

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