

troductory text of paragraph (c) of this section and subparagraph (12) of paragraph (c) of this section is used, the label shall bear the statement "with ----- acid added" or "with added ----- acid," the blank to be filled in with the name of the acid used.

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. 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 and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in six copies. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective 60 days after its date of publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055-1056, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371)

Dated: October 5, 1972.

ROBERT C. BRANDENBURG,
Acting Associate Commissioner
for Compliance.

[FR Doc.72-17566 Filed 10-13-72;8:46 am]

SUBCHAPTER C—DRUGS

PART 135—NEW ANIMAL DRUGS

SUBPART C—SPONSORS OF APPROVED APPLICATIONS

PART 135b—NEW ANIMAL DRUGS FOR IMPLANTATION OR INJECTION

Selenium, Vitamin E Injection

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (30-315V) filed by Burns-Biotec Laboratories, Inc., Subsidiary of Chromalloy American Corp., 7711 Oakport Street, Oakland, CA 94621, proposing the safe and effective use of selenium, Vitamin E injection for the treatment of horses. The supplemental application is approved.

To facilitate referencing, Burns-Biotec Laboratories, Inc., is being assigned a code number and placed in the list of firms in § 135.501 (21 CFR 135.501).

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), Parts 135 and 135b are amended as follows:

1. Section 135.501 is amended in paragraph (c) by adding a new code number 070 as follows:

§ 135.501 Names, addresses, and code numbers of sponsors of approved applications.

(c) * * *

Code No.: Firm name and address

070—Burns-Biotec Laboratories, Inc., Subsidiary of Chromalloy American Corp., 7711 Oakport St., Oakland, CA 94621.

2. Part 135b is amended by adding the following new section:

§ 135b.53 Selenium, vitamin E injection, veterinary.

(a) **Specifications.** The drug is an emulsion containing in each milliliter, 5.48 milligrams sodium selenite (equivalent to 2.5 milligrams selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 250 milligrams polyoxyethylated vegetable oil, and 0.1 milligram thimerosal, and water for injection.

(b) **Sponsor.** See code No. 070 in § 135.501(c) of this chapter.

(c) **Conditions of use.** (1) The drug is intended for use for the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(2) The drug is administered by intravenous or deep intramuscular injection in divided doses in 2 or more sites in the gluteal or cervical muscles at a dosage level of 1 milliliter per 100 pounds of body weight and may be repeated at 5 to 10 day intervals.

(3) Do not use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (10-14-72).

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

Dated: October 6, 1972.

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

[FR Doc.72-17567 Filed 10-13-72;8:46 am]

PART 135f—NEW ANIMAL DRUGS FOR MISCELLANEOUS USE

Gentamicin Sulfate Intrauterine Solution

The Commissioner of Food and Drugs has evaluated a new animal drug application (46-724V) filed by Schering Corp., 86 Orange Street, Bloomfield, NJ 07003, proposing the safe and effective use of gentamicin sulfate intrauterine solution for control of bacterial infections of the uterus in horses. The 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), Part 135f is amended by adding a new section as follows:

§ 135f.3 Gentamicin sulfate intrauterine solution.

(a) **Specifications.** Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) **Sponsor.** See code No. 032 in § 135.501(c) of this chapter.

(c) **Conditions of use.** (1) The drug is indicated for use for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(2) It is administered at a dosage level of 2 to 2.5 grams per day for 3 to 5 days during estrus, each dose being diluted with 200 to 500 milliliters of sterile physiological saline before aseptic infusion into the uterus.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Not for use in horses intended for food.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (10-14-72).

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

Dated: October 5, 1972.

C. D. VAN HOUWELING,

Director,

Bureau of Veterinary Medicine.

[FR Doc.72-17568 Filed 10-13-72;8:46 am]

[DESI 8218]

POLYMYXIN B SULFATE OINTMENT

Revocation of Certification or Release

In the FEDERAL REGISTER of June 5, 1971 (36 F.R. 10992), the Commissioner of Food and Drugs announced (DESI 8218) the conclusions of the Food and Drug Administration following evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Polymyxin B Sulfate Ointment; formerly marketed by Pfizer Inc., 235 East 42d Street, New York, NY 10017 (NDA 8-218).

