

Code No.

Firm name and address

 Armour Pharmaceutical
 Co., Post Office Box
 3113, Omaha, Nebr.
 68108.

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

§ 135b.40 Repository corticotropin injection.

(a) *Specifications.* The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.P. (I.U.) units per cubic centimeter.

(b) *Sponsor.* See code No. 075 in § 135.501(c) of this chapter.

(c) *Special considerations.* The drug should be refrigerated. With prolonged use supplement daily diet with potassium chloride at one gram for small animals and from 5 to 10 grams for large animals.

(d) *Conditions of use.* (1) It is used as an intramuscular or subcutaneous injection in cattle and small animals for stimulation of the adrenal cortex where there is a general deficiency of ACTH. It is also a therapeutic agent for primary bovine ketosis.

(2) It is administered to cattle initially at 200 to 600 units followed by a dose daily or every other day of 200 to 300 units and to small animals at one unit per pound of body weight to be repeated as indicated.

(3) For use only by or on the order of a licensed veterinarian.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (4-8-72).

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

Dated: March 30, 1972.

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

[FR Doc. 72-5400 Filed 4-7-72; 8:47 am]

PART 135b—NEW ANIMAL DRUGS FOR IMPLANTATION OR INJECTION

Sulfadimethoxine

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (13-527V) filed by Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., Myerstown, Pa. 17067 proposing the safe and effective use of sulfadimethoxine injection for the treatment of dogs and cats. The supplemental application is approved. In addition, the applicable regulations are revised to incorporate editorial changes.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(1), 82 Stat. 347; 21 U.S.C. 360b(1)) and under authority delegated to the Commissioner (21 CFR 2.120), the following is amended:

by revising paragraph (a) designating it as paragraph (a) (3) (i) and (ii), by redesignating paragraph (c) (3) as paragraph (a) (3) (iii), and by adding a new paragraph (b) as follows:

paragraph (a) (3) (i) and (ii), by redesignating paragraph (c) (3) as paragraph (a) (3) (iii), and by adding a new paragraph (b) as follows:

§ 135b.15 Sulfadimethoxine injection.

(a) (1) *Specifications.* Sulfadimethoxine injection containing 400 milligrams per milliliter.

(3) *Conditions of use.* (1) It is intended for use in dogs and cats for the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by Streptococci, Staphylococci, Escherichia, Salmonella, Klebsiella, Proteus, or Shigella organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.

(ii) It is administered by intravenous or subcutaneous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours.

(b) (1) *Specifications.* Sulfadimethoxine injection containing 100 milligrams per milliliter.

(2) *Sponsor.* See code No. 069 in § 135.501(c) of this chapter.

(3) *Conditions of use.* (1) It is used or intended for use in the treatment of sulfadimethoxine-susceptible bacterial infections in cats and dogs.

(ii) It is administered by intravenous or intramuscular injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight daily thereafter for 3 to 5 days.

(iii) For use by or on the order of a licensed veterinarian.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (4-8-72).

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

Dated: March 30, 1972.

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

[FR Doc. 72-5401 Filed 4-7-72; 8:47 am]

PART 135b—NEW ANIMAL DRUGS FOR IMPLANTATION OR INJECTION

Iron Dextran Complex Injection

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (10-865V) filed by Fort Dodge Laboratories, Fort Dodge, Iowa 50501, proposing revised labeling regarding the safe and effective uses of iron dextran complex injection in baby pigs. The supplemental application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(1), 82 Stat. 347; 21 U.S.C. 360b(1)) and under authority delegated to the Commissioner (21 CFR 2.120), § 135b.38 is amended by revising para-

graph (b) and by adding two new subparagraphs to paragraph (c) as follows:

§ 135b.38 Iron dextran complex injection.

(b) *Sponsor.* (1) See code No. 054 in § 135.501(c) of this chapter for the sponsor of the usages provided by paragraph (c) (1) and (2) of this section.

(2) See code No. 017 in § 135.501(c) of this chapter for the sponsor of usages provided by paragraph (c) (3) and (4) of this section.

