing program of specific practices to assure equal opportunity in employment, Section 76.311(b)(2)(i) requires each cable television system to "[d]efine the responsibility of each level of management to insure a positive application and vigorous enforcement of . . . [its] policy of equal opportunity, and establish a procedure to review and control managerial and supervisory performance." Accordingly, the second element in developing an equal opportunity program consistent with our rules is identification of the individual(s) responsible for administration and implementation of the cable system's policy. Whether employment decisions are made by one individual or by several persons, the cable operator must develop a procedure to insure that these decisions are consistent and are not based on discriminatory factors, no matter how inadvertent.

12. Section 76.311(b)(2)(iii) provides that each cable system should make reasonable efforts to "[c]ommunicate the system's equal employment opportunity policy and program and its employment needs to sources of qualified applicants without regard to race, color, religion, national origin or sex, and solicit their recruitment assistance on a continuing basis." Accordingly, an objective of any equal employment opportunity policy and program should be to assure that employees and prospective employees are aware that the cable system is an equal opportunity employer and does not discriminate against any individual because of his or her race, color, religion, or national origin. Each operator's program should, therefore, in some manner, describe its efforts to communicate its policy to employees and prospective employees.[4] In addition to other outreach techniques described herein, this requires the posting of notices advising employees and applicants of the operator's policy and of their employment rights if they believe they have been the victims of discrimination.

13. Section 76.311(b)(2)(iv) of the Rules provides that each cable system should "[c]onduct a continuing campaign to exclude every form of prejudice or discrimination based upon race, color, religion, national origin or sex, from the system's personnel policies and practices and working conditions." The system's total employment system and each major element of the personnel process must be analyzed to assure that none of the policies and procedures relating thereto, regardless of how neutral they appear, have an unreasonably adverse effect on minorities and women. In this regard, each cable operator's equal employment program should set forth the outreach techniques it uses to solicit for consideration minority and women applicants. An applicant should also examine the effectiveness of its recruitment sources to determine whether sufficient qualified minority and female applicants are being referred. Those sources which are not providing the needed service should be eliminated and new sources developed. In this regard, there are numerous outreach techniques which can be used to increase minority and female applicants.[5]

14. In addition to the major objective of broadening a system's pool of applicants so that qualified minorities and women have an equal chance to be considered for employment, a cable operator's equal employment program must be designed to assure that such persons are placed and promoted in a nondiscriminatory manner. To assure that minorities and women are given due consideration for promotional opportunities, the operator's porgram must also contain a description of any efforts being undertaken to foster the advancement of minorities and women in the organizational structure. Closely connected with this aspect of the cable operator's policy are the training efforts—both internal and external—which are or will be undertaken to qualify minorities and women for upgraded positions or to train applicants who demonstrate sufficient potential. This does not mean a formal training program is required. A cable system's equal employment opportunity program should, however, also contain a description of any training it has undertaken to upgrade the skills of minorities and women. Furthermore, the operator's program should assure that such items as compensation, fringe benefits, and opportunity to perform overtime work are allocated in a nondiscriminatory fashion. Comments are invited on this and other aspects of the foregoing policy clarification.

Analysis of EEO Program

15. Having clarified some of the necessary elements of an effective affirmative action program, we now turn to a consideration of how both the cable operator and the Commission can evaluate the implementation of such a program, apart from analysis of FCC Form 395's. Section 76.311(b)(2)(v) of the Rules requires each cable television system to:

> Conduct continuing review of job structure and employment practices and adopt positive recruitment, training, job design, and other measures needed to assure genuine equality of opportunity to participate fully in all organizational units, occupations, and levels of responsibility in the system.

16. One analytical tool for evaluating an effective affirmative action program is a determination of the percentages of minority groups and women in the local labor pool area from which employees are

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[4] See Section III, sample affirmative action plan (Appendix 2). See also present Section 76.311(c)(2)(i).

