

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

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (9-13-72).

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

Dated: September 6, 1972.

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

[FR Doc.72-15560 Filed 9-12-72;8:53 am]

PART 135c—NEW ANIMAL DRUGS IN ORAL DOSAGE FORMS

PART 135g—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

Phenothiazine, Hexachlorophene; Revocation

Based upon a notice of withdrawal of approval of new animal drug application with respect to Bisophene, a new animal drug containing phenothiazine and hexachlorophene (Docket No. FDC-D-467) appearing elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs concludes that the new animal drug regulations should be amended to revoke provisions for the use of phenothiazine and hexachlorophene in combination.

Therefore, pursuant to provisions of Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(1)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 135c and 135g are amended as follows:

Section 135c.11 *Phenothiazine and hexachlorophene in combination* is revoked.

Sections 135g.50 *Hexachlorophene* and 135g.51 *Phenothiazine* are revoked.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (9-13-72).

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

Dated: September 6, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-15555 Filed 9-12-72;8:53 am]

PART 135c—NEW ANIMAL DRUGS IN ORAL DOSAGE FORMS

PART 149a—DICLOXACILLIN

Sodium Dicloxacillin Monohydrate Capsules, Veterinary

The Commissioner of Food and Drugs has evaluated a new animal drug application (55-032V) filed by Bristol Laboratories, Division of Bristol-Myers Co., Post Office Box 657, Syracuse, N.Y. 13201 proposing the safe and effective use of sodium dicloxacillin monohydrate capsules for the treatment of dogs. The application is approved.

Because said drug is subject to batch certification under provisions of section 512(n) of the Federal Food, Drug, and Cosmetic Act, this order provides for appropriate amendments to the antibiotic drug certification regulations.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512 (i) and (n), 82 Stat. 347; 350-51; 21 U.S.C. 360b (i) and (n)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 135c and 149a are amended as follows:

1. Part 135c is amended by adding the following new section:

§ 135c.73 Sodium dicloxacillin monohydrate capsules, veterinary.

(a) *Specifications.* The drug is in capsule form and conforms to the certification requirements of § 149a.14 of this chapter.

(b) *Sponsor.* See code No. 044 in § 135.501(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs in the treatment of pyoderma (pyogenic dermatitis) known to be due to penicillinase-producing staphylococci which have been shown to be sensitive to the drug.

(2) It is administered to dogs at the rate of 5 milligrams to 10 milligrams per pound of body weight, three times daily. In severe cases the dose may be increased to 25 milligrams per pound of body weight three times daily. Treatment should be continued for 24 to 48 hours after the animal has become afebrile or asymptomatic. The drug should be administered 1 to 2 hours before feeding to insure maximum absorption.

(3) For use in the treatment of dogs only. Not for use in animals which are raised for food production.

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

2. Part 149a is amended by adding the following new section:

§ 149a.14 Sodium dicloxacillin monohydrate capsules, veterinary.

(a) *Requirements for certification—*
(1) *Standards of identity, strength, quality, and purity.* Sodium dicloxacillin monohydrate capsules, veterinary, are composed of sodium dicloxacillin monohydrate and one or more suitable diluents and lubricants. Each capsule contains sodium dicloxacillin monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of dicloxacillin that it is represented to contain. The moisture content is not more than 5 percent. The sodium dicloxacillin monohydrate conforms to the requirements of § 149a.1(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter, except that in lieu of the requirements of § 148.3(a)(1), it shall be labeled in accordance with the requirements prescribed by § 1.106(c) 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:

(a) The sodium dicloxacillin monohydrate used in making the batch for potency, safety, moisture, pH, organic chlorine content, free chloride content, crystallinity, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The sodium dicloxacillin monohydrate used in making the batch: 10 containers, each containing not less than 500 milligrams.

(b) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 5 micrograms of dicloxacillin per milliliter (estimated) for the microbiological agar diffusion assay and to the prescribed concentration for the iodometric assay.

