hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are legally sufficient to justify the relief sought.

The Office of Management and Budget (OMB) has exempted this regulation from the OMB requirements of Executive Order 12291 pursuant to section 8(b) of that Order.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164 (5 U.S.C. 601–612)), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from the tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

(Sec. 408(c), 72 Stat. 1786 (21 U.S.C. 346(c))

List of Subjects in 21 CFR Parts 193 and 561

Food additives, Feed additives, Pesticides and pests.

Dated: May 16, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 193—[AMENDED]

1. In Part 193:

a. The authority citation for Part 193 continues to read as follows:

Authority: 21 U.S.C. 348.

b. In § 193.98, paragraph (c) is added to read as follows:

§ 193.98 Cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate.

* * * * *

(c) A tolerance of 0.05 ppm is established for residues of the insecticide cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate in food commodities exposed to the insecticide during treatment of food-handling establishments where food and food products are held, processed, prepared, or served. Treatments may be made by general surface, spot, and/or crack and crevice applications.

(1) General surface treatments shall be limited to a maximum of 3.8 grams of active ingredient per 1,000 square feet, applying to walls, floors, and ceilings with a low-pressure system. Cover or remove all food processing and/or handling equipment during application. Do not apply directly to food products. Reapplications may be made at 10-day intervals.

(2) Crack and crevice or spot treatments shall be limited to a maximum of 0.1 percent of the active ingredient by weight, applied with a low-pressure system with a pinpoint or variable pattern nozzle. Cover exposed food or remove from premises. Do not apply directly to food. Reapplications may be made at 10-day intervals.

(3) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by the Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

PART 561—[AMENDED]

2. In Part 561:

a. The authority citation for Part 561 continues to read as follows:

Authority: 21 U.S.C. 348.

b. In § 561.96, new paragraph (c) is added, to read as follows:

§ 561.96 Cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate.

* * * * *

(c) A tolerance of 0.05 part per million is established for residues of the insecticide cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate in feed commodities exposed to the insecticide during treatment of feed-handling establishments where feed and feed products are held, processed, prepared, or served. Treatments may be made by general surface, spot, and/or crack and crevice applications.

(1) General surface treatments shall be limited to a maximum of 3.8 grams of active ingredient per 1,000 square feet, applying to walls, floors, and ceilings with a low-pressure system. Cover or remove all feed processing and/or handling equipment during application. Do not apply directly to feed products. Reapplications may be made at 10-day intervals.

(2) Crack and crevice or spot treatments shall be limited to a maximum of 0.1 percent of the active ingredient by weight, applied with a low-pressure system with a pinpoint or variable pattern nozzle. Cover exposed food or remove from premises. Do not apply directly to feed. Reapplications may be made at 10-day intervals.

(3) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by EPA, and it shall be used in accordance with such label and labeling.

[FR Doc. 88–11571 Filed 5–24–88; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333 and 444

[Docket No. 83N–0096]

Antibiotic Drug Products; Updating and Technical Changes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the monograph in 21 CFR Part 333 that establishes conditions under which over-the-counter (OTC) first aid antibiotic drug products are generally recognized as safe and effective and not misbranded. FDA is concurrently amending the antibiotic regulations in 21 CFR Part 444 to be consistent with the monograph for OTC first aid antibiotic drug products. These amendments involve noncontroversial technical changes to clarify that neomycin sulfate as a single ingredient in a cream base is included in the final monograph and in 21 CFR 444.542b.

DATES: 21 CFR 333.110(e) and 333.120(a)(10) are effective December 12, 1988. 21 CFR 444.542b(a)(1) and (2) are effective May 25, 1988; comments on the amendment to 21 CFR 333.110 and 333.120 by June 24, 1988; comments, notice of participation, and request for hearing on the amendment to 21 CFR 444.542b by June 24, 1988; data, information, and analyses to justify a hearing on the amendment to 21 CFR 444.542b by July 25, 1988.

