(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., August 31, 1973, unless otherwise modified, changed, or suspended by order of this Commission.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15, and 17 (2). Interprets or applies secs. 1(10–17), 15 (4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; 49 U.S.C. 1(10–17), 15(4), and 17(2).)

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

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.73-5043 Filed 3-14-73;8:45 am]

Title 50—Wildlife and Fisheries

CHAPTER I—BUREAU OF SPORT FISHERIES AND WILDLIFE, FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 33—SPORT FISHING

Certain Wildlife Refuges in California

The following special regulations are issued and are effective March 15, 1973.

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas.

General conditions: Fishing shall be in accordance with applicable State regulations. Portions of refuges which are open to fishing are designated by signs and/or delineated on maps. The maps are available at the respective refuge headquarters and from the office of the Regional Director, Bureau of Sport Fisheries and Wildlife, Post Office Box 3737, Portland, OR 97208.

Colusa National Wildlife Refuge—(Headquarters: Sacramento National Wildlife Refuge, Route 1, Box 311, Willows, CA 95988).

Special Conditions: (1) The taking of frogs is permitted except that the refuge is closed to sport fishing and the taking of frogs during the migratory waterfowl hunting season.

(2) The use of boats without motors is permitted for fishing and the taking of frogs.

Delevan National Wildlife Refuge—(Headquarters: Sacramento National Wildlife Refuge, Route 1, Box 311, Willows, CA 95988).

Special Conditions: (1) The taking of frogs is permitted except that the refuge is closed to sport fishing and the taking of frogs during the migratory waterfowl hunting season.

(2) The use of boats without motors is permitted for fishing and the taking of frogs.

Modoc National Wildlife Refuge—(Headquarters: Sheldon-Hart-Modoc National Antelope Refuges, Post Office Box 111, Lakeview, OR 97630).

Special Conditions: (1) Fishing will be permitted in designated areas only during the migratory waterfowl hunting season.

(2) The taking of frogs on refuge lands is prohibited except by special permit obtainable at refuge headquarters, Alturas, Calif.

Sacramento National Wildlife Refuge, Route 1, Box 311, Willows, CA 95988.

Special Conditions: (1) The taking of frogs is permitted except that the refuge is closed to sport fishing and the taking of frogs during the migratory waterfowl hunting season.

(2) The use of boats without motors is permitted for fishing and the taking of frogs.

San Luis National Wildlife, 535 J Street, Los Banos, CA 93635.

Special Conditions: (1) Fishing permitted from sunrise to 1 hour after sunset.

(2) The refuge is closed to sport fishing during the migratory waterfowl hunting season.

(3) Use of boats is prohibited.

Salton Sea National Wildlife Refuge, Post Office Box 247, Calipatria, CA 92233.

Special Condition: (1) Fishing is permitted in that portion of the refuge which is inundated by the Salton Sea.

The provisions of these special regulations supplement the regulations which govern fishing on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 33, and are effective through December 31, 1973.

L. EDWARD PERRY,
Acting Regional Director, Bureau of Sport Fisheries and Wildlife.

MARCH 8, 1973.

[FR Doc.73-5019 Filed 3-14-73;8:45 am]

PART 33—SPORT FISHING

Certain Wildlife Refuges in Idaho

The following special regulations are issued and are effective on March 15, 1973.

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas.

General conditions: Fishing shall be in accordance with applicable State regulations except for special conditions listed.

All areas open to fishing are designated by signs and delineated on maps available at the respective refuge headquarters and from the office of the Regional Director, Bureau of Sport Fisheries and Wildlife, Post Office Box 3737, Portland, OR 97208.

Deer Flat National Wildlife Refuge, Route 1, Box 1457, Nampa, ID 83651. Sport fishing is permitted on the entire refuge year-round except as stipulated under special conditions.

Special conditions: (1) Fishing is not permitted on the public hunting area during the migratory waterfowl hunting season.

(2) Boats with motors may be used during daylight hours only (interpreted here to be 1 hour before sunrise to 1 hour after sunset) from April 15 through September 30, 1973.

(3) Shoreline fishing is prohibited on the islands of the Snake River sector from February 1 to May 31.

Kootenai National Wildlife Refuge, Star Route No. 1, Box 88, Bonners Ferry, ID 83805.

Sport fishing is permitted on portions of Kootenai River, Deep Creek, and Myrtle Creek within the refuge.

Minidoka National Wildlife Refuge, Route 4, Rupert, Idaho 83350.

Sport fishing is permitted on the entire refuge year-round except as stipulated under special conditions.

Special conditions: (1) Shoreline fishing shall be permitted on the entire refuge year around.

(2) Boat fishing is permitted on the main reservoir from Minidoka Dam to the west end of Bird Island, April 1 through September 30, 1973, and from Smith Springs to the east end of the refuge October 1 through June 30, 1973, during daylight hours only.

(3) Boat crossing lanes at Smith and Gifford Springs' open year around.

The provisions of these special regulations supplement the regulations which govern fishing on wildlife refuge areas generally and which are set forth in Title 50, Code of Federal Regulations, Part 33, and are effective through December 31, 1973.

L. EDWARD PERRY,
Acting Regional Director, Bureau of Sport Fisheries and Wildlife.

MARCH 7, 1973.

[FR Doc.73-4999 Filed 3-14-73;8:45 am]

PART 33—SPORT FISHING

Certain Wildlife Refuges in Oregon and California

The following special regulations are issued and are effective on March 15, 1973.