(ii) *Assay procedure.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 141.110 of this chapter.

(b) *Iodometric assay.* Proceed as directed in § 141.506 of this chapter.

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

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (9-13-72).

(Sec. 512 (i) and (n), 82 Stat. 347; 350-51; 21 U.S.C. 360b (i) and (n))

Dated: September 6, 1972.

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

[FR Doc.72-15565 Filed 9-12-72;8:54 am]

[DESI 8539]

CERTAIN ANTIBIOTIC-CONTAINING ANTIDIARRHEAL PREPARATIONS

Revocations of Certification or Release

In the FEDERAL REGISTER of July 2, 1970 (35 F.R. 10792), the Commissioner of Food and Drugs announced (DESI 8539) 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 antiinfective drugs for oral use:

1. Streptomagma Tablets; dihydrostreptomycin base (as sulfate) 150 milligrams, attapulgit 350 milligrams, pectin

45 milligrams, and aluminum hydroxide 70 milligrams; Wyeth Laboratories, Inc., Post Office Box 8299, Philadelphia, Pa. 19101 (NDA 60-119).

2. Polymagma Oral Suspension; each 30 cc. containing dihydrostreptomycin base (as sulfate) 300 milligrams, polymyxin B sulfate 120,000 units, attapulgitte 3 grams, and pectin 270 milligrams; Wyeth Laboratories, Inc. (NDA 60-120).

3. Polymagma Tablets; dihydrostreptomycin sulfate equivalent to dihydrostreptomycin base 75 milligrams, polymyxin B sulfate 25,000 units per tablet, activated attapulgitte 350 milligrams, pectin 45 milligrams, and aluminum hydroxide 70 milligrams; Wyeth Laboratories, Inc. (NDA 60-121).

4. Streptomagma Liquid; each fluid ounce containing dihydrostreptomycin base (as sulfate) 300 milligrams, kaolin 2.92 grams, and pectin 259 milligrams; Wyeth Laboratories, Inc. (NDA 60-122).

5. Kectil Suspension; each 5 milliliters containing dihydrostreptomycin sulfate equivalent to 50 milligrams dihydrostreptomycin base, sulfaganidine 250 milligrams, sulfadiazine 250 milligrams, aminopentamide sulfate 0.033 milligram, bismuth subcarbonate 250 milligrams, pectin 25 milligrams, and kaolin 500 milligrams; Bristol Laboratories, Division of Bristol Myers Co., Thompson Road, Post Office Box 657, Syracuse, N.Y. 13201 (NDA 60-067).

6. Strycin Syrup; each 5 cc. containing streptomycin 250 milligrams (as the sulfate); E. R. Squibb & Sons, Inc., Georges Road, New Brunswick, N.J. 08903 (NDA 60-124).

7. Donnagel with Neomycin Liquid, each 30 cc. containing neomycin base (as neomycin sulfate) 210 milligrams, kaolin 6 grams, pectin 142.8 milligrams, hyoscine sulfate 0.1037 milligram, atropine sulfate 0.0194 milligram, and scopolamine hydrobromide 0.0065 milligram; A. H. Robins Co., 1407 Cummings Drive, Richmond, Va. 23220 (NDA 10-807).

8. Sorboquel with Neomycin Tablets; neomycin 150 milligrams (as the sulfate), polycarbophil 0.4 gram, and thihexinol methylbromide 15 milligrams; White Laboratories, Inc., Galloping Hill Road, Kenilworth, N.J. 07033 (NDA 12-625).

9. Cremomycin; each 30 cc. contains neomycin sulfate 300 milligrams (equivalent to 210 milligrams neomycin base), succinylsulfathiazole 3 grams, colloidal kaolin 3 grams, and pectin 0.27 gram; Merck & Co., Inc., Rahway, N.J. 07065 (NDA 9-444).

10. Bacimycin Tablets; neomycin 25 milligrams (as the sulfate) and bacitracin 2,500 units; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, Ohio 45215 (NDA 60-054).

11. Kaomycin Suspension; each fluid ounce containing neomycin sulfate 300 milligrams (equivalent to 210 milligrams neomycin base), kaolin 5.832 grams and pectin 0.130 gram; The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49001 (NDA 8-539).

12. Neomycin Sulfate—Kaolin—Pectin Oral Suspension; each fluid ounce containing neomycin sulfate 300 milligrams

(equivalent to 210 milligrams neomycin base), kaolin 6 grams, and pectin 0.13 gram; E. W. Heun Co., 2303 Schuetz Road, St. Louis, Mo. 63141 (NDA 60-318).

13. Quintess-N Solution; each 30 cc. containing neomycin sulfate 320 milligrams (equivalent to 225 milligrams neomycin base), activated attapulgitte 3 grams, and activated colloidal attapulgitte 0.9 gram; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 50-232).

14. Neomycin Sulfate—Kaolin—Pectin Suspension; each fluid ounce containing neomycin sulfate 300 milligrams (equivalent to 210 milligrams neomycin base), kaolin 6 grams, and pectin 130 milligrams; Vitamix Pharmaceuticals, Inc., Division of Wynn Pharmaceuticals, Inc., 2900 North 17th Street, Philadelphia, Pa. 19132 (NDA 60-352).

The Commissioner considered the Academy's reports, as well as other available information, and concluded there is a lack of substantial evidence, as defined in the Federal Food, Drug, and Cosmetic Act, that these drugs are effective for the uses prescribed, recommended, or suggested in their labeling; and in the case of those drugs which are combinations, there is also a lack of substantial evidence that each component of the combinations contributes to the total effects claimed for such combination drugs.

The ratio of benefit-to-risk with such drugs is regarded as unfavorable in that, for example, even the so-called non-absorbable drugs such as neomycin and the streptomycins may be absorbed from an inflamed or diseased gastrointestinal tract and result in eighth cranial nerve toxicity; there is a possibility of development of hypersensitivity and blood dyscrasias with sulfonamides; the presence of an antibiotic in a mixture that is likely to be used to treat conditions of undetermined etiology may result in development of resistant strains of organisms; and flexibility of dosage required to safely achieve desired effects from individual components is lacking in the fixed-combinations.

The Commissioner announced his intention to initiate proceedings to amend the antibiotic drug regulations to delete provisions for certification or release of the above-listed drugs and any similar drugs for oral administration in man. Interested persons who might be adversely affected by removal of these drugs from the market were invited to submit, within 30 days after FEDERAL REGISTER publication of the announcement, any pertinent data bearing on the proposal to so amend the antibiotic drug regulations.

Three responses were received to the notice. (1) Wyeth Laboratories submitted material consisting of a discussion by Wyeth of the opinions of the NAS/NRC panels and also a summary of the studies in progress and planned. (2) William L. Hewitt, M.D., chairman of an NAS/NRC panel, states that grounds for imputing ineffectiveness or a hazard are lacking and that further studies are needed; however, the Commissioner con-

cludes that no new data on which a different decision could be based have been presented. (3) The Upjohn Co. submitted proposed revised labeling for its product and has been informed that the revised labeling is not acceptable.

In addition to the products listed above (for which the conditions of certification are described in §§ 141b.133, 141b.136, 146b.104, 146b.108, 146b.128, 146b.131, 146e.410, 148i.6, and 148i.11), §§ 141a.20, 141b.123, 146a.38, 146b.118, 146e.403, and 146e.412 describe the conditions for certification of other antibiotic-containing antidiarrheal preparations. Editorial amendments to §§ 146a.62, 146a.111, 146b.124, 146c.228, 146c.237, 146c.244, 146c.246, 146d.312, 146e.411, 146e.422, and 146e.430 are necessary because of the revocation of § 146e.410, herein.

Accordingly, the Commissioner concludes: (1) That the antibiotic drug regulations should be amended to revoke provision for certification or release of such antibiotic drugs for human use and (2) that all outstanding certificates and releases heretofore issued for such drugs should be revoked.

