**ADDRESS:** Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of September 3, 1987 (52 FR 33472), FDA announced that a food additive petition (FAP 7B4011) had been filed by Ferro Corp., 7050 Krick Rd., Bedford, OH 44146. The firm's petition proposed that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the additional safe use of 2,4-di-*tert*-butylphenyl-3,5-di-*tert*-butyl-4-hydroxybenzoate as a light stabilizer for olefin copolymers complying with § 177.1520(c), items 3.1 and 3.2.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed increased use of the food additive is safe, and that 21 CFR 178.2010(b) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 8, 1989, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 178**

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 178 is amended as follows:

## PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

**Authority:** Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.2010 is amended in the table of paragraph (b) by revising the spelling of the entry "2,4-Di-*tert*-butylphenyl 3,5-di-*tert*-butyl-4-hydroxybenzoate" (CAS Reg. No. 4221–80–1) to read "2,4-Di-*tert*-butylphenyl-3,5-di-*tert*-butyl-4-hydroxybenzoate (CAS Reg. No. 4221–80–1)", and by revising item 2 under the heading "Limitations" for that entry to read as follows:

**§ 178.2010 Antioxidants and/or stabilizers for polymers.**

* * * * *

(b) * * *

| Substances | Limitations |
|---|---|
| * * * * * | |
| 2,4-Di-*tert*-butylphenyl-3,5-di-*tert*-butyl-4-hydroxybenzoate. | For use only: * * * |
| (CAS Reg. No. 4221–80–1).. | 2. At levels not to exceed 0.25 percent by weight of olefin polymers having a density of not less than 0.94 gram per cubic centimeter and complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2: (1) when used in single-use articles that contact food of types I, II, IV–B, VI–A, VI–B, VII–B, and VIII, identified in table 1 of § 176.170(c) of this chapter; and (2) when used in repeated-use articles that contact food of types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of § 176.170(c) of this chapter. The additive is used under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. |
| * * * * * | |

Dated: March 29, 1989.

**Richard J. Ronk,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 89–8151 Filed 4–5–89; 8:45 am]

BILLING CODE 4160–01–M

**21 CFR Part 444**

**[Docket No. 89N–0033]**

## Antibiotic Drugs; Tobramycin-Dexamethasone Ophthalmic Suspension

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of tobramycin, tobramycin-dexamethasone ophthalmic suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

**DATES:** Effective May 8, 1989; comments, notice of participation, and request for hearing by May 8, 1989; data, information, and analyses to justify a hearing by June 5, 1989.

**ADDRESS:** Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Peter A. Dionne, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4290.

**SUPPLEMENTARY INFORMATION:** FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of tobramycin, tobramycin-dexamethasone ophthalmic suspension. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended by adding new 21 CFR 444.380c to provide for the inclusion of accepted standards for the product.

### Environmental Impact

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.

### Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective May 8, 1989. However, interested persons may, on or before May 8, 1989, submit written comments to the Dockets Management Branch (address above). Two 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 this final rule 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 May 8, 1989, a written notice of participation and request for hearing, and (2) on or before June 5, 1989, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for 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 in 21 CFR Part 444

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 444 is amended as follows:

## PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

1. 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.

2. New § 444.380c is added to Subpart D to read as follows:

### § 444.380c Tobramycin-dexamethasone ophthalmic suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tobramycin-dexamethasone ophthalmic suspension is an aqueous suspension containing, in each milliliter, 3.0 milligrams of tobramycin and 1.0 milligram of dexamethasone in a suitable and harmless aqueous vehicle. It may or may not contain one or more suitable and harmless dispersants, preservatives, buffers, and tonicity agents. Its tobramycin potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of tobramycin that it is represented to contain. Its dexamethasone content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of dexamethasone that it is represented to contain. It is sterile. Its pH is not less than 5.0 and not more than 6.0. It passes the identity tests for tobramycin and dexamethasone. The tobramycin used conforms to the standards prescribed by § 444.80(a)(1), except heavy metals. The dexamethasone used conforms to the standards prescribed by the USP XXI.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The tobramycin used in making the batch for potency, moisture, pH, identity, and residue on ignition.