ADDRESS: Written comments, notice of participation, requests for hearing, data, information, and analyses to justify a hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: This document revises the final monograph for OTC first aid antibiotic drug products in 21 CFR Part 333 (December

11, 1987; 52 FR 47312) and the regulations for antibiotic drug products in 21 CFR Part 444. The final monograph for OTC first aid antibiotic drug products does not specifically list single ingredient neomycin sulfate cream products nor do the oligosaccharide antibiotic drug regulations in 21 CFR Part 444. The agency had intended that both regulations include single ingredient neomycin sulfate in a cream base. Accordingly, the amendments set forth in this document clarify that neomycin sulfate in a cream base is acceptable in OTC first aid antibiotic drug products. In addition, the amendment revises the labeling in § 444.542b(a)(2) to provide for single ingredient neomycin sulfate cream products and revises the OTC first aid antibiotic monograph in § 333.120(a)(10) to more clearly state that the only other neomycin sulfate cream formulation in the monograph must also meet certain requirements for tests, methods of assay, and potency.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

These amendments institute changes that are of a minor substantive nature. Because the amendments are not controversial and because, when effective, they provide clarification of the final monograph for OTC first aid antibiotic drug products and the antibiotic regulations in 21 CFR Part 444, FDA finds that notice, public procedure, and delayed effective date are unnecessary and not in the public interest. However, for consistency with the effective date for the final monograph for OTC first aid antibiotic drug products (21 CFR Part 333), the amendments to § 333.110 and § 333.120 will become effective on December 12, 1988. The amendment to 21 CFR 444.542b will become effective on May 25, 1988. However, interested persons may, on or before June 24, 1988, submit written comments on the amendment to 21 CFR Part 333 to the Dockets Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy. Regarding the amendment to 21 CFR Part 444, interested persons may, on or before June 24, 1988, submit written comments to the Dockets Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by the amendment to 21 CFR Part 444 may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 24, 1988, a written notice of participation and request for hearing, and (2) on or before July 25, 1988, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. 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 hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order, and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 333

First aid antibiotic drug products, over-the-counter drugs.

21 CFR Part 444

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 333 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 333.110 is amended by redesignating paragraph (e) as paragraph (f) and by adding new paragraph (e) to read as follows:

§ 333.110 First aid antibiotic active ingredients.

* * * * *

(e) Neomycin sulfate cream containing, in each gram, 3.5 milligrams of neomycin in a suitable cream base: *Provided,* that it meets the tests and methods of assay in § 444.542b(b).

* * * * *

3. Section 333.120 is amended by revising paragraph (a)(10) to read as follows:

§ 333.120 Permitted combinations of active ingredients.

* * * * *

(a) * * *

(10) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin and 10,000 units of polymyxin B in a suitable vehicle: *Provided,* that it meets the tests, methods of assay, and potency in § 444.5421(b).

* * * * *

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

4. The authority citation for 21 CFR Part 444 continues to read as follows:

Authority: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357); 21 CFR 5.10.

5. Section 444.542b is amended by revising the section heading, the introductory text of paragraph (a)(1), and paragraph (a)(2), to read as follows:

§ 444.542b Neomycin sulfate cream; neomycin sulfate-cream (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Neomycin sulfate cream contains, in each gram, 3.5 milligrams of neomycin in a suitable cream base, with or without one or more suitable and harmless emollients, perfumes, dispersants, and preservatives. The following other drugs may be combined

with neomycin sulfate cream in the indicated amounts per gram:

* * * *

(2) *Labeling.* If it contains a corticosteroid, it shall be labeled in accordance with the requirements prescribed by § 432.5 of this chapter, and its expiration date is 12 months. If it does not contain a corticosteriod, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that is 12 months after the month during which the batch was certified.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

* * * * *

Dated: May 17, 1988.

George R. White,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-11716 Filed 5-24-88; 8:45 am]

BILLING CODE 4160-01-M

EPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 26, 26A, and 602

[T.D. 8187]

Estate and Gift Taxes; Effective Date; Rules and Return Requirements; Relating to the Generation-Skipping Transfer Tax; and OMB Control Numbers Under the Paperwork Reduction Act; Corrections

AGENCY: Internal Revenue Service, Treasury.

ACTION: Corrections to temporary regulations.