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), Parts 141a, 141b, 146a, 146b, 146c, 146d, 146e, and 148i are amended as follows:

PART 141a—PENICILLIN AND PENICILLIN-CONTAINING DRUGS; TEST AND METHODS OF ASSAY

§ 141a.20 [Revoked]

1. Part 141a is amended by revoking § 141a.20 *Capsules buffered penicillin with pectin hydrolysate*.

PART 141b—STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) AND STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

§§ 141b.123, 141b.133, and 141b.136 [Revoked]

2. Part 141b is amended by revoking § 141b.123 *Streptomycin-penicillin-sulfonamide with kaolin and pectin; dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin*; § 141b.133 *Streptomycin-polymyxin in gel; dihydrostreptomycin-polymyxin in gel*; § 141b.136 *Streptomycin-polymyxin tablets; dihydrostreptomycin-polymyxin tablets*.

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

§ 146.38 [Revoked]

3. Part 146a is amended by revoking § 146a.38 *Capsules buffered penicillin*.

with pectin hydrolysate (capsules buff-potassium penicillin with pectin sate).

§ 146a.62 [Amended]

4. Section 146a.62 *Procaine penicillin G-neomycin in oil, veterinary* is amended by revising the second sentence in paragraph (a) to read as follows: "The neomycin used conforms to the standards prescribed by § 1481.1(a) (1) (i), (v), and (vi) of this chapter."

§ 146a.111 [Amended]

5. Section 146a.111 *Procaine penicillin-neomycin-polymyxin in oil, veterinary; procaine penicillin-neomycin-polymyxin ointment, veterinary* is amended by revising the seventh sentence in paragraph (a) to read as follows: "The neomycin used conforms to the standards prescribed by § 1481.1(a) (1) (i), (v), and (vi) of this chapter."

PART 146b—CERTIFICATION OF STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) AND STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) CONTAINING DRUGS

6. Section 146b.104 is amended by revising the section heading and paragraphs (a) and (c) to read as follows:

§ 146b.104 *Streptomycin tablets, veterinary; dihydrostreptomycin tablets, veterinary.*

(a) *Standards of identity, strength, and purity.* Streptomycin tablets, veterinary, and dihydrostreptomycin or dihydrostreptomycin tableted with or without glucuronolactone, kaolin, or other suitable and harmless absorbent ingredients, pectin, and dried aluminum hydroxide gel, with or without bismuth glycolylarsanilate and one or more suitable sulfonamides, and with or without the addition of one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. It may contain chlorhexidine dihydrochloride or vitamin A and/or bismuth subcarbonate. The potency of each tablet is not less than 37.5 milligrams. If it contains chlorhexidine dihydrochloride, each tablet contains 375 milligrams of chlorhexidine dihydrochloride and 37.5 milligrams of dihydrostreptomycin. Its moisture content is not more than 10 percent. Tablets not exceeding 15 millimeters in diameter, or not intended only for preparing solutions, shall disintegrate within 1 hour. The streptomycin or dihydrostreptomycin used conforms either to the standards prescribed by § 146b.101 (a) or § 146b.103, except the standards for sterility, pyrogens, and histamine content, or to the standards prescribed by § 146b.114(a). 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.

(b) *Labeling.* In addition to the labeling requirements prescribed by § 1.106

(c) of this chapter (regulations issued under section 502(f) of the act), each package shall bear on the outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The statement "Expiration date -----," the blank being filled in with the date that is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of test and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed in paragraph (a) of this section.

(2) If it contains, in addition to streptomycin or dihydrostreptomycin one or more of the other active ingredients specified in paragraph (a) of this section, after the name "streptomycin tablets" or "dihydrostreptomycin tablets," wherever it appears, the words "with -----," the blank being filled in with the established name of each such other ingredient and the words being in juxtaposition with such name.