(B) The dexamethasone used in making the batch for all USP XXI specifications.

(C) The batch for tobramycin potency, dexamethasone content, sterility, pH, tobramycin identity, and dexamethasone identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The tobramycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Tobramycin potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 2.5 micrograms of tobramycin per milliliter (estimated).

(2) *Dexamethasone content.* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 254 nanometers, a column packed with microparticulate (3 to 10 micrometers in diameter) reversed phase packing material such as octadecyl hydrocarbon bonded silicas, a flow rate of 1.5 milliliters per minute, and an injection volume of 20 microliters. Mobile phase, working standard and sample solutions, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Mix acetonitrile:water (45:55). Filter the mobile phase through a suitable glass fiber filter or equivalent that is capable of removing particulate contamination to 1 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph pumping system.

(ii) *Preparation of working standard and sample solutions*—(A) *Working standard solution.* Accurately weigh approximately 25 milligrams of the dexamethasone working standard into a 25-milliliter volumetric flask containing methanol. Shake until dissolved. Dilute to volume with methanol. Further dilute 4.0 milliliters of this solution to 100 milliliters with methanol to obtain a solution containing approximately 40 micrograms of dexamethasone per milliliter. Mix well.

(B) *Sample solutions.* Remove an accurately measured representative portion from each container. Dilute the solution thus obtained with sufficient methanol to obtain a solution containing 40 micrograms of dexamethasone per milliliter (estimated).

(iii) *System suitability requirements*—(A) *Tailing factor.* The tailing factor ($T$) is satisfactory if it is not more than 1.6 at 10 percent of peak height in lieu of 5 percent of peak height.

(B) *Efficiency of the column.* The efficiency of the column ($n$) is satisfactory if it is greater than 5,500 theoretical plates.

(C) *Resolution.* The resolution ($R$) between the peak for dexamethasone and its nearest eluting impurity is satisfactory if it is not less than 1.1.

(D) *Coefficient of variation.* The coefficient of variation ($S_R$ in percent) of 5 replicate injections is satisfactory if it is not more than 2.0 percent. If the system suitability requirements have been met, then proceed as described in § 436.216(b) of this chapter. Alternate chromatographic conditions are acceptable provided reproducibility and resolution are comparable to the system. However, the sample preparation described in paragraph (b)(2)(ii)(B) of this section should not be changed.

(iv) *Calculations.* Calculate the dexamethasone content of the container as follows:

$$\text{Milligrams of dexamethasone per container} = \frac{A_u \times P_s \times d}{A_s \times 1{,}000}$$

where:

$A_u$ = Area of the dexamethasone peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

$A_s$ = Area of the dexamethasone peak in the chromatogram of the dexamethasone working standard;

$P_s$ = Dexamethasone content in the dexamethasone working standard solution in micrograms per milliliter; and

$d$ = Dilution factor of the sample.

(3) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(5) *Tobramycin identity.* Proceed as directed in § 436.318 of this chapter, except prepare the sample for assay as follows: decant 1 milliliter into a test tube. Add 100 milligrams of sodium sulfate to the test tube and shake until the sodium sulfate has been dispersed. Centrifuge to obtain a clear supernatant. Use the supernatant as the sample solution.

(6) *Dexamethasone identity.* The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(2) of this section, compares qualitatively to that of the dexamethasone working standard.

Dated: March 28, 1989.

**Daniel L. Michels,**

*Director, Office of Compliance, Center for Drug Evaluation and Research.*

[FR Doc. 89-8152 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-01-M

## 21 CFR Part 176

[Docket No. 87F-0206]

## Indirect Food Additives, Paper and Paperboard Components

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a polymer prepared from urea, ethanedial, formaldehyde, and propionaldehyde for use as a starch and protein reactant in coatings for paper and paperboard intended to contact dry food. This action is in response to a petition filed by Sun Chemical Corp. (now known as Sequa Chemicals).

