

Title 21—FOOD AND DRUGS

Part I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS PART 121—FOOD ADDITIVES

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

Components of Paper and Paperboard in Contact With Aqueous and Fatty Foods

The Commissioner of Food and Drugs, having evaluated the data in a petition (FAP 0B2540) filed by Nalco Chemical Co., 180 North Michigan Avenue, Chicago, IL 60601, and other relevant material, concludes that the food additive

List of substances

Phosphoric acid esters and polyesters (and their sodium salts) of triethanolamine formed by the reaction of triethanolamine with polyphosphoric acid to produce a mixture of esters having an average nitrogen content of 1.5 percent and an average phosphorus content of 32 percent (as PO₂).

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective on its date of publication in the FEDERAL REGISTER (9-29-72).

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

Dated: September 22, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-16572 Filed 9-28-72; 8:45 am]

regulations should be amended, as set forth below, to provide for the safe use of a composition of acid esters and polyesters formed by the reaction of polyphosphoric acid and triethanolamine as an adjuvant to control pitch and scale formation in the manufacture of paper and paperboard in contact with aqueous and fatty foods.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786, 21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 2.120), § 121.2526 is amended in paragraph (a)(5) by alphabetically inserting in the list of substances a new item, as follows:

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

	*	*	*	*	*
(a)	*	*	*	*	*
(5)	*	*	*	*	*

Limitations

For use as an adjuvant prior to the sheet forming operation to control pitch and scale formation in the manufacture of paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under type I, IV, V, VII, VIII, and IX, and used at a level not to exceed 0.075 percent by weight of dry paper or paperboard fibers.

PART 121—FOOD ADDITIVES

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

COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS; CORRECTION

In F.R. Doc. 72-15559 appearing at page 18528 in the issue of Wednesday, September 13, 1972, the fifth line of the entry under the "Limitations" column under § 121.2526(b)(2) is corrected to read "Use D through G described in * * *."

Dated: September 22, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-16576 Filed 9-28-72; 8:45 am]

SUBCHAPTER C—DRUGS

[DESI 7501]

PART 148p—POLYMYXIN

Certain Polymyxin B Sulfate Preparations for Oral Use; Revocations of Certification or Release

In the FEDERAL REGISTER of August 26, 1970 (35 F.R. 13602), and April 2, 1971

(36 F.R. 6118), the Commissioner of Food and Drugs announced (DESI 7501) the conclusions of the Food and Drug Administration following evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs for oral use:

1. Aerosporin Compressed Tablets containing polymyxin B sulfate; Burroughs Wellcome and Co., Inc., 3030 Corwallis Road, Research Triangle Park, NC 27709. (NDA 7-934)

2. Polymyxin B Sulfate Soluble Tablets; Pfizer Inc., 235 East 42nd Street, New York, NY 10017. (NDA 8-318)

The notice stated that these drugs were regarded as probably effective and possibly effective for their labeled indications. The indications have been reclassified as lacking substantial evidence of effectiveness in that such evidence has not been submitted pursuant to the above notices.

Accordingly, the Commissioner concludes that the antibiotic drug regulations should be amended to revoke provisions for certification or release of such antibiotic drugs for human use.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-1051, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner (21 CFR 2.120), Part 148p is amended as follows:

Part 148p is amended by revoking § 148p.2 *Polymyxin sulfate tablets* and § 148p.6 *Polymyxin B sulfate soluble tablets*.

Any person who will be adversely affected by the removal of any such drug from the market may file objections to this order and request a hearing, showing reasonable grounds therefore. The statement of reasonable grounds and request for a hearing shall be submitted in writing within 30 days after publication hereof in the FEDERAL REGISTER, shall state the reasons why the antibiotic drug regulations should not be so amended, and shall include a well-organized and full factual analysis of the clinical and other investigational data the objector is prepared to prove in support of his objections.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing. When it clearly appears from the data incorporated into or referred to by the objections and from the factual analysis in the request for a hearing that no genuine issue of fact precludes the action taken by this order, the Commissioner will enter an order on these data, making findings and conclusions on such data.

If a hearing is requested and justified by the objections, the issues will be defined and a hearing examiner named. The provisions of Subpart F of 21 CFR Part 2 shall apply to such hearing, except as modified by 21 CFR 146.1(f),

and to judicial review in accord with section 707(f) and (g) (21 U.S.C. 371 (f) and (g)) of the Federal Food, Drug, and Cosmetic Act. (35 F.R. 7250, May 8, 1970).

Objections and requests for a hearing should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852. Received objections and requests for a hearing may be seen in the above office during regular business hours, Monday through Friday.

Effective date. This order shall become effective 40 days after its date of publication in the FEDERAL REGISTER. If objections are filed, the effective date will be extended as necessary to rule thereon. In so ruling, the Commissioner will specify another effective date.