(3) In lieu of the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity. If it contains bismuth subcarbonate, its label and labeling shall include reference to its use only in cats and dogs.

(4) If it is intended for use in animals raised for food production, it shall be used in accordance with § 135c.15 or § 135c.44 of this chapter.

7. Section 146b.108 is amended by revising the section heading and paragraphs (a) and (c) to read as follows:

§ 146b.108 *Streptomycin syrup, veterinary; streptomycin in gel (streptomycin oral suspension), veterinary; dihydrostreptomycin syrup, veterinary; dihydrostreptomycin in gel (dihydrostreptomycin oral suspension), veterinary.*

(a) *Standards of identity, strength, quality, and purity.* Streptomycin syrup, veterinary, and dihydrostreptomycin syrup, veterinary, are streptomycin or dihydrostreptomycin dissolved in a suitable and harmless diluent that contains one or more suitable and harmless preservatives. Streptomycin in gel, veterinary, and dihydrostreptomycin in gel, veterinary, are streptomycin and dihydrostreptomycin dissolved or suspended in a suitable and harmless gel base that contains a suitable and harmless adsorbent and one or more suitable and harmless preservatives. Each such drug may contain one or more suitable and harmless suspending or dispersing agents, flavorings, pectin, chlorhexidine dihydrochloride, bismuth glycolylarsanilate, bismuth magma, or bismuth subcarbonate, suitable mineral salts, procaine hydro-

chloride, a suitable antispasmodic agent, and one or more suitable sulfonamides. Its potency is not less than 10 milligrams per milliliter; however, if it contains chlorhexidine dihydrochloride, each milliliter contains 12.5 milligrams of chlorhexidine dihydrochloride and 1.25 milligrams of dihydrostreptomycin. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2), (4), (5), and (6) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standards for sterility, pyrogens, moisture, and histamine content. 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.

(c) *Labeling.* In addition to the labeling requirements prescribed by § 1.106(c) of this chapter (regulations issued under section 502(f) of the act), each package shall bear on the outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The statement "Expiration date -----," the blank being filled in with the date that is 18 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 24 months or 36 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section.

(2) If it contains, in addition to streptomycin or dihydrostreptomycin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "streptomycin sirup," "streptomycin in gel," "dihydrostreptomycin sirup," or "dihydrostreptomycin in gel," wherever such name appears, the words "with -----" (the blank being filled in with the established name of each such other ingredient)," in juxtaposition with such name.

(3) In lieu of the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(4) If it is intended for use in animals raised for food production, it shall be used in accordance with § 135c.15 of this chapter.

§ 146b.124 [Amended]

8. Section 146b.124 *Streptomycin-polymyxin-neomycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment* is amended by revising the seventh sentence in paragraph (a) to read as follows:

"The neomycin used conforms to the standards prescribed by § 1481(a) (1) (i), (v), and (vi) of this chapter."

§§ 146b.118, 146b.128, 146b.131 [Revoked]

9. Part 146b is amended by revoking § 146b.118 *Streptomycin - penicillin - sulfonamide with kaolin and pectin; dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin*; § 146b.128 *Streptomycin-polymyxin in gel; dihydrostreptomycin-polymyxin in gel*; and § 146b.131 *Streptomycin - polymyxin tablets; dihydrostreptomycin-polymyxin tablets*.

PART 146c—CERTIFICATION OF CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS

§§ 146c.228, 146c.237, 146c.244, 146c.246 [Amended]

10. Section 146c.228 *Chlortetracycline hydrochloride-neomycin tablets veterinary; tetracycline hydrochloride-neomycin tablets veterinary* is amended by revising the second sentence of paragraph (a) to read as follows: "The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (iv), (v), and (vi) of this chapter."

11. Section 146c.237 *Chlortetracycline-neomycin-streptomycin ointment; chlortetracycline - neomycin - dihydrostreptomycin ointment; tetracycline hydrochloride - neomycin - streptomycin ointment; tetracycline hydrochloride-neomycin - dihydrostreptomycin ointment* is amended by revising the second sentence in paragraph (a) (2) to read as follows:

"The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (v), and (vi) of this chapter."