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas.

General conditions. Fishing shall be in accordance with applicable State regulations and special conditions listed. Portions of refuges which are open to fishing are designated by signs and/or delineated on maps. The maps are available at the respective refuge headquarters and from the office of the Regional Director, Bureau of Sport Fisheries and Wildlife, Post Office Box 3737, Portland, OR 97208.

OREGON

Ankeny National Wildlife Refuge—(Headquarters: William L. Finley National Wildlife Refuge, Route 2, Box 208, Corvallis, OR 97330).

Special conditions: (1) The use of boats is not permitted.

(2) During the open season, fishing shall be permitted each day from 1 hour before sunrise to 1 hour after sunset. Use of artificial lights will not be permitted.

Hart Mountain National Antelope Refuge—(Headquarters: Sheldon-Hart Mountain National Antelope Refuges, Post Office Box 111, Lakeview, OR 97630).

Klamath Forest National Wildlife Refuge—(Headquarters: Tule Lake National Wildlife Refuge, Route 1, Box 74, Tulelake, CA 96134).

Special condition: (1) Use of boats is not permitted.

Malheur National Wildlife Refuge, Post Office Box 113, Burns, OR 97720.

Special conditions: (1) Refuge waters, with the exception of Krumbo Reservoir, are closed to the use of boats for fishing purposes.

(2) The use of motors on boats is not permitted on Krumbo Reservoir.

Upper Klamath National Wildlife Refuge—(Headquarters: Klamath Basin National Wildlife Refuges, Route 1, Box 74, Tulelake, CA 96134).

Special condition: (1) Speedboats shall not exceed 10 miles per hour in any stream, creek, or canal, and that portion of Pelican Bay west of a line beginning at a point on the north shore of Pelican Bay one-fourth mile east of Crystal Creek and extending due south to opposite shore of the lake.

William L. Finley National Wildlife Refuge, Route 2, Box 208, Corvallis, OR 97330.

Special conditions: (1) Use of boats is not permitted.

(2) During the open season, fishing shall be permitted each day from 1 hour before sunrise to 1 hour after sunset. Use of artificial lights will not be permitted.

Cold Springs National Wildlife Refuge—(Headquarters: Umatilla National Wildlife Refuge, Post Office Box 239, Umatilla, OR 97882).

Special conditions: (1) The refuge is closed to sport fishing during the migratory waterfowl hunting season.

(2) Boats without motors may be used for purpose of fishing.

McKay Creek National Wildlife Refuge—(Headquarters: Umatilla National Wildlife Refuge, Post Office Box 239, Umatilla, OR 97882).

Special condition: (1) The refuge is closed to sport fishing during the migratory waterfowl hunting season.

The provisions of these special regulations supplement the regulations which govern fishing on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 33, and are effective through December 31, 1973.

L. EDWARD PERRY,
Acting Regional Director, Bureau of Sport Fisheries and Wildlife.

MARCH 8, 1973.

[FR Doc.73-5001 Filed 3-14-73;8:45 am]

PART 33—SPORT FISHING

Certain Wildlife Refuges in Washington

The following special regulation is issued and is effective on March 15, 1973.

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas.

General conditions. Fishing shall be in accordance with applicable State regulations. Portions of the refuge which are open to fishing are designated by signs and/or delineated on maps. The maps are available at the refuge headquarters and from the office of the Regional Director, Bureau of Sport Fisheries and Wildlife, Post Office Box 3737, Portland, OR 97208.

McNary National Wildlife Refuge, Post Office Box 19, Burbank, WA 99323.

Special conditions: (1) The refuge is closed to sport fishing during the migratory waterfowl hunting season.

(2) The use of boats or floating devices of any description is prohibited.

Columbia National Wildlife Refuge, Post Office Drawer F, Othello, WA 99344.

Special conditions: (1) Mallard Lake, Migraine Lake, Seabrock Lake, Royal Lake, Crab Creek, Marsh Management Units I and III are open April 15 through August 15, 1973.

(2) The use of boats and the use of outboard motors are prohibited on lakes so posted.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 33, and are effective through December 31, 1973.

L. EDWARD PERRY,
Acting Regional Director, Bureau of Sport Fisheries and Wildlife.

MARCH 7, 1973.

[FR Doc.73-5000 Filed 3-14-73;8:45 am]

PART 33—SPORT FISHING

Horicon National Wildlife Refuge, Wis.

The following special regulation is issued and is effective on March 15, 1973.

§ 33.5 Special regulations; sport fishing, for individual wildlife refuge areas.

WISCONSIN

HORICON NATIONAL WILDLIFE REFUGE

Sport fishing on the Horicon National Wildlife Refuge, Mayville, Wis., is permitted only on the areas designated by signs as open to fishing. These open areas are delineated on maps available at refuge headquarters and from the office of the Regional Director, Bureau of Sport Fisheries and Wildlife, Federal Building, Fort Snelling, Twin Cities, Minn. 55111. Sport fishing shall be in accordance with all applicable State regulations subject to the following special conditions:

(1) The open season for sport fishing on the refuge extends from May 15, 1973, through September 15, 1973, inclusive.

(2) The use of boats is not permitted.

(3) Fishing during daylight hours only.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally which are set forth in Title 50, Part 33, and are effective through September 15, 1973.

ROBERT G. PERSONIUS,
Refuge Manager, Horicon National Wildlife Refuge, Mayville, Wis.

MARCH 6, 1973.