SUMMARY: This document contains corrections to Treasury Decision 8187, which was published in the **Federal Register** for Tuesday, March 15, 1988 (53 FR 8441). T.D. 8187 issued temporary regulations relating to the effective date provisions, return requirements, and certain special rules for the tax on generation-skipping transfers. This action was necessary because of changes to the applicable tax law made by the Tax Reform Act of 1986. These regulations affect all persons making or receiving a generation-skipping transfer.

FOR FURTHER INFORMATION CONTACT: Maurice B. Foley, 202-566-4336 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of these corrections relate to generation-skipping transfer taxes under Chapter 3 of the Internal Revenue Code of 1986, as added by section 1431 of the Tax Reform Act of 1986, concerning the effective date, return requirements, and certain special rules.

Need For Corrections

As published, Treasury Decision 8187 contains a number of errors that, if not corrected, would cause confusion to taxpayers and practitioners.

Corrections of Publication

Accordingly, the publication of temporary regulations (T.D. 8187), which was the subject of FR Doc. 88-5502, is corrected as follows:

PART 26—[AMENDED]

§ 26.2600-1 [Corrected]

Paragraph 1. In § 26.2600-1(b), under the heading of Table of contents, page 8443, second column, in d. 2. ii., the language "25, 1985, and before January 1, 1987." should be removed and the language "25, 1985, and before January 1, 1988." added in its place.

§ 26.2601-1 [Amended]

Par. 2. In § 26.2601-1(b)(1)(v)(A), page 8445, first column, the sixth line of the paragraph headed "Constructive additions", the language "that portion of the trust, the value of the" should be removed and the language "that portion of the trust, and the release, exercise or lapse is treated to any extent as a taxable transfer under Chapter 11 or Chapter 12, the value of the" added in its place.

Par. 3. In § 26.2601-1(b)(1)(vi), page 8446, second column the third line of the paragraph headed "Appreciation and income", the language "paragraphs (b)(2)(i) and (ii) of this" should be removed and the language "paragraphs (b)(iv) and (v) of this" added in its place.

Par. 4. In § 26.2601-1(b)(2)(v), page 8446, third column, fourteenth line of the paragraph headed "Additions to revocable trusts", the language "§ 26.2601-1(b)(1)(V)(B) for rules" should be removed and the language "26.2601-1(b)(1)(V)(B) for rules" added in its place.

Par. 5. In § 26.2601-1(b)(2)(vi), Example (6), page 8447, first column, seventh line of the example, the language "C (none of whom were skip persons) in equal" should be removed and the language "C in equal" added in its place.

Par. 6. In § 26.2601-1(b)(3)(v), page 8447, third column, the twelfth line of paragraph (v), the language "transfer. See paragraph (b)(3)(i) of this" should be removed and the language "transfer. See paragraph (b)(2)(iv) of this" added in its place.

Par. 7 In § 26.2662-1(d)(2)(i), page 8450, third column, last line of paragraph (d)(2)(i), the language "or before May 2, 1988." should be removed and the language "or before June 13, 1988." added in its place.

Donald E. Osteen,

Director, Legislation and Regulations Division.

[FR Doc. 88-11718 Filed 5-24-88; 8:45 am]

BILLING CODE 4830-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 167

[OPP-250079; FRL-3383-7]

Notification to the Secretary of Agriculture of a Final Regulation on the Registration of Pesticide and Active Ingredient Producing Establishments and Submission of Pesticide Reports

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification to the Secretary of Agriculture.

SUMMARY: Notice is given that the Administrator of EPA has forwarded to the Secretary of the U.S. Department of Agriculture a final regulation that requires producers of pesticide active ingredients to register their establishments and submit reports to EPA. This action is required by section 25(a)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: David Hannemann, Office of Compliance Monitoring (EN-342), Environmental Protection Agency, Rm. E-701, 401 M Street SW., Washington, DC 20460, (202-382-7825).

SUPPLEMENTARY INFORMATION: Section 25(a)(2)(B) of FIFRA provides that the Administrator shall provide the Secretary of Agriculture with a copy of any final regulation at least 30 days prior to signing it for publication in the **Federal Register.** If the Secretary comments in writing regarding the final regulation within 15 days after receiving