12. Section 146c.244 *Tetracycline hydrochloride-neomycin spray ointment topical* is amended by revising the sixth sentence in paragraph (a) to read as follows:

"The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (v), and (vi) of this chapter."

13. Section 146c.246 *Tetracycline hydrochloride-neomycin in oil suspension* is amended by revising the second sentence in paragraph (a) (1) to read as follows:

"The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (v), and (vi) of this chapter."

PART 146d—CERTIFICATION OF CHLORAMPHENICOL AND CHLORAMPHENICOL - CONTAINING DRUGS

§ 146d.312 [Amended]

14. Section 146d.312 *Chloramphenicol-neomycin ointment* is amended by revising the second sentence of paragraph (a) to read as follows: "The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (v), and (vi) of this chapter."

PART 146e—CERTIFICATION OF BACITRACIN AND BACITRACIN-CONTAINING DRUGS

§§ 146e.403, 146e.411, 146e.422, and 146e.430 [Amended]

15. Section 146e.403 *Bacitracin tablets; zinc bacitracin tablets; bacitracin methylene disalicylate tablets; bacitracin suppositories; zinc bacitracin suppositories (if they are represented for vaginal use); bacitracin implantation pellets; zinc bacitracin implantation pellets (if they are represented for use by implanting under the skin of animals)* is amended by deleting the words "with or without kaolin and pectin and" from the first sentence in paragraph (a).

16. Section 146e.411 *Bacitracin-neomycin topical ointment; zinc bacitracin-neomycin topical ointment* is amended by revising the second sentence of paragraph (a) (1) to read as follows:

"The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (v), and (vi) of this chapter."

17. Section 146e.422 *Bacitracin-polymyxin-neomycin ointment* is amended by revising the second sentence of paragraph (a) (1) to read as follows:

"The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (v), and (vi) of this chapter."

18. Section 146e.430 *Bacitracin-neomycin-polymyxin powder topical; zinc bacitracin-neomycin-polymyxin powder topical* is amended by revising the seventh sentence of paragraph (a) to read as follows:

"The neomycin used conforms to the standards prescribed by § 148i.1(a) (1) (i), (iv), (v), and (vi) of this chapter."

§ 146e.410 [Revoked]

19. Part 146e is amended by revoking § 146e.410 *Bacitracin-neomycin tablets; zinc bacitracin-neomycin tablets; bacitracin methylene disalicylate-neomycin tablets*.

PART 148i—NEOMYCIN SULFATE

§§ 148i.6 and 148i.11 [Revoked]

20. Part 148i is amended by revoking § 148i.6 *Neomycin sulfate-kaolin-pectin oral suspension; neomycin sulfate-akolin-pectin- oral suspension (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a) (1) of this section)*.

21. Part 148i is amended by revoking § 148i.11 *Neomycin sulfate-thihexinol methylbromide-polycarbophil 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 therefor. 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-or-

ganized 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 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, 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 and how the outstanding stocks of the affected drugs are to be handled.

(Secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended, 21 U.S.C. 352, 357)

Dated: September 5, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-15544 Filed 9-12-72; 8:53 am]

[DESI 50417]

PART 141e—BACITRACIN AND BACITRACIN-CONTAINING DRUGS; TEST AND METHODS OF ASSAY

PART 146e—CERTIFICATION OF BACITRACIN AND BACITRACIN-CONTAINING DRUGS

PART 148i—NEOMYCIN SULFATE

Confirmation of Order Revoking Provisions for Certification of Certain Ophthalmic Combination Drugs

An order was published in the FEDERAL REGISTER of July 6, 1972 (37 F.R. 13253), amending the antibiotic drug regulations to repeal provisions for certification of bacitracin-neomycin sulfate ophthalmic ointment and neomycin sulfate gramicyclin ophthalmic ointment. It