[5] In addition to the outreach techniques suggested for broadcasters at 54 FCC 2d 359, the following might prove useful: (1) Assist secondary schools and colleges in programs designed to enable minority and women graduates of these institutions to compete in the open employment market on an equitable basis; (2) Continue to actively recruit minority and femal high school students for part-time work as needed.

drawn or reasonably could be drawn—referred to herein as an availability survey. We recognize, in this regard, that there is no single definition of "local labor pool area." It follows, therefore, that each applicant should develop his own definition of what is "local" and supply corresponding data.[6]

17. In evaluating utilization of minorities and women, the information set forth in the availability survey will be compared to the applicant or operator's current workforce, a breakdown by job category of which appears on the most recently filed FCC Form 395. Specifically, underutilization may be defined as either employing minorities and women in jobs that do not make adequate use of their skills, or having fewer such persons on the applicant or operator's work force than could reasonably be expected by their availability. If there is a substantial incongruity in the proportion of minorities and/or women in the applicant or operator's work force and the availability in the local labor pool area, then specific remedial steps may be required to correct the deficiencies, unless there is a satisfactory explanation for the incongruity. (See paras. 22–24, infra.)

18. Because the written affirmative action program proposed herein seeks to assess progress and because the courts have recognized that such programs are evolving and dynamic,[7] we are proposing that updated statements, including current statistical data and availability surveys, together with any changes or amendments to existing programs, be filed on or before a fixed date to be established and each third, or perhaps each fifth, year thereafter. We believe that three to five years is an appropriate time period to provide reasonably current data and yet allow for trends to develop.

19. We seek comment on the appropriate threshold for the filing of written EEO programs. It would appear that the imposition of such requirements may be unnecessarily burdensome on cable systems with less than five (or perhaps 10) full-time employees, and that reliable statistical analysis is more difficult for smaller employment units. Requiring programs to be filed by all cable units with five or more full-time employees would cover about 19,000 employees, or approximately 75% of all cable industry employees. Alternatively, raising the cable threshold to 10 would cover about 14,000 employees, representing approximately 55% of the cable industry positions. Regardless of the threshold ultimately adopted, all operators and applicants will continue to be required to comply with other applicable portions of Section 76.311, and to file an annual report of complaints.[8] If a review of Annual Employment reports or other information indicates that closer Commission scrutiny and follow-up is warranted, we may reqire additional reports, data, or other appropriate remedial steps from any operator or applicant, regardless of the number of full-time employees.[9] Such additional remedial steps are expected to be ordered in only very limited circumstances.

20. Comments are specifically requested on all of the matters raised in paragraphs 15–19 above. We also invite comment on the proposed amendment which would exempt from coverage in a given plan any minority group insignificantly represented in the cable system's labor pool area,[10] including the question of what population proportion might define "significant."[11] In addition, attached is a sample affirmative action program which includes the elements which we feel are necessary to develop and carry out an effective equal employment opportunity program in accordance with Section 76.311 of the Rules, as clarified herein. Comments are invited on thisp rogram and whether it should be adopted as a guideline in conjunction with our proposed amendments to Section 76.311(c), or whether such a program should be adopted as an official Commission form.

ENFORCEMENT AND MONITORING

21. Generally speaking, we recognize that the development of an equal employment opportunity program containing the foregoing elements manifests an intent to comply with our rules. The adequacy of such programs will, of course, be subject to review by the Commission to determine whether each operator and applicant is following personnel policies and practices designed to promote the full realization of equal opportunity in employment for minorities and women. Both the Commission and the courts have recognized that non-proportionate minority and female employment—standing alone—does not necessarily evidence discrimination requiring administrative action. Thus, in *Stone v. F.C.C.*, 466 F. 2d 316, rehearing denied, 466 F. 2d 331 (1971), the court noted that disproportionate minority employment was in a "zone of reasonableness" in light of the licensee's affirmative recruitment practices. Conversely, ". . . a disparity that is reasonable in light of a recruitment policy might not be reasonable in its absence." *Bilingual Bicultural Coalition of Mass Media, Inc. v. F.C.C.*, 492 F. 2d 656 (D.C. Cir. 1974). In this regard, it should be noted that such a "zone" is not static and that continued operation of an affirmative action plan should result in additional employment opportunities for minorities and women.

22. Where it appears that any cable system's EEO program is not achieving the desired results or that certain elements of its employment procedures are questionable, we may—as a preliminary remedial step—request more specific data by race and sex on such areas as applicant flow, hires, promotions and terminations.[12]

In those cases where it appears that a more comprehensive analysis of a particular operator's employment practices is warranted, the Commission may consider the use of on-site investigations. In such instances, the on-site visit may consist of a complete analysis of the system's equal employment practices in an attempt to resolve existing differences. As a remedy for employers whose performance suggests significantly deficient EEO programs, the Commission may require establishment of specific goals and timetables. A "goal" is a numerical employment objective—a target—which should be fixed realistically in terms of the number of job opportunities expected and the number of qualified minorities and women in the local labor market. A "timetable," on the other hand, is a period during which employment goals should be obtained. Where required, goals and timetables should be set forth to numerically demonstrate the operator's good faith intention to increase minority and female utilization. A numerical projection will also enable the Commission to periodically assess the progress of the employer's corrective action program. We are guided in this course of action by statutory and case law which views goals and timetables as methods of eliminating the effects of past discrimination and guaranteeing against discrimination in the immediate future.

23. Absent discrimination, one would expect that in time minorities and women will be employed in some reasonable relationship to their numbers in the area. It has been recognized that factors other than discrimination may account for disparities between an employer's minority and female work force and their availability.[13] If, however, an extremely low rate of minority and female employment persists in a cable system's work

[6] Generally speaking, where a system is located in a Standard Metropolitan Statistical Area, we proposed to consider the S.M.S.A. as the labor pool area. In this situation, the necessary data may be obtained from state employment agencies "Manpower Information for Affirmative Action Programs" which is available in most localities. The specific figures generally shown in Tables I and II in those releases can be used in the analysis of population, unemployment and work force availability. Where a cable system is not in an S.M.S.A., city or county figures will suffice. The publications "General Population Characteristics" and "General Social and Economic Characteristics" should provide the required information. They are in the PC(1)–B and PC(1)–C series of State Reports of the U.S. Bureau of Census' U.S. Census of Population: 1970, obtainable from any Department of Commerce Field Office.

[7] Bilingual Bicultural Coalition of Mass Media, Inc. v. F.C.C., 492 F. 2d 656 (D.C. Circuit 1974).

[8] We are proposing an amendment to Section 76.311(d) to clarify that such annual complaint reports are required of all cable systems.

[9] See para. 22, infra.

[10] See note 6, supra.

[11] Of course, women ostensibly are significantly represented virtually everywhere, and thus would be covered in most every plan.

[12] See 54 FCC 2d at 357, note 1, for examples of such additional reporting requirements which have been applied to broadcast licensees.

[13] For example, availability of particular skills among women or minority groups, the employer's capacity for special job training or recruiting, etc. Also, the rate of turnover and anticipated expansion will have a bearing on the length of time it will take to correct any significant disparity.

force, or if it is apparent that a system's affirmative action program is not having practical effects, such systems may be required to establish employment goals and timetables to increase minority and female participation on their work force.[14] When such a corrective action program is ordered, the fixing of the goals and timetables would initially be left to the operator. This is a virtual necessity for a realistic framework of goals and timetables. However, it is our belief that projected hiring and promotion goals should be the maximum that can be realistically achieved during each year of the adopted timetable. The success of a corrective action program depends, in large measure, on setting realstic goals in terms of the number of minorities and women that can actually be hired, trained or promoted over a given period of time and on taking positive, continuing steps to achieve those goals. Our assessment, in this respect, will be based on whether the operator has established meaningful goals and made substantial efforts to achieve those goals.

24. Where there is a disparity in minority and female employment that is reasonable in light of the cable system's equal employment opportunity program, further administrative action by way of show cause hearing or otherwise would appear unwarranted. However, since a substantial incongruity in minority or female employment calls into question whether a cable system is being operated in the public interest, where it appears that a cable operator has followed discriminatory employment practices, we retain the option to order a hearing to resolve any substantial and material questions of fact relating to the system's employment policies and practices. We trust that most cases will not proceed to such extremes. Comment is invited on the proposals for EEO monitoring and enforcement outlined above.

COMPLAINTS

25. Under our proposed procedures, we shall continue to refer complaints of discrimination against cable applicants and operators to appropriate state, local and Federal agencies. This is consistent with our view that it is not our responsibility to remedy employment discrimination per se, but rather to assure that the public interest continues to be served by our certificating or licensing. We urge complainants alleging discrimination because of race, color, religion, sex or national origin to initially file their grievances with the appropriate state, local [15] or federal agency given primary jurisdiction in such matters because we lack the resources and the expertise to give them the same evaluation as those agencies whose primary function lies in the area of discrimination complaints. Where no state or local agency with primary jurisdiction exists, complaints are referred to the U.S. Equal Employment Opportunity Commission (EEOC), which possesses jurisdiction over employers of 15 or more individuals. Age discrimination charges are referred to the Wage and Hour Division of the U.S. Department of Labor's Employment Standards Administration. Where complaints are referred to other agencies, the Commission requests notification of that agency's final determination so the Commission may decide what further action is warranted.[16] In the event that no federal, state or local agency has jurisdiction over an individual employment discrimination complaint concerning a cable system, we invite complainants to address to the Commission their specific allegations indicating violations of our EEO rules for our determination of the appropriate action in the matter.

26. The receipt of such a complaint may result in an internal audit of the applicant or operator's Form 395 and EEO program to determine if the applicant or operator appears to be discriminating against women or minorities. Where we make such a determination, we will notify the local franchising authority or other governmental entity asserting jurisdiction to franchise, license, certify, or otherwise regulate cable television at the State or local level of the determination and of any remedial action which we may direct the applicant or operator to take to correct the situation. Where any Federal, State or local agency or court of competent jurisdiction makes a final determination that the employment practices of any applicant or operator are discriminatory, we shall consider such findings and orders as is appropriate in light of the facts supporting them. For the reasons set out at Paras. 7 and 21, supra, a finding by another agency will not necessarily present a substantial question or a basis for further inquiry under our own Act and rules. Comments are invited on the foregoing proposed complaint procedure.

CONCLUSION

27. In this Notice, we have outlined the development of our EEO rules as they relate to cable television and CARS operators, licensees, and applicants. We have also discussed the ingredients of an acceptable affirmative action program, and our compliance review and complaint procedures. In this respect, we have stressed the remedial rather than the punitive aspects of our rules and policies. However, we have also endeavored to erase any doubts about the seriousness with which we view the obligation of our applicants and operators to provide equal employment opportunity to all persons.

28. Authority for the rule making proposed herein is contained in Section 4 (i) and (j), 303, 307 and 403 of the Communications Act of 1934, as amended.

29. All interested persons are invited to file written comments on or before November 10, 1976, and reply comments on or before December 10, 1976. It is hoped that comments, either formal or informal, will be submitted by all segments of the public, the communications bar, national and state cable associations, and individual cable television operators and applicants. All relevant and timely comments and reply comments will be considered by the Commission before final action is taken in this proceeding. In reaching a decision in this matter, the Commission may take into account any other relevant information before it, in addition to the comments invited by this Notice.

30. In accordance with the provisions of Section 1.419 of the Commission's Rules, an original and 11 copies of all comments, replies, pleadings, briefs, or other documents filed in this proceeding shall be furnished to the Commission. However, in an effort to obtain the widest possible response in this proceeding from cable operators and members of the public, informal comments (without extra copies) will be accepted. Copies of all responses will be availabl efor public inspection during regular business hours in the Commission's Docket Reference Room (Room 239) at its Headquarters in Washington, D.C. (1919 "M" Street NW.).

Adopted: July 30, 1976.

Released: August 13, 1976.

FEDERAL COMMUNICATIONS COMMISSION,[17]
VINCENT J. MULLINS,
Secretary.

Part 76 of Chapter I of Title 47 of the Code of Federal Regulations is proposed to be amended as follows:

Section 76.311(c) and paragraph (d) (1) are revised to read as follows:

§ 76.11 Equal employment opportunities.

* * * * *

(c) *Equal employment programs to be filed with the Commission.* (1) The operator of each cable television system having 5 (or 10) or more full-time employees, or [within the meaning of paragraph (b) (3)] together with other cable television systems constituting a single employment unit with a total of 5 (or 10) or more full-time employees, shall

[14] In establishing goals there is no requirement that employees be displaced or that unneeded persons be hired. Further, as noted above, many localized factors may distort the resemblance between minority/female employment percentages and minority/female labor market percentages, even in the absence of discriminatory employment barriers. These factors must be considered if the goals established are to be realistic and attainable. Accordingly, the operator would be required to develop realistic goals and apply every good faith effort to meet those goals. Our rules prohibit preferential treatment on the basis of race, color, religion, sex or national origin.

[15] Local agencies could include franchising authorities, especially where EEO matters are covered in the franchise.

[16] Section 76.411 of the rules requires each cable television system to file an annual report of complaints, which, pursuant to Section 76.311(d)(i), must recite the respective disposition or current status of each complaint. An editorial change in 76.411 (Appendix One) seeks to make clear that the obligation to report EEO complaints falls on all cable systems, regardless of number of employees.