The notice stated that this drug was regarded as probably effective and possibly effective for its 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 notice. By letter of July 19, 1971, Pfizer Inc. stated that the drug is no longer marketed.

Accordingly, the Commissioner concludes that the antibiotic drug regulations should be amended to revoke provisions for certification or release of such antibiotic drug 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), Parts 148i, 148n and 148p are amended as follows:

PART 148i—NEOMYCIN SULFATE

1. Section 148i.16 is amended by revising paragraph (b) (1) (ii) to read as follows:

§ 148i.16 Neomycin sulfate-polymyxin B sulfate ointment.

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

(ii) *Polymyxin content.* Proceed as directed in § 141.110 of this chapter, except add to each concentration of the polymyxin standard response line a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 10 percent potassium phosphate buffer, pH 6.0 (solution 6), and shake well. Remove the buffer layer and repeat the extraction procedure with each of three more 20 to 25 milliliter quantities of solution 6. Combine the extractives in a suitable volumetric flask and fill to volume with solution 6. Further dilute an aliquot with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated). Its content of polymyxin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of units of polymyxin that it is represented to contain.

PART 148n—OXYTETRACYCLINE

2. Section 148n.20 is amended by revising the introductory text of paragraph (b) (1) (ii) to read as follows:

§ 148n.20 Oxytetracycline hydrochloride-polymyxin B sulfate topical ointment.

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

(ii) *Polymyxin B content.* Proceed as directed in § 141.110 of this chapter, preparing the sample for assay by either of the following methods:

PART 148p—POLYMYXIN

§ 148p.3 [Revoked]

3. In Part 148p by revoking § 148p.3 *Polymyxin B sulfate ointment.*

4. Section 148p.9 is amended by revising paragraph (b) (1) to read as follows:

§ 148p.9 Sterile polymyxin B sulfate-benzalkonium chloride urethral lubricant.

(b) *Tests and methods of assay.*
(1) *Potency.* Proceed as directed in § 141.110 of this chapter, preparing the sample for assay by either of the following methods:

(i) Accurately weigh a representative portion of the ointment (usually 1.0 gram) and transfer it to a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake with four 25 milliliter portions of 10 percent potassium phosphate buffer, pH 6.0 (solution 6), and combine the aqueous extractives. After adjusting the volume of the combined extractives to 100 milliliters with solution 6, remove an aliquot and further dilute with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(ii) Place an accurately weighed representative portion of the sample into a high-speed glass blender jar containing sufficient 1.0 milliliter polysorbate 80 and 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

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 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 publish an order stating his 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 701 (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, Depart-

ment 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: October 6, 1972.

ROBERT C. BRANDENBURG,
*Acting Associate Commissioner
for Compliance.*

[FR Doc.72-17565 Filed 10-13-72;8:46 am]

Title 23—HIGHWAYS

Chapter I—Federal Highway Administration, Department of Transportation

PART 1—ADMINISTRATION OF FEDERAL AID FOR HIGHWAYS

Environmental Impact and Related Statements

Section 1.32 of Title 23 of the Code of Federal Regulations provides in the last sentence that "Selected orders and memorandums are contained in Appendix A to this part." On September 7, 1972, the Federal Highway Administration issued policy and procedure memorandum 90-1 entitled "Environmental Impact and Related Statements."

This memorandum implements the National Environmental Policy Act of 1970, section 4(f) of the Department of Transportation Act, and other statutes designed to protect the environment, with regard to all Federal or federally assisted highway programs and projects. This supersedes a previous issuance dated August 24, 1971.

Part 1 of Title 23 of the Code of Federal Regulations is amended by adding the following policy and procedure memorandum at the end of Appendix A.

Issued on October 2, 1972.

R. R. BARTELSMEYER,
*Acting Federal
Highway Administrator.*

ENVIRONMENTAL IMPACT AND RELATED STATEMENTS

PAR.

1. Purpose.
2. Authority.
3. Definitions.
4. Policy.
5. Application.
6. Procedures.

Appendix A—Procedures on Historic Preservation.

Appendix B—Example of Design Concurrence Letter.