[FR Doc.73-5013 Filed 3-14-73;8:45 am]

Title 21—Food and Drugs

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

ENVIRONMENTAL IMPACT STATEMENTS

Procedures for Preparation

In the FEDERAL REGISTER of July 12, 1972 (37 FR 13636), the Commissioner of Food and Drugs published proposed procedures for consideration of environmental impact factors pursuant to the National Environmental Policy Act of 1969 (Public Law 91-190; 83 Stat. 852 et seq.; 42 U.S.C. 4321-4347).

During the 60-day comment period, 15 comments were received on the proposal; from the Environmental Protection Agency, one college of agriculture, three trade associations, and regulated industries. The principal points raised and the Commissioner's conclusions are as follows:

A. *Applicability.* Seven comments questioned whether routine actions of the Food and Drug Administration, such as approval of new drug applications, new animal drug applications, antibiotic drug monographs, food additive petitions and color additive petitions constitute major actions significantly affecting the quality of the human environment which would require issuance of environmental impact statements. Two comments doubted that destruction of condemned, enjoined, detained, or recalled articles would ever amount to a major agency action requiring an environmental impact statement. Five comments proposed establishing categories of animal drugs which would be excluded from environmental impact consideration. The Commissioner concludes that the National Environmental Policy Act applies to the categories of agency action in § 6.1(b) and that FDA shall therefore consider the need for preparing environmental impact statements for them. No environmental impact statement will be issued if the agency action is not major or it does not significantly affect the quality of the human environment.

B. *Environmental impact analysis reports.* Five comments stated that the FDA has no authority to require new drug applications, new animal drug applications, new antibiotic drug applications, food additive petitions and color additive petitions to include environ-

mental impact analysis reports, or to refuse to accept or file such an application or petition for failure to include such a report, or to reject such an application or petition for failure to include an adequate environmental impact analysis report. Seven comments objected that the filing of environmental impact analysis reports would cause lengthy delays in the processing of such applications and petitions. The Commissioner concludes that the National Environmental Policy Act, as interpreted by the courts, amends the Federal Food, Drug, and Cosmetic Act to the extent that it requires consideration of environmental issues in the review by the FDA of these applications and petitions, and that the FDA therefore has the authority to require submission of adequate environmental data as a criterion for accepting, filing, and approving them.

Five comments proposed that an applicant or a petitioner be required to file an environmental impact analysis report only when the FDA determines that a specific application or petition constitutes a major agency action significantly affecting the quality of the human environment. One comment suggested that submission of an environmental impact analysis report be required for destruction of condemned, enjoined, detained, or recalled articles only when the agency determines that destruction of an article constitutes a major FDA action significantly affecting the quality of the human environment. The Commissioner concludes that environmental impact analysis reports are necessary for all applications and petitions submitted to FDA and for all destructions of condemned, enjoined, detained, and recalled articles in order to provide sufficient environmental data and information to enable the agency to determine whether an environmental impact statement must be issued on the action involved. The amount and detail of the information provided in the environmental impact analysis report will be expected to vary depending upon the nature of the action involved.

Three comments proposed prompt notification to an applicant if its environmental impact analysis report is inadequate. Three comments also recommended that notice be afforded an applicant when the FDA deems the amendment to an existing regulation or the supplement to an existing approval is substantial enough to require submission of an environmental impact analysis report. Notice in both these instances will be given in accordance with existing regulations of the FDA providing that an applicant will be notified if its application is incomplete for filing.

C. *Trade secrets and confidential information.* Twelve comments expressed concern that submission of an environmental impact analysis report by an applicant or petitioner would necessitate disclosure of trade secrets and confidential information, particularly with respect to a description of the manufacturing process required in the report. Seven comments proposed that applicants and petitioners have the opportunity to review environmental impact statements before they are made available to the public to prevent disclosure of trade secrets and confidential information by the statements. The Commissioner concludes that data and information which constitute trade secrets or confidential information under 21 CFR Part 4 should not be submitted in an environmental impact analysis report, although they are submitted as part of an application or petition itself. A new paragraph (h) is therefore added to § 6.1 to this effect. The FDA is not precluded from considering trade secrets or confidential information submitted by an applicant or petitioner in its environmental assessment of an application or petition. However, no trade secrets or confidential information submitted in the application or petition will be disclosed in an environmental impact statement circulated outside the Department.

D. *Time for consideration of environmental impact statements.* Nine comments proposed time limitations for the preparation and review of environmental impact statements for food additive petitions, new drug applications and new animal drug applications on the grounds that sections 409(c), 505(c), and 512(c) of the Federal Food, Drug, and Cosmetic Act require the agency to act on such applications and petitions within 180 days after filing. The Commissioner concludes that the National Environmental Policy Act, as interpreted by the courts, amends the Federal Food, Drug, and Cosmetic Act to the extent that it requires the FDA to give full consideration without restrictions of time to all environmental issues relevant to FDA approval of food additive petitions, new drugs and new animal drugs. Every effort will be made to stay within the statutory time periods and the regulations so provide.