(Secs. 502, 507, 52 Stat. 1050-1051, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357)

Dated: September 19, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-16575 Filed 9-28-72; 8:45 am]

PART 148s—VANCOMYCIN

Vancomycin Hydrochloride and Vancomycin Hydrochloride for Oral Solution

Vancomycin hydrochloride for oral and parenteral use, a drug previously approved under section 507 of the Federal Food, Drug, and Cosmetic Act, is packaged in one-dose sterile vials. These vials are inconvenient to use when more than one patient is being treated orally. The Commissioner of Food and Drugs has evaluated the data submitted concerning the repackaging of vancomycin hydrochloride in a multidose bottle for oral use and concludes that the regulations should be amended to provide for the certification of the repackaged drug. The section heading of § 148s.1 (21 CFR 148s.1) is being revised to conform with U.S.P. nomenclature.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357) and under authority delegated to the Commissioner (21 CFR 2.120), Part 148s is amended by revising § 148s.1 and by adding two new sections as follows:

1. In § 148s.1 by revising the section heading and the first sentence of paragraph (a) (1) as follows:

§ 148s.1 Sterile vancomycin hydrochloride.

(a) *Requirements for certification—*
(1) *Standards of identity, strength, quality, and purity.* Sterile vancomycin hydrochloride is the hydrochloride salt of a kind of vancomycin or a mixture of two or more such salts. * * *

2. The following two new sections are added to Part 148s:

§ 148s.2 Vancomycin hydrochloride.

(a) *Requirements for certification—*

(1) *Standards of identity, strength, quality, and purity.* Vancomycin hydrochloride is the hydrochloride salt of a kind of vancomycin or a mixture of two or more such salts. It is soluble in water and moderately soluble in dilute methyl alcohol. It is insoluble in higher alcohols, acetone, and ether. It is so purified and dried that:

(i) It contains not less than 900 micrograms of vancomycin per milligram, calculated on an anhydrous basis.

(ii) It passes the safety test.

(iii) Its moisture content is not more than 5 percent.

(iv) Its pH in an aqueous solution containing 50 milligrams per milliliter is not less than 2.5 and not more than 4.5.

(v) It contains not more than 15 percent of factor A.

(vi) It gives a positive identity test for vancomycin.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 146.2 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, safety, moisture, pH, factor A content, and identity.

(ii) Samples required: 12 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 141.110 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample of approximately 30 milligrams in sufficient sterile distilled water to give a stock solution of 1 milligram per milliliter (estimated). Further dilute an aliquot of the stock solution with 0.1M potassium phosphate buffer, pH 4.5 (solution 4), to the reference concentration of 10 micrograms of vancomycin per milliliter (estimated).

(2) *Safety.* Proceed as directed in § 141.5 of this chapter.

(3) *Moisture.* Proceed as directed in § 141.502 of this chapter.

(4) *pH.* Proceed as directed in § 141.503 of this chapter, using a solution containing 50 milligrams per milliliter.

(5) *Identity and factor A content.* Proceed as directed in § 148s.1(b) (7).

§ 148s.11 Vancomycin hydrochloride for oral solution.

(a) *Requirements for certification—*

(1) *Standards of identity, strength, quality, and purity.* Vancomycin hydrochloride for oral solution is vancomycin hydrochloride packaged in a suitable dispensing container. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of grams of vancomycin that it is represented to contain. Its moisture content is not more than 5 percent. When reconstituted as directed in the labeling, its pH is not less than 2.5 and not more than 4.5. The vancomycin hydrochloride used conforms to the standards prescribed by § 148s.2(a) (1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 146.2 of this chapter, each such request shall contain:

(i) Results of tests and assay on:

(a) The vancomycin hydrochloride used in making the batch for potency, safety, moisture, pH, factor A content, and identity.

(b) The batch for potency, moisture, and pH.

(ii) Samples required:

(a) The vancomycin hydrochloride used in making the batch: 12 packages, each containing approximately 500 milligrams.

(b) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 141.110 of this chapter, preparing the sample for assay as follows: Empty the contents into an accurately measured volume of distilled water as directed in the labeling of the drug. Further dilute an aliquot with 0.1M potassium phosphate buffer, pH 4.5 (solution 4), to the reference concentration of 10 micrograms of vancomycin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 141.502 of this chapter.

(3) *pH.* Proceed as directed in § 141.503 of this chapter, using the drug reconstituted as directed in the labeling.

Data supplied by the manufacturer concerning the subject antibiotic have been evaluated. Since the conditions prerequisite to providing for its certification have been complied with and since the matter is noncontroversial, notice and public procedure and delayed effective date are not prerequisites to this promulgation.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (9-29-72).

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

Dated: September 22, 1972.

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

[FR Doc. 72-16573 Filed 9-28-72; 8:45 am]

PART 148w—CEPHALOSPORIN

Cephaloridine

The Commissioner of Food and Drugs has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act, as amended, with respect to the certification of a new vial size for cephaloridine. As the designation of vial sizes is not required by the regulations for the certification of an antibiotic, the Commissioner concludes that the regulations should be amended by deleting the reference to vial sizes in § 148w.2 (21 CFR 148w.2).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic