

RULES AND REGULATIONS

Bureau, and the Director of the National Center for Antibiotic Analysis of that Office and Bureau are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 145.3 of this chapter.

(Sec. 701(a), 52 Stat. 1055; 21 U.S.C. 371(a))

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (3-8-72).

Dated: February 25, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-3453 Filed 3-7-72;8:45 am]

SUBCHAPTER C—DRUGS

**PART 135c—NEW ANIMAL DRUGS
IN ORAL DOSAGE FORMS**

Sulfadimethoxine

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (31-715V) filed by Hoffmann-La Roche, Inc., Nutley, N.J. 07110, providing for an increase in the milk withdrawal period following administration of sulfadimethoxine boluses to milk-producing cows from 48 hours to 60 hours. The supplemental application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), § 135c.13 is amended in paragraph (e) by revising item 1 in table 2 in the "Limitations" column by deleting the words "48 hours (4 milkings)" and substituting therefor the words "60 hours (5 milkings)".

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (3-8-72).

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(1))

Dated: March 1, 1972.

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

[FR Doc.72-3455 Filed 3-7-72;8:48 am]

**PART 141—TESTS AND METHODS OF
ASSAY OF ANTIBIOTIC AND ANTI-
BIOTIC-CONTAINING DRUGS**

**Increase in Final Concentrations in
Certain Semisynthetic Penicillins**

No adverse comments were received in response to the notice published in the FEDERAL REGISTER of December 8, 1971 (36 F.R. 23312), proposing that the tables in § 141.506(b) (1) and (2) be amended to increase the final concentrations of the semisynthetic penicillins, except nafcillin, in the iodometric assay. Accordingly, the Commissioner of Food and Drugs concludes that the proposal should be adopted.

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), § 141.506 is amended as follows:

§ 141.506 Iodometric assay.

- (b) * * *
- (1) * * *

Antibiotic	Initial solvent	Diluent (solution number as listed in § 141.102(a))	Final concentration in units or milligrams of activity per milliliter of standard solution
Ampicillin.....	***	***	1.25 milligrams.
***	***	***	***
Cloxacillin.....	***	***	1.25 milligrams.
***	***	***	Do.
Dicloxacillin.....	***	***	Do.
Methicillin.....	***	***	Do.
Oxacillin.....	***	***	1.25 milligrams.
***	***	***	***

- (2) * * *

Antibiotic	Initial solvent	Diluent (solution as listed in § 141.102(a))	Final concentration in units or milligrams of activity per milliliter of sample
***	***	***	***
Ampicillin.....	***	***	1.25 milligrams.
***	***	***	Do.
Ampicillin trihydrate.....	***	***	***
***	***	***	Do.
Buffered sodium methicillin.....	***	***	1.25 milligrams.
***	***	***	Do.
Sodium ampicillin.....	***	***	1.25 milligrams.
***	***	***	Do.
Sodium cloxacillin monohydrate.....	***	***	Do.
Sodium dicloxacillin monohydrate.....	***	***	Do.
Sodium methicillin.....	***	***	Do.
***	***	***	***
Sodium nafcillin monohydrate.....	***	***	1.25 milligrams.
Sodium oxacillin.....	***	***	Do.
***	***	***	***

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

Effective date. This order shall become effective 30 days after its date of FEDERAL REGISTER publication.

Dated: February 28, 1972.

H. E. SIMMONS,
Director, Bureau of Drugs.

[FR Doc.72-3456 Filed 3-7-72;8:48 am]

PART 146a—CERTIFICATION OF PENICILLIN AND PENICILLIN-CONTAINING DRUGS

**PART 148—ANTIBIOTIC DRUGS:
PACKAGING AND LABELING REQUIREMENTS**

Sodium Ampicillin

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 507,

512(n), 59 Stat. 463, as amended, 82 Stat. 350; 21 U.S.C. 357, 360b(n)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), Parts 146a and 148 are amended as follows:

§ 146a.119 [Amended]

1. In Part 146a by deleting the last sentence of paragraph (b) in § 146a.119 *Sodium ampicillin*.

2. In Part 148 by revising the introductory text of § 148.2 *Packaging requirements* to read as follows:

§ 148.2 Packaging requirements.