E. *Alleged regulatory duplication.* Seven comments contended that the requirement to include a description of manufacturing processes in environmental impact analysis reports unnecessarily duplicates regulatory activity since the Environmental Protection Agency and various State and local authorities already administer air and water quality standards controlling the emission of pollutants. Two comments made an identical contention with respect to the requirement of environmental impact analysis reports for destruction of condemned, enjoined, detained, or recalled articles. The Commissioner finds that existing Federal, State, and local regulation of air and water pollution does not eliminate the independent statutory obligation of the FDA under NEPA to consider all relevant environmental factors in performing its regulatory activities. The Commissioner concludes that, to fulfill its responsibilities under the National Environmental Policy Act, the FDA must require the submission of environmental data and information on the discharge of pollutants in the manufacture of any drug, food additive or color additive it reviews for marketing and in the destruction of all articles removed from the market as a result of legal action it initiates. Once a description of the pollutants expected to be discharged is included, a statement of other applicable Federal, State, and local requirements, and information showing that they are satisfied, will ordinarily be sufficient for this aspect of the environmental impact analysis report.

F. *Destruction of perishable articles.* One comment expressed concern that perishable articles condemned, enjoined, detained, or recalled might create an environmental and health hazard while awaiting environmental impact consideration prior to destruction. Section 6.3 (c) of the regulation permits immediate destruction of such articles without environmental impact statement consideration in order to protect the public health.

G. *Direct solicitation of comments from Federal agencies.* The Environmental Protection Agency proposed that comments on draft environmental impact statements be directly solicited from those Federal agencies concerned with the substance of the statements by reason of jurisdiction by law or special expertise to insure maximum input to the agency's environmental statement review process pursuant to the NEPA guidelines of the Council on Environmental Quality. The Commissioner concurs with this proposal, and provision for direct solicitation is therefore included in § 6.3(a)(3).

H. *Investigational new drugs.* The Environmental Protection Agency questioned the exemption afforded investigational new drugs from environmental impact statement consideration in § 6.1 (d)(5) of the proposal. Since an investigational new drug is not permitted to be commercially marketed, the Commissioner concludes that allowing limited investigation in most instances is not a major action and does not significantly affect the quality of the human environment. In those instances where an environmental impact statement may be required, the applicant will be so notified and § 6.1(d)(5) is amended to so provide.

I. *Additional changes.* In addition to the amendments adopted on the basis of comments received, the Commissioner concludes that additional amendments be made to the regulation, as follows:

1. All provisions of the proposal governing hazardous substances are deleted since jurisdiction for such substances is being transferred from FDA to the Consumer Product Safety Commission.

2. Sections 6.1(e) and 6.1(g) are amended to delete the provision requiring that an applicant in its environmental impact analysis report analyze whether the proposed action is a major Federal action significantly affecting the quality of the human environment. The National Environmental Policy Act requires the FDA to make this determination, and in any event an applicant may comment on this issue in an environ-

mental impact analysis report if he wishes to do so.

3. Section 6.3(b) of the proposal is amended to reflect the Commissioner's conclusion that environmental consideration of condemned, enjoined, or recalled articles and disposition of laboratory waste materials should be undertaken on a case-by-case basis and that the disposal methods considered be consistent with Federal, State, and local regulations to safeguard the human environment and the public health.

4. The provision for public hearings on final environmental impact statements in § 6.3(a)(6) is deleted from the final order since they are not required by NEPA or by the Council on Environmental Quality.

Therefore, having considered the comments received and other relevant material, the Commissioner concludes that the proposal, with changes, should be adopted as set forth below. Accordingly, pursuant to the National Environmental Policy Act of 1969 (sec. 102(2)(C), 83 Stat. 853; 42 U.S.C. 4332), and pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 505, 507, 512, 701, 706, 52 Stat. 1052 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 59 Stat. 468 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–404 as amended, 82 Stat. 343–351; 21 U.S.C. 348, 355, 357, 360b, 371, 376), and under authority delegated to the Commissioner (21 CFR 2.120), title 21, Chapter I is amended:

1. By adding a new Part 6 as follows:

PART 6—ENVIRONMENTAL IMPACT CONSIDERATIONS

Sec.
6.1 Applicability.
6.2 Content and format of environmental impact statements.
6.3 Preparation and review procedures.
6.4 Responsible agency officials.
6.5 Submission of comments to other agencies.
6.6 Public availability of environmental impact statements.

AUTHORITY: Sec. 701, 52 Stat. 1055–56 as amended by 70 Stat. 919 and 72 Stat. 948, 21 U.S.C. 371; sec. 10, 74 Stat. 378, 15 U.S.C. 1269; sec. 102(2)(C), 83 Stat. 853, 42 U.S.C. 4332; the Guidelines issued by the Council on Environmental Quality (36 FR 7724); Executive Order 11514 of March 4, 1970 (35 FR 4247).

§ 6.1 Applicability.

(a) (1) An environmental impact statement shall be prepared, circulated, and filed pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 for every major agency action that significantly affects the quality of the human environment.

(2) Agency decisions shall include a careful consideration of all environmental effects of proposed actions.

(b) The need for preparing an environmental impact statement shall be considered for the following agency actions pursuant to environmental criteria established by the agency and the department:

(1) Recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved;

(2) Destruction of articles condemned after seizure or enjoined;

(3) Destruction of articles following detention or recall at agency request;

(4) Disposition of Food and Drug Administration laboratory waste materials;

(5) Issuance of licenses for biological products;

(6) Establishment by regulation of labeling or other requirements for marketing articles;

(7) Establishment by regulation of standards for articles (except food standards);

(8) Approval of new drug and abbreviated new drug applications and old drug monographs;

(9) Approval of new animal drug and abbreviated new animal drug aplications and old animal drug monographs;

(10) Approval of antibiotic drug monographs;

(11) Approval of food additive petitions;

(12) Approval of color additive petitions; and

(13) Policy, regulations, and procedure making which significantly affect the quality of the human environment.

(c) An environmental impact statement will not be required for amendments to existing regulations and approvals of supplements to existing approvals unless the change is substantial.

(d) The agency has carefully considered the environmental effects of the following types of actions and has concluded that since they are not major agency actions significantly affecting the quality of the human environment, environmental impact statements are not required for them:

(1) Recommendations for court action concerning foods, drugs, devices, cosmetics, and electronic products;

(2) Factory inspections;

(3) Seafood inspections;

(4) Issuance or amendment of food standards; and

(5) Investigational new drug applications and investigational new animal drug applications, unless the agency notifies the applicant that one is required.

(e) Whenever a person submits any application or petition requesting action by the agency (except action specified in paragraph (d) of this section), he shall include an environmental impact analysis report on the requested action. Failure to include an adequate environmental impact analysis report in an application or petition shall be sufficient grounds to refuse to accept or file the application or petition.

(f) Whenever a manufacturer, distributor, or dealer proposes to destroy a food, drug, cosmetic, device, or electronic product which has been condemned, enjoined, detained, or banned by regulation, he shall submit to the agency an environmental impact analysis report analyzing the environmental impact of the disposition of such articles.

(g) An environmental impact analysis report shall be submitted to the agency in the following format:

ENVIRONMENTAL IMPACT ANALYSIS REPORT

Date: _____
Name of applicant: _____
Address: _____

1. Describe the proposed action: _____

2. Discuss the probable impact of the action on the environment (including primary and secondary consequences): _____

3. Discuss the probable adverse environmental effects which cannot be avoided: _____

4. Evaluate alternatives to the proposed action: _____

5. Describe the relationship between local short-term uses of the environment with respect to the proposed action and the maintenance and enhancement of long-term productivity: _____

6. Describe any irreversible and irretrievable commitment of resources which would be involved in the proposed action should it be implemented: _____

7. Discuss the objections raised by other agencies, organizations, or individuals which are known to the applicant: _____

8. If proposed action should be taken prior to 90 days from the circulation of a draft environmental impact statement or 30 days from the filing of a final environmental impact statement, explain why: _____

9. Analyze whether the benefit to the public of the proposed action will outweigh the action's potential risks to the environment: _____

_____ (Date)

_____ (Signature of responsible official)

(h) Data and information which constitute trade secrets or confidential information under Part 4 of this chapter shall not be submitted in an environmental impact analysis report.

(i) Upon receipt of an environmental impact analysis report, the responsible agency official shall make an independent assessment as to whether an environmental impact statement shall be prepared for the proposed action.

§ 6.2 Content and format of environmental impact statements.

(a) When it is determined that an environmental impact statement is required, draft and final environmental impact statements shall cover the following points:

(1) There shall be a description of the proposed action including adequate information and technical data to permit a careful assessment of the environmental impact. Where relevant, exhibits should be provided.

(2) The probable impact that the proposed action will have on the environ-

ment shall be analyzed and shall include the impact on ecological systems such as wildlife, fish, and other marine life. Both primary and secondary significant consequences for the environment should be included in the analysis.

(3) There shall be a description of any probable adverse environmental effects which cannot be avoided (such as water or air pollution, undesirable land use patterns, damage to life systems, threats to health, or other consequences adverse to the environmental goals set forth in section 101(b) of the National Environmental Policy Act).

(4) Alternatives to the proposed action must be described, in accordance with section 102(2)(D) of the National Environmental Policy Act, which requires the responsible agency to "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." A rigorous exploration and objective assessment of alternative actions that might avoid some or all of the adverse environmental effects is essential. Sufficient analysis of alternatives and their costs and impact on the environment should accompany the proposed action through the agency review process in order to avoid eliminating prematurely options which might have fewer adverse environmental effects.

(5) The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity must be discussed. Thus, realizing that each generation is trustee of the environment for succeeding generations, the agency must assess the action for cumulative and long-term effects.

(6) There must be a statement concerning any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented. This requires the agency to identify the extent to which the action curtails the range of beneficial uses of the environment.

(7) Where appropriate, there must be a discussion of the problems and objections raised by other Federal, State, and local agencies and by private organizations and individuals, and a disposition of the issues raised by these problems and objections. This section may be added at the end of the review process in the final text of the environmental statement.

(b) When it is determined that an environmental impact statement is required, draft and final environmental impact statements shall be prepared in the following format:

("DRAFT" OR "FINAL") ENVIRONMENTAL IMPACT STATEMENT, FOOD AND DRUG ADMINISTRATION (RESPONSIBLE OPERATING DIVISION)

1. Indicate administrative action or legislative action.

2. Describe the action, indicating any States or counties particularly affected.

3. Analyze the environmental impact of the proposed action.

4. Describe any unavoidable adverse environmental effects of the action.

5. Describe and assess alternative courses of action considered.

6. Describe any irreversible and irretrievable commitments of resources involved in implementing the action.

7. Where appropriate, evaluate any objections to the action raised by interested persons.

8. (a) For draft statements, state the date and form of FEDERAL REGISTER publication by which comments have been requested from all interested persons and attach a copy of the notice.

(b) For final statements, list all persons from which written comments have been received and attach a copy of each.

9. Give the date that the draft or final statement was made available to the Council on Environmental Quality and to the public.

§ 6.3 Preparation and review procedures.

(a) When it is determined that an environmental impact statement is required, the statement shall be prepared as follows:

(1) *Preparation of draft environmental impact statement.* A draft environmental impact statement shall be prepared by the responsible agency official as designated in § 6.4. When appropriate during the preparation of a draft environmental impact statement, the responsible agency official shall consult with Federal, State, and local officials and other interested persons.

(2) *Distribution of draft environmental impact statements.* After the responsible agency official has prepared a draft environmental impact statement, he shall forward 20 copies of the draft statement to the Office of the Secretary which shall thereupon forward 10 copies to the Council on Environmental Quality. At the same time the draft statement will be made available for public inspection by the Office of the Assistant Commissioner for Public Affairs and the Hearing Clerk.

(3) *Solicitation of comments.* (i) After the preparation and distribution of a draft environmental impact statement, comments will be solicited from all interested persons. Sixty days are allowed for reply, after which it is presumed that no comments will be made unless a specified extension of time is requested.

(ii) Where the subject of a draft environmental impact statement is also the subject of a notice of proposed rule making or a notice of filing published in the FEDERAL REGISTER, the FEDERAL REGISTER notice shall state that the environmental impact analysis report and the draft environmental impact statement are available upon request and shall solicit comments by all interested persons.

(iii) Where the subject of a draft environmental impact statement is not also the subject of a notice published in the FEDERAL REGISTER, a notice will be published in the FEDERAL REGISTER describing the proposed action, stating that the environmental impact analysis report and the draft environmental impact statement are available upon request, and soliciting comments by all interested persons. This notice may be published by the agency or the department, or the agency or the department may request that the Council on Environmental Quality publish it.

(iv) Comments shall be solicited from Federal agencies having jurisdiction by law or special expertise with respect to the environmental impact of a proposed action by sending them a copy of a draft environmental impact statement.

(v) All comments on draft environmental impact statements shall be submitted in quintuplicate to the Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 6—88, 5600 Fishers Lane, Rockville, MD 20852, where they shall be available for public inspection during working hours, Monday through Friday.

(vi) When the responsible agency official concludes that no environmental impact statement is necessary and the proposed action is the subject of a notice of proposed rule making or a notice of filing published in the FEDERAL REGISTER, the FEDERAL REGISTER notice shall state that no environmental impact statement is necessary and, where applicable, that the environmental impact analysis report is available upon request.

(4) *Time for consideration prior to decision.* Draft environmental impact statements shall be prepared, forwarded to the Council on Environmental Quality, and made available to the public early enough in the consideration of the proposed action to permit meaningful review of the environmental issues involved. To the maximum extent practicable, no final action shall be taken on the proposal earlier than 90 days after a draft environmental impact statement has been prepared, forwarded to the Council, and made available to the public.

(5) *Final environmental impact statements.* The final text of an environmental impact statement shall be prepared by the responsible agency official after comments on the draft statement have been reviewed and shall include an evaluation of all comments. The final statement shall receive full consideration in the agency's decisionmaking process. The responsible agency official shall forward 20 copies of the final statement to the Office of the Secretary which shall thereupon forward 10 copies to the Council on Environmental Quality, and copies of the final statement shall be made available for public inspection by the Office of the Assistant Commissioner for Public Affairs and the Hearing Clerk. To the maximum extent practicable, no agency action shall take place earlier than 30 days after the final statement has been forwarded to the Council on Environmental Quality and made available to the public.

(6) Where the subject of an environmental impact statement is an agency action governed by specific time requirements under statute or regulation, every effort shall be made to comply with the provisions of this part within the time specified, and those time requirements shall be extended only as long as is absolutely necessary to permit the agency

to consider or issue an environmental impact statement of the action.

(b) When the proposed action involves destruction of condemned, enjoined, detained or recalled articles or disposition of Food and Drug Administration laboratory waste materials, the agency shall adhere to disposal guidelines consistent with Federal, State, and local regulations applicable on a case-by-case basis. This shall be reflected in environmental impact statements when they are issued on such actions.

(c) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of paragraph (a) (1) through (5) of this section impracticable. Compliance with the requirements for environmental analysis under the National Environmental Policy Act is impossible in instances which require immediate regulatory action to safeguard the public health. The responsible agency official shall give written notice to the Council on Environmental Quality of those actions having potentially significant individual environmental impact as to which no environmental impact statement is filed because public health considerations require immediate action.

§ 6.4 Responsible agency officials.

(a) When environmental impact statements are required, the following agency officials are responsible for preparing the statements as indicated:

(1) The office of the Commissioner is responsible for preparing a draft or final environmental impact statement on actions not delegated by the Commissioner.

(2) The director of each bureau is responsible for preparing a draft or final environmental impact statement on actions delegated to that bureau by the Commissioner under § 2.121 of this chapter.

(3) The Executive Director for Regional Operations is responsible for preparing a draft or final environmental impact statement on the destruction of articles condemned after seizure, enjoined, under import detention, or under detention or recalled at agency request.

(b) Every action memorandum proposing an agency action included under § 6.1(b) shall contain an evaluation of the environmental impact of the proposed action and shall be accompanied by a draft or final environmental impact statement if one is required.

§ 6.5 Submission of comments to other agencies.

When the Food and Drug Administration is requested by the Office of the Secretary to comment on environmental impact statements prepared by other agencies, the Commissioner shall prepare such comments as he deems appropriate and shall submit them to the Office of the Secretary, which shall prepare an appropriate response for submission to the requesting agency and the Council on Environmental Quality.

§ 6.6 Public availability of environmental impact statements.

(a) All draft and final environmental impact statements and all environmental impact analysis reports shall be available for public inspection through the office of the Assistant Commissioner for Public Affairs and the Hearing Clerk.

(b) Draft and final environmental impact statements will be available immediately after preparation. An environmental impact analysis report will be available at the time a draft environmental impact statement is circulated or, if no environmental impact statement is necessary, at the time of publication of the FEDERAL REGISTER notice announcing the availability of the report.

PART 8—COLOR ADDITIVES

2. In Part 8, by adding a new item J to the form in § 8.4(c), as follows:

§ 8.4 Petitions proposing regulations for color additives.

* * * * *

(c) * * *

J. The petitioner is required to submit an environmental impact analysis report analyzing the manufacturing process and the ultimate use or consumption of the color additive pursuant to § 6.1 of this chapter.

* * * * *

PART 121—FOOD ADDITIVES

3. In Part 121:

a. By adding a new item H to the form in § 121.51(c), as follows:

§ 121.51 Petitions proposing regulations for food additives.

* * * * *

(c) * * *

H. The petitioner is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the food additive pursuant to § 6.1 of this chapter.

* * * * *

b. By adding the following sentence to § 121.53:

§ 121.53 Substantive amendments to petitions.

* * * Where the substantive amendment proposes a substantial change to the petition which may affect the quality of the human environment, the petitioner is required to submit an environmental impact analysis report pursuant to § 6.1 of this chapter.

PART 130—NEW DRUGS

4. In Part 130:

a. By adding a new item 15 to the form in § 130.3(a)(2), as follows:

§ 130.3 New drugs for investigational use in human beings; exemptions from section 505(a).

(a) * * *

(2) * * *

15. When requested by the agency, an environmental impact analysis report pursuant to § 6.1 of this chapter.

* * * * *

b. Section 130.4 is amended by adding a new item 15 to the form in paragraph (c)(2), and by redesignating paragraph (f)(6) as paragraph (f)(7) and adding a new paragraph (f)(6) as follows:

§ 130.4 Applications.

* * * * *

(c) * * *

(2) * * *

15. The applicant is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

* * * * *

(f) *Abbreviated new drug applications.* * * *

(6) An environmental impact analysis report analyzing the environmental impact of the manufacturing process and ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

* * * * *

c. By adding a new subparagraph (8) to § 130.5(d), as follows:

§ 130.5 Reasons for refusing to file applications.

(d) * * *

(8) The applicant fails to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

* * * * *

d. By adding the following sentence to the end of § 130.9(a)(1):

§ 130.9 Supplemental applications.

(a)(1) * * * A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 6.1 of this chapter.

* * * * *

e. By adding a new subparagraph (7) to § 130.12(a), as follows:

§ 130.12 Refusal to approve the application.

(a) * * *

(7) The applicant fails to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

* * * * *

PART 135—NEW ANIMAL DRUGS

5. In Part 135:

a. By adding a new subparagraph (10) to § 135.3(b), as follows:

§ 135.3 New animal drugs for investigational use; exemptions from section 512(a) of the Act.

* * * * *

(b) * * *

(10) When requested by the agency, the sponsor shall submit an environmental impact analysis report pursuant to § 6.1 of this chapter.

* * * * *

b. In § 135.4a(b), by redesignating subparagraph (13) *Assembling and binding the application* as subparagraph (15) and adding a new subparagraph (14) as follows (a new subparagraph (13) has recently been proposed):

§ 135.4a New animal drug applications.

* * * * *

(b) * * *

(14) *Environmental impact analysis report.* The applicant is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the new animal drug pursuant to § 6.1 of this chapter.

* * * * *

c. By adding a new subparagraph (9) to § 135.12(a), as follows:

§ 135.12 Refusal to approve an application.

(a) * * *

(9) The applicant fails to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the new animal drug pursuant to § 6.1 of this chapter.

* * * * *

d. By adding the following sentence to § 135.13a(a)(1):

§ 135.13a Supplemental new animal drug applications.

(a)(1) * * * A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 6.1 of this chapter.

* * * * *

e. By adding a new paragraph (d) to § 135.13b, as follows:

§ 135.13b Supplemental applications for animal feeds bearing or containing new animal drugs.

* * * * *

(d) A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 6.1 of this chapter.

PART 146—ANTIBIOTIC DRUGS; PROCEDURAL AND INTERPRETATIVE REGULATIONS

6. In Part 146, by adding a new paragraph (i) to § 146.10, as follows:

§ 146.10 New antibiotic and antibiotic-containing products.

* * * * *

(i) An environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the antibiotic drug pursuant to § 6.1 of this chapter.

Effective date. This order shall become effective on March 15, 1973.

(Sec. 102(a)(2)(C), 83 Stat. 853; 42 U.S.C. 4332; secs. 409, 505, 507, 512, 701, 706, 52 Stat. 1052 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 59 Stat. 468 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–404 as amended, 82 Stat. 343–351; 21 U.S.C. 348, 355, 360b, 371, 376)

Dated: March 12, 1973.

SHERWIN GARDNER,
Deputy Commissioner of Food and Drugs.

[FR Doc.73-5008 Filed 3-14-73;8:45 am]

PART 8—COLOR ADDITIVES

Subpart—Provisional Regulations

POSTPONEMENT OF CLOSING DATES OF PROVISIONAL LISTING

Pursuant to the provisions of title II of the Color Additive Amendments of 1960 (sec. 203(a)(2), Public Law 86-618, 74 Stat. 404; 21 U.S.C. 376, note) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs is authorized to postpone the closing date of a provisional listing of a color additive on his own initiative or upon application of an interested person. He is also authorized to promulgate and keep current a list or lists of the color additives and of the particular uses thereof, whenever in his judgment such action is consistent with the protection of the public health.