**DATES:** Effective April 6, 1989; written objections and requests for a hearing by May 8, 1989.

**ADDRESS:** Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of July 16, 1987 (52 FR 26740), FDA announced that a food additive petition (FAP 7B4006) had been filed by Sun Chemical Corp., P.O. Box 70, Chester, SC 29706, proposing that § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) be amended to provide for the safe use of a polymer prepared from urea, ethanedial, formaldehyde, and propionaldehyde for use as a starch and protein reactant in coatings for paper and paperboard intended to contact dry food.

The company changed its name after the filing of the petition. The new company name is Sequa Chemicals, One Sequa Dr., Chester, SC 29706-0070.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that 21 CFR 176.180 should be amended in paragraph (b)(2) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the

petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 8, 1989 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 176**

Food additives, Food packaging, Paper and paperboard.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 176 is amended as follows:

## PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR Part 176 continues to read as follows:

**Authority:** Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding a new entry under the headings "List of substances" and "Limitations" to read as follows:

**§ 176.180 Components of paper and paperboard in contact with dry food.**

* * * * *

(b) * * *

(2) * * *

| List of substances | Limitations |
|---|---|
| * * * * * | |
| Polymer prepared from urea, ethanedial, formaldehyde, and propionaldehyde (CAS Reg. No. 106569-82-8). | For use only as a starch and protein reactant in paper and paperboard coatings. |
| * * * * * | |

Dated: March 29, 1989.

**Richard J. Ronk,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 89-8150 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-01-M

## DEPARTMENT OF THE TREASURY

## Office of Foreign Assets Control

## 31 CFR Part 515

## Cuban Assets Control Regulations

**AGENCY:** Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This rule describes the procedures to be followed in issuing specific licenses to persons who engage in service transactions related to travel to Cuba, carrier service transactions related to travel to Cuba, and service transactions related to forwarding remittances to close relatives in Cuba. The Regulations were amended on November 23, 1988, to require persons engaged in these services to secure specific licenses. This rule delineates the procedures that will be followed by the Office of Foreign Assets Control in processing license applications.

**EFFECTIVE DATE:** April 6, 1989.

**FOR FURTHER INFORMATION CONTACT:** William B. Hoffman, Chief Counsel (telephone: 202/376-0412) or Steven I. Pinter, Chief of Licensing (telephone: 202/376-0236), Office of Foreign Assets Control, Department of the Treasury, 1331 G Street NW., Washington, DC 20220.

**SUPPLEMENTARY INFORMATION:** The amendment provides that applicants are to be granted provisional authority after submitting satisfactory license applications, pending completion of the license application review process. As part of that process, the public is invited to comment concerning the qualification and fitness of applicants. The rule also explains the general criteria on which a license may be denied, suspended, or revoked.

Because the Regulations involve a foreign affairs function, Executive Order 12291 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required under the Administrative Procedure Act or any other law, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are also inapplicable.

**List of Subjects in 31 CFR Part 515**

Administrative practice and procedure, Cuba, Currency, Travel and transportation expenses.

## PART 515—[AMENDED]

1. The "Authority" citation for Part 515 continues to read as follows:

**Authority:** 50 U.S.C. App. 5, as amended; 22 U.S.C. 2370(a); Proc. 3447, 27 FR 1085, 3 CFR 1959–1963 Comp. p. 157; E.O. 9193, 7 FR 5205, 3 CFR 1938–1943 Cum. Supp. p. 1174; E.O. 9989, 13 FR 4891, 3 CFR 1943–1946 Comp. p. 748.

2. Paragraph (i)(3) is added to § 515.560 to read as follows:

**§ 515.560 Certain transactions incident to travel to and within Cuba.**

* * * * *

(i) * * *

(3) *Procedures governing issuance, denial, suspension, or revocation of licenses.*—(i) *Provisional authority.* Following submission of a complete application as described in paragraphs (i)(1)(iii) and (i)(2)(iii), the applicant will be notified in writing that provisional authority has been granted to provide the services contemplated in the application. This provisional authority to provide services will remain in effect pending a final decision to grant or deny the license.