NOTICES

DEPARTMENT OF STATE

Agency for International Development
AMERICANS FOR CHILDREN'S RELIEF, INC.,

Register of Voluntary Foreign Aid Agencies

[40x185]February 12, 1968 (33 FR. 4591) is hereby revoked.

Urban Park Affairs.

rededelegated to the following officials of the National Capital and Urban Park Affairs;

as an ex-officio member of the National Planning Commission.

DIRECTOR AND ASSISTANT TO THE DIRECTOR, OFFICE OF NATIONAL CAPITAL AND URBAN PARK AFFAIRS

Delegation of Authority Regarding Representation on National Capital Planning Commission

Section 1. The authority vested in the Director, National Park Service to serve as an ex officio member of the National Capital Planning Commission is hereby redelegated to the following officials of the National Park Service.

First alternate—Director, Office of National Capital and Urban Park Affairs; Second alternate—Assistant to the Director, Office of National Capital and Urban Park Affairs.

Sec. 2. Delegation Order No. 50 of February 12, 1968 (33 FR. 4591) is hereby revoked.

[Act of July 12, 1932; 20 Cat. 701]

DATED: June 19, 1970.

HARLETT S. CROWLEY,

Director,
Office for Private Overseas Program.

[FR Doc. 70-8330; Filed, June 30, 1970; 8:37 a.m.]

DEPARTMENT OF THE INTERIOR

National Park Service
[Order No. 58]

DIRECTOR AND ASSISTANT TO THE DIRECTOR, OFFICE OF NATIONAL CAPITAL AND URBAN PARK AFFAIRS

Delegation of Authority Regarding Representation on National Capital Planning Commission

Section 1. The authority vested in the Director, National Park Service to serve as an ex officio member of the National Capital Planning Commission is hereby redelegated to the following officials of the National Park Service.

First alternate—Director, Office of National Capital and Urban Park Affairs; Second alternate—Assistant to the Director, Office of National Capital and Urban Park Affairs.

Sec. 2. Delegation Order No. 50 of February 12, 1968 (33 FR. 4591) is hereby revoked.

[Act of July 12, 1932; 20 Cat. 701]

DATED: June 19, 1970.

ELIZABETH L. DILL,
Acting Director,
National Park Service.

[FR Doc. 70-8330; Filed, June 30, 1970; 8:45 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

DEPARTMENT OF THE INTERIOR

[DESI 0172 NY]

CERTAIN BACITRACIN CONTAINING DRUGS

Drugs for Veterinary Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following preparations by Hoffmann-La Roche Inc., Nutley, N.J. 07110:

1. Hancock's Broiler Finisher; contains 1.429 grams bacitracin per pound.
2. Broiler Premix; contains 1,666 grams bacitracin per ton.
3. Hancock's Broiler Starter; contains 1.111 grams bacitracin per pound.
4. Turkey Premix; contains 1.668 grams bacitracin per ton.
5. Broiler Premix; contains 2.0 grams bacitracin (from bacitracin methylene disalicylate) per pound.
6. E & G Broiler Premix; contains 1.600 grams bacitracin (from bacitracin methylene disalicylate) per ton.
7. Broiler Finisher Premix; contains 2.0 grams bacitracin (from bacitracin methylene disalicylate) per pound.
8. Poultry Premix; contains 1.0 gram bacitracin (from bacitracin methylene disalicylate) per pound.
9. Premix No. 2; contains 2.5 grams bacitracin (from bacitracin methylene disalicylate) per pound.
10. Broiler Premix; contains 1.600 grams bacitracin (from bacitracin methylene disalicylate) per pound.
11. Turkey Premix; contains 1 gram bacitracin (from bacitracin methylene disalicylate) per pound.
12. Premix No. 3-B; contains 2.5 grams bacitracin (from bacitracin methylene disalicylate) per pound.
13. Vitamin No. 3 Premix; contains 2.5 grams bacitracin (from bacitracin methylene disalicylate) per pound.
14. Turkey Premix 2X; contains 2.0 grams bacitracin (from bacitracin methylene disalicylate) per pound.
15. Turkey Premix; contains 1.0 gram bacitracin (from bacitracin methylene disalicylate) per pound.
16. Premix No. 671 Medicated; contains 2.5 grams bacitracin (from bacitracin methylene disalicylate) per pound with 4,956 percent 3-nitro-4-hydroxyphenylacetic acid.

The Academy classified these premixes as probably effective for faster gains and improved feed efficiency in poultry.

The Academy further stated:

1. Claims for growth promotion or stimulation are disallowed. Claims for faster gains and/or feed efficiency should be stated as "may result in faster gains and/or improved feed efficiency under appropriate conditions."
2. Each ingredient designated as active in a preparation containing more than one drug must be effective, or contribute to the effectiveness of the preparation, to warrant acceptance as a therapeutic ingredient.
3. When using bacitracin alone, a minimum of 25 grams of bacitracin activity per ton of complete feed is necessary for improving rate of gain and/or feed efficiency for poultry.

The Food and Drug Administration concurs in the Academy's findings except the Administration concludes that the appropriate claim for faster weight gains and improved feed efficiency should be "For increased rate of weight gain and improved feed efficiency for (under appropriate conditions of use)."

This evaluation is concerned only with the drugs' effectiveness and safety to the animal to which administered. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites as residues in food products derived from treated animals.

This announcement is published (1) to inform manufacturers of the subject drugs of the findings of the Academy and the Food and Drug Administration and (2) to inform all interested persons that such articles to be marketed must be the subject of approved new animal drug applications and otherwise comply with all other requirements of the Federal Food, Drug, and Cosmetic Act.