Requests have been received to postpone the closing dates of provisional listings of the color additives in § 8.501 of the color additive regulations. For those color additives listed in paragraphs (a) and (b) of § 8.501 where the uses in products such as foods, drugs, and lipsticks involve ingestion, reports on teratological potentials have been submitted to the Food and Drug Administration, in accordance with the provisions of the notice published in the FEDERAL REGISTER of September 11, 1971 (36 FR 18336).

A notice was published in the FEDERAL REGISTER of January 31, 1973 (38 FR 2996), to clarify the status of metallic salts and vegetable substances when used as color components in hair dye. The notice stated that it was the intention of the Food and Drug Administration to provisionally list, on an interim basis, metallic salts and vegetable substances for use as color components in hair dye. Any such substances will be removed from the provisional list, and thus disapproved for any further use, unless the requirements of that notice are satisfied.

In addition, requests have been received to restore the color additives, D&C Brown No. 1 and External D&C Violet No. 2, for use in coloring externally applied cosmetics, to the provisional list. These color additives previously had been provisionally listed for use in externally applied drugs and cosmetics. The closing dates of the provisional listing were terminated because the sponsor no longer had any commercial interest in these color additives. Subsequently, petitions were received from other interested persons, who had also been using the colors and conducting tests, to permanently list each of these color additives for use in externally applied cosmetics, and to restore them to the provisional list pending the processing of these petitions. In the light of their previous provisional listing and the continuing scientific investigations, the Commissioner concludes that these colors should be restored to the provisional list.

The Commissioner of Food and Drugs finds that postponement of the closing date of the currently provisionally listed color additives is consistent with the protection of the public health and with the objective of carrying to completion the scientific investigations, including multigeneration reproduction studies and stability testings, and regulatory review thereof, necessary for making a determination as to the listing of such color additives, or specified uses thereof, under section 706 of the act. These extensions are granted on condition, that, where applicable, progress reports on the respective multigeneration reproduction studies shall be received on or before July 1, 1973, by the Food and Drug Administration.

The Commissioner of Food and Drugs also finds that the provisional listing of metallic salts and vegetable substances for use as color components in hair dye, and the restoring to the provisional list of D&C Brown No. 1 and External D&C Violet No. 2 are consistent with the protection of the public health.

Therefore, pursuant to authority of the Federal Food, Drug, and Cosmetic Act (sec. 203(a)(2) and (d)(1), Public Law 86-618; 74 Stat. 404-405; 21 U.S.C. 376, note) and under authority delegated to the Commissioner (21 CFR 2.120), Part 8 of the color additive regulations is amended as follows:

1. The closing dates for the color additives listed in paragraphs (a), (b), (c), (e), (f), and (g) of § 8.501 of the color additive regulations are changed to read: "December 31, 1973, or until a new closing date is established".

2. Paragraph (b) is further amended by inserting therein the following item:

	Closing date	*Restrictions*
* * *	* * *	* * *
D&C Brown No. 1.	Dec. 31, 1973, or until a new closing date is established.	For coloring externally-applied cosmetics.
* * *	* * *	* * *

3. Paragraph (c) is further amended by inserting the following item:

	Closing date	*Restrictions*
* * *	* * *	* * *
External D&C Violet No. 2.	Dec. 31, 1973, or until a new closing date is established.	For coloring externally-applied cosmetics.
* * *	* * *	* * *

4. Paragraph (g) is further amended by inserting therein an alphabetical order the following items:

	Closing date	Restrictions
• • •	• • •	• • •
Metallic salts...	Dec. 31, 1973, or until a new closing date is established.	For use as color components in hair dye.
• • •	• • •	• • •
Vegetable substances.	Dec. 31, 1973, or until a new closing date is established.	For use as color components in hair dye.
• • •	• • •	• • •

Notice and public procedure and delayed effective date are not prerequisites to the promulgation of this order, since section 203(a)(2) of Public Law 86-618 provides for this issuance.

Effective date. This order is effective as of January 1, 1973.

(Sec. 203(a)(2) and (d)(1), Public Law 86-618; 74 Stat. 404-405; 21 U.S.C. 376, note)

Dated: March 12, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.73-5009 Filed 3-14-73;8:45 am]

[DESI 11048]

PART 148i—NEOMYCIN SULFATE

Antiperspirants and Deodorants; Postponement of Effective Date of Final Order

An order was published in the FEDERAL REGISTER of December 5, 1972 (37 FR 25820), to become effective in 40 days, amending Part 148i of the antibiotic drug regulations to repeal provisions for certification of antiperspirants and deodorants for topical use containing aluminum chlorohydroxide complex in combination with neomycin sulfate.

Having received objections and a request for a hearing, the Commissioner of Food and Drugs concludes that the effective date of the order should be postponed to allow time for completion of review of the objections and the material submitted. When this review is completed, the Commissioner will announce in the FEDERAL REGISTER whether or not requests for hearing with reasonable grounds have been received. Therefore, the effective date of the order of December 5, 1972 (37 FR 25820), is hereby postponed pending said review.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended, 21 U.S.C. 352, 357) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: March 12, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.73-5134 Filed 3-14-73;10:17 am]