[17] Statement of Commissioner Hooks filed as part of original document.

file a statement of its equal employment opportunity program, indicating specific practices to be followed in order to assure equal employment opportunities for females, Negroes, Oriental, American Indians, and Spanish-surnamed Americans in such aspects of employment practices as a recruitment, selection, training, placement, promotion, pay, working conditions, demotion, layoff, and termination. [Guidelines for the preparation of such statements are set out at ____ FCC 2d____.] [1]

(2) If, pursuant to paragraph (c)(1) of this section or § 76.13(a)(8), a cable operator has been exempted from the requirement that it file an equal employment opportunity program statement, but has failed to satisfy the conditions of that exemption at any time during the first three months of a calendar year, it shall file the statement on or before May 31 of that year.

(3)(i) Where, pursuant to paragraph (b)(3) of this section a program is jointly established by two or more cable systems with an aggregate total of 5 (or 10) or more full-time employees, a multiple cable operator shall file a combined statement.

(ii) A multiple cable operator shall file a separate equal employment opportunity statement for each headquarters office if that office has five (or ten) or more full-time employees, and its work is primarily related to the operation of more than one cable television system under common ownership or control.

(4) The program need not include any minority group which is represented in insignificant numbers in the labor recruitment or population area, in which case a statement of explanation must be filed.

(5) Updated program statements, including current statistical data and availability surveys, together with any changes or amendments to existing programs, shall be filed on or before _____, and each third (or fifth) year thereafter.

(d) * * *

(1) All operators of cable television systems, regardless of their number of full-time employees, shall submit an annual report to the Commission no later than May 31 of each year indicating whether any complaints regarding violations by the operator of equal employment provisions of Federal, State, territorial, or local law have been filed during the preceding calendar year before any body having competent jurisdiction.

* * * * *

SAMPLE EEO PROGRAM (CABLE TV)

PREFACE

The following *sample* affirmative action program is provided to assist cable television operators and applicants in the development and presentation of their own plans. By no means is the sample intended as an all-inclusive document. It is a guide that may be adapted to the uniqueness of each employment situation. Indeed, operators are encouraged to supplement these suggestions with any special features of their EEO plans not covered herein. Similarly, we expect them to omit from their plans the sample elements which are not warranted or feasible in their particular circumstances, so long as all major aspects of the pertinent EEO rules are covered. For example, an availability survey is essential for meaningful analysis of the effectiveness of any EEO program, hence some form of Sections IX and X must be included. Section VI, on the other hand, might be deleted if the operator has no internal or external training programs. We realize that workforce availability data is not readily obtainable for all localities; however, we urge applicants to assemble as much information as possible concerning the population from which employees are drawn. We suggest the following sources as reference points: Office of Department of Commerce (U.S. Census of Population Reports), Bureau of Labor Statistics, National Technical Information Service, State Employment Office, Chamber of Commerce, local employer's associations, and community organizations.

I. POLICY STATEMENT

It is the policy of _____ to provide equal employment opportunity to all individuals without regard to race, color, religion, sex, or national origin in all personnel actions including recruitment, evaluation, selection, promotion, compensation, training and termination.

(Name of organization)

To ensure implementation of this policy and to ensure conformance with the requirements set forth in Title VII of the Civil Rights Act of 1964 and FCC Rules and Regulations, _____ has developed a positive, continuing result-oriented Affirmative Action Plan, and is committed to apply good faith efforts toward the attainment of these objectives.

(Name of organization)

II. RESPONSIBILITY FOR IMPLEMENTATION

All company officials and managers are responsible for implementation of affirmative action and for seeing that stated objectives are effectively accomplished. _____, _____, is responsible for the administration of the system's policy and plan and will keep senior management informed of progress on a regular basis.

(Name) (Title)

III. POLICY DISSEMINATION

( ) Where a significant percentage of employees, employment applicants, or residents of the community of a cable television system are Spanish-surnamed Americans, all notices, applications and other equal employment opportunity information is posted or distributed in both Spanish and English. Similar use is made of other languages where appropriate.

( ) We seek the cooperation of the unions represented in our employment units to help develop and implement our EEO program and all new or re-negotiated union agreements contain an effective nondiscrimination clause.

Internal Communications: To assure that all members of the staff are cognizant of our equal employment oportunity policy and their individual responsibilities in carrying out this policy, the following communication efforts are made:

( ) Appropriate notices are posted informing applicants and employees that the system is an Equal Opportunity Employer and of their right to notify an appropriate local, state, or federal Communications Commission, if they believe they have been the victims of discrimination.