(3) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(4) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (4-8-72).

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

Dated: March 30, 1972.

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

[FR Doc. 72-5399 Filed 4-7-72; 8:46 am]

[DESI 50359]

PART 148i—NEOMYCIN SULFATE
Certain Preparations for Ophthalmic Use Containing Antibiotics and Corticosteroids; Revocation

In a notice [DESI 50359] published in the FEDERAL REGISTER of March 9, 1971 (36 F.R. 4559), the Commissioner of Food and Drugs announced his conclusions following evaluation of reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following drugs:

1. Predmycin Ophthalmic Solution, containing neomycin sulfate, prednisolone, and phenylephrine hydrochloride; Allergan Pharmaceuticals, 1000 South Grand Avenue, Santa Ana, Calif. 92705 (NDA 50-359).

2. Prednicidin Ophthalmic Suspension, containing neomycin sulfate, gram-icidin, prednisolone acetate, and phenylephrine hydrochloride; Tilden-Yates Laboratories, Inc., Fairfield Road, Wayne, N.J. 07470 (NDA 60-637).

The notice stated that these drugs were regarded as possibly effective for their labeled indications. The indication have been reclassified as lacking substantial evidence of effectiveness in that such evidence has not been submitted pursuant to the notice of March 9, 1971.

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

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), § 148i.9 is amended in paragraph (a) (1) by deleting subdivision (iii) and redesignating subdivision (iv) as (iii) and subdivision (v) as (iv), to read as follows:

§ 148i.9 Neomycin sulfate -----
 ophthalmic suspension; neomycin sulfate ----- ophthalmic solution (the blanks being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a) (1) of this section).

(a) Requirements for certification—
 (1) Standards for identity, strength, quality, and purity. The drug is a suspension or a solution containing, in each milliliter, 3.5 milligrams of neomycin and the following other active ingredients in a suitable and harmless vehicle:

- (i) 15 milligrams of cortisone acetate; or
- (ii) 5 milligrams or 25 milligrams of hydrocortisone acetate; or
- (iii) 1 milligram or 2 milligrams of prednisolone; or
- (iv) 1 milligram of sodium dexamethasone phosphate.

It may also contain one or more suitable and harmless buffers, dispersants, and

preservatives. It is sterile. Its pH is not less than 6.0 and not more than 8.0. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a) (1) (i), (iv), (vi), and (vii). 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 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

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 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. 352, 357)

Dated: March 28, 1972.

SAM D. FINE,
 Associate Commissioner
 for Compliance.

[FR Doc.72-5420 Filed 4-7-72;8:47 am]

Title 24—HOUSING AND URBAN DEVELOPMENT

Chapter X—Federal Insurance Administration, Department of Housing and Urban Development

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

List of Eligible Communities

Section 1914.4 is amended by adding in alphabetical sequence a new entry to the table, which entry reads as follows:

§ 1914.4 List of eligible communities.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
California	San Mateo	Brisbane
Connecticut	Fairfield	Fairfield	Apr. 7, 1972.
Do.	do.	New Canaan	Do.
Massachusetts	Hampshire	Northampton	Do.
New Jersey	Middlesex	Highland Park Borough.	Do.
Texas	Bexar	Unincorporated areas.	Do.
West Virginia	Logan	do.	I 54 045 0000 05 through I 54 045 0000 22	West Virginia Insurance Department, State Capitol, Charleston, W. Va. 25305.	Office of the Clerk of the County Court of Logan County, City of Logan Courthouse, Logan, W. Va. 25801.	Do.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 F.R. 17804, Nov. 28, 1968), as amended (secs. 408-410, Public Law 91-152, Dec. 24, 1969), 42 U.S.C. 4001-4127; and Secretary's delegation of authority to Federal Insurance Administrator, 34 F.R. 2680, Feb. 27, 1969)

Issued: March 29, 1972.

GEORGE K. BERNSTEIN,
 Federal Insurance Administrator.

[FR Doc.72-5342 Filed 4-7-72;8:45 am]