Each antibiotic drug subject to certification under section 507 or 512(n) of the act shall be packaged in immediate containers which shall be of such composition as not to cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be tight containers as defined by the U.S.P., except that if the antibiotic drug is dispensed as an ointment or cream, the immediate containers shall be well-closed containers as defined by the U.S.P. If the antibiotic drug is packaged for dispensing, it may be packaged in combination with a container of a suitable and harmless diluent approved by the Commissioner.

Since these amendments do not change restrictions for the subject drugs, notice and public procedure and delayed effective date are not prerequisites to their promulgation.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (3-8-72).

(Secs. 507, 512(n), 59 Stat. 463, as amended, 82 Stat. 350; 21 U.S.C. 357, 360b(n))

Dated: February 27, 1972.

H. E. SIMMONS,
Director, Bureau of Drugs.

[FR Doc.72-3457 Filed 3-7-72;8:48 am]

[DESI 11103]

**PART 148i—NEOMYCIN SULFATE
Neomycin Sulfate—Hydrocortisone
Acetate Suppositories; Revocation**

In a notice (DESI 11103) published in the FEDERAL REGISTER of February 26, 1971 (36 F.R. 3535), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Protef Rectal Suppositories containing neomycin sulfate and hydrocortisone acetate; the Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49001 (NDA 11-103). The notice stated that this drug was regarded as possibly effective for certain of its labeled indications and lacking

substantial evidence of effectiveness for the others. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that such evidence has not been submitted pursuant to the notice of February 26, 1971.

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

Therefore, 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), Part 148i is amended by revoking § 148i.12 *Neomycin sulfate—hydrocortisone acetate suppositories*.

Any person who will be adversely affected by the removal of this drug from the market may file objections to this order and request a hearing, showing reasonable grounds for the hearing. 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 to conduct the hearing. 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 701 (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 for ruling thereon. In so ruling, the Commissioner will specify another effective date.

(Secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 353, 357)

Dated: February 25, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-3458 Filed 3-7-72; 8:48 am]

[DESI 50015]

**PART 148i—NEOMYCIN SULFATE
Neomycin Palmitate—Hydrocortisone
Acetate - Trypsin - Chymotrypsin
Ointment; Revocation**

In a notice (DESI 50015) published in the FEDERAL REGISTER of October 15, 1970 (35 F.R. 16203), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on Biozyme-HC Ointment containing neomycin palmitate, hydrocortisone acetate, and trypsin-chymotrypsin concentrate; Armour Pharmaceutical Co., Division, Armour and Co., 401 Wabash Avenue, Post Office Box 1022, Chicago, Ill. 60690 (NDA 50-015). The notice stated that the drug was regarded as possibly effective for the various labeled indications. On April 15, 1971, Armour Pharmaceutical Co., submitted clinical data in behalf of the drug. This data was reviewed and found to be inadequate to establish effectiveness. Therefore, the drug has been reclassified as lacking substantial evidence of effectiveness.

Accordingly, the Commissioner concludes that the antibiotic drug regulations should be amended to delete provisions for certification of such combination drug.

Therefore, 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), Part 148i is amended in § 148i.33 as follows:

By revising the section heading and paragraph (a) (1) to read as follows:

§ 148i.33 Neomycin palmitate-trypsin-chymotrypsin ointment.

(a) *Requirements for certification—*
(1) *Standards of identity, strength, quality, and purity.* The drug is an ointment containing in each gram of a suitable and harmless ointment base neomycin palmitate equivalent to 3.5 milligrams of neomycin and 10,000 units of trypsin-chymotrypsin proteolytic activity. The moisture content is not more than 1 percent. The neomycin palmitate used conforms to the requirements of § 148.32(a)(1) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

* * * * *
Any person who will be adversely affected by the removal of any such drug

from the market may file objections to this order, request a hearing, and show reasonable grounds for the hearing. 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 to conduct the hearing. 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 701 (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 for ruling thereon. In so ruling, the Commissioner will specify another effective date.

(Secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463 as amended; 21 U.S.C. 353, 357)

Dated: February 25, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-3459 Filed 3-7-72; 8:48 am]

Title 46—SHIPPING

**Chapter I—Coast Guard,
Department of Transportation**

[CFR 72-35]

TANK VESSELS AND SMALL PASSENGER VESSELS; GENERAL REQUIREMENTS FOR ELECTRICAL SYSTEMS

The purpose of these amendments to the electrical systems regulations is to define the term "non-sparking fan," to standardize common terms, to update