( ) Other (specify)

_____

_____

External Communications: In order to assure that all prospective applicants and the general public are aware of our EEO policy, the following specific communications efforts are made:

( ) The system's employment application form contains a notice in bold type informing prospective employees that discrimination because of race, color, religion, national origin or sex is prohibited and that they may notify the appropriate local, state, or federal agency, including the Federal Communications Commission, if they believe they have been the victim of discrimination.

( ) Other (specify)

_____

_____

IV. RECRUITING AND SELECTION

_____ actively seeks and encourages minorities and women to apply for existing and future available job openings. In so doing, contact was made with the following organizations in the past (three) year(s):

(Name of organization)

_____

Organization and Address

_____

Number of Referrals

( ) Selection techniques or tests (if used) are designed to avoid discriminatory effects.

( ) Present employees are encouraged to refer minority or female applicants.

V. JOB HIRES

During the period _____ through _____, we receive a total of (_____) applications for employment. Of these applicants (_____) were hired.

(month-day-year) (month-day-year) (month-day-year)

Analysis of our recruiting performance and new hires reveals that:

( ) Sufficient minorities and women are applying for available positions.

( ) An insufficient number of qualified minorities and/or women are applying for positions. Therefore, we are expanding our recruitment sources to include:

_____

Organization

_____

Address

VI. TRAINING

( ) We provide on-the-job training to upgrade the skills of employees. Tangible benefits of such training to minority and women employees during the past (three) year(s) may be briefly described as follows:

_____

_____

( ) We utilize the following other sources to assist in training potential employees or qualifying current employees for higher-level positions:

_____

_____

( ) There are no specific internal or external programs for upgrading the skills of employees.

VII. PROMOTION AND TRANSFER

It is our policy to provide promotions on a nondiscriminatory basis. Further, to assure that minorities and women are given due

[1] Assuming the sample program is not adopted as an official form.

consideration for promotional opportunities, special effort is taken to encourage minorities and women to qualify and apply for advancement. During the past twelve months our policy has had the following results:

( ) Those of the system's staff who make decisions on hiring placement and promotion are personally instructed that minority employees and females are to be considered without discrimination, and that job areas in which there is little or no minority or female representation should be reviewed to determine whether this results from discrimination.

( ) Minority groups and female employees are given equal opportunity for positions which lead to higher positions. We inquire as to the interests and skills of all lower-paid employees with respect to any of the higher-paid positions, followed by assistance, counselling, and effective measures to enable employees with interest and potential to qualify themselves for such positions.

( ) Seniority practices are reviewed periodically to insure that such practices are nondiscriminatory and do not have a discriminatory effect.

VIII. COMPENSATION

( ) Rates of pay and fringe benefits for present employees with equivalent duties have been examined within the last (three) year(s) and any inquiries found have been adjusted.

( ) Opportunity to perform overtime work is provided on a basis that does not discriminate against qualified minority groups or female employees.

IX. AVAILABILITY SURVEY

The following analysis has been prepared to determine the extent to which minorities and/or women are represented in the cable system's labor or population area. In determining the available minority and female work force, we have used information obtained from:

( ) Office of Department of Commerce
( ) "General Population Characteristics"
( ) "General Social and Economic Characteristics"
( ) Bureau of Labor Statistics
( ) National Technical Information Service
( ) "Manpower Information for Affirmative Action Programs"
( ) State Employment Office
( ) Chamber of Commerce
( ) Local employer's association
( ) Community organizations (specify)
( ) Other (specify)

	Women	Negro	Oriental	American Indian	Spanish surnamed American
Percentage of women and each minority group in the work force					
Percentage of women and each minority group in the population (to be used only if work force data is unavailable)					

The above information is relative to: ( ) S.M.S.A. ( ) City ( ) County ( ) Other (specify)

Based on the data, the following groups are not significantly repreesnted in the cable system's area _____ (attach statement of explanation).

X. EFFECTIVENESS OF AFFIRMATIVE ACTION PLAN

This section should contain a brief narrative discussion of the effectiveness of the operator's efforts to ensure Equal Employment Opportunity. For example, the operator should review the current workforce breakdown, which data appears on the most recently filed FCC Form 395. This data should be compared to the Availability Survey appearing in Section IX to determine whether there is a substantial incongruity in the proportion of women and/or any significantly represented minority group in the system's workforce to their availability in the local labor pool area. If a substantial incongruity is determined to exist, any changes instituted to overcome the deficiency should be set forth. The operator may wish to explain why any discrepancies which may exist are not unreasonable. Any rifficulties experienced in implementing the affirmative action plan might also be described, together with any steps proposed to surmount these difficulties in the future.

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