Manufacturers of the subject drugs are provided 6 months from the date of publication of this announcement in the Federal Register to submit adequate documentation in support of the labeling used.

Each holder of a new animal drug application which became effective prior to October 10, 1962, is requested to submit updating information as needed to make the application current with respect to the information on drug composition, and also including information regarding manufacturing methods, facilities, and controls, in accordance with the requirements of section 512 of the act.

Written comments regarding this announcement, including requests for an informal conference, may be addressed to the Bureau of Veterinary Medicine, Food and Drug Administration, 5500 Fishers Lane, Rockville, Md. 20852.

The manufacturer of the listed drugs has been mailed a copy of the NAS-NRC
NOTICES

CERTAIN DIHYDROSTREPTOMYCIN AND STREPTOMYCIN CONTAINING DRUGS

Drugs for Veterinary Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following preparations:

1. Dihydrostreptomycin Sulfate Crystalloid Solution; each cubic centimeter contains 400 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate); by Chas. Pfizer & Co., Inc., 400 East 42nd Street, New York, N.Y. 10017.

2. Crystalloid Dihydrostreptomycin Sulfate Solution; each cubic centimeter contains 250 or 500 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate); by Pure Laboratories, Inc., 50 Intervale Road, Parsippany, N.J. 07054.

3. Dihydrostreptomycin Sulfate; each cubic centimeter contains 500 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate); by Philadelphia Laboratories, Inc., 814 Roosevelt Boulevard, Philadelphia, Pa. 19114.

4. Dihydrostreptomycin Sulfate injection; each cubic centimeter contains 500, 400, or 250 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate); by Maury Biological Co., 6109 South Western Avenue, Los Angeles, Calif. 90047.

5. Dihydrostreptomycin Sulfate-Streptomycin Sulfate Solution Veterinary; each milliliter contains 250 milligrams of dihydrostreptomycin base (as dihydrostreptomycin sulfate) and 500 milligrams of streptomycin base (as streptomycin sulfate); by Maury Biological Co.

6. Dihydrostreptomycin Sulfate-Streptomycin Sulfate Solution Veterinary; each milliliter contains 125 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate) and 250 milligrams streptomycin base (as streptomycin sulfate); by Maury Biological Co.

7. Combistrep; each cubic centimeter contains 125 milligrams streptomycin base (as streptomycin sulfate), 125 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate), and 250 milligrams streptomycin base (as streptomycin sulfate); by Chas. Pfizer & Co., Inc.

The Academy evaluated these products as potential candidates for treatment of certain disease in cattle, horses, swine, dogs, cats, and turkeys when such disease conditions are caused by pathogens sensitive to streptomycin sulfate, and/or dihydrostreptomycin sulfate.

The Academy further stated:

1. Irritaiton resulting from subcutaneous use of these drugs should be detailed on the labeling.

2. Caution statements on the labeling should describe the neurotoxicity of streptomycin and/or dihydrostreptomycin.

3. Labeling should qualify the disease or conditions to which the drug is applicable. If the disease condition cannot be so qualified the claim must be dropped.

4. The correct frequency of administration of the drug should be stated on the labels.

5. The value of the synergism statement on the labels is questioned.

6. The dosages listed on the labels are inconsistent; the minimum dose for domestic mammals should provide 5 milligrams of drug per pound of bodyweight every 12 hours.

7. Labels should carry a warning statement pertaining to the development of streptomycin dihydrostreptomycin resistant microorganisms.

8. Terminology that tends to be misleading or that may be an overstatement of the activity of the drug should be deleted from the labeling.

9. The label dosages recommended for treatment of disease in poultry are not adequately documented.

10. The Food and Drug Administration concurs in the academy's findings.

This evaluation is concerned only with these drugs' effectiveness and safety to the animal to which administered. It does not take into account the safety for the food use of food derived from drug-treated animals. Nothing in this announcement will constitute a bar to further proceedings with respect to questions of safety of these drugs or their metabolites as residues in food products derived from treated animals.

This announcement is published to inform the holders of new animal drug applications of the findings of the academy and the Food and Drug Administration and to inform all interested persons that such articles to be marketed must be the subject of approved new animal drug applications and otherwise comply with all other requirements of the Federal Food, Drug, and Cosmetic Act.

Holders of new animal drug applications are provided 6 months from the date of publication to submit adequate documentation in support of the labeling use of these drugs.

Each holder of a new animal drug application which became effective prior to October 10, 1962, is requested to submit updating information as needed to make the application current with regard to manufacture of the drug, including information on drug components and composition, and also including information regarding manufacturing methods, facilities, and controls, in accordance with the requirements of section 512 of the act.

Written comments regarding this announcement, including requests for an informal conference, may be addressed to the Bureau of Veterinary Medicine, Food and Drug Administration, 6000 Fishers Lane, Rockville, Md. 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 512, 62 Stat. 1050-51, 82 Stat. 343-51; 21 U.S.C. 352, 360b) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 19, 1970.

R. E. DUGGAN,
Acting Associate Commissioner
for Compliance.

[FR Doc. 70-6531; Filed, June 30, 1970; 8:46 a.m.]

CERTAIN PENICILLIN-CONTAINING COMBINATION DRUGS

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following antibiotic drugs:

A. Benzathine Penicillin G with Procaine Penicillin G Injection, marketed as:
   1. Bicillin C-R Aqueous Suspension (NDA 50-138) and

B. Procaine Penicillin G with Sodium or Potassium Penicillin G for Injection, marketed as:
   1. Abbottcin 800 M for Suspension (NDA 60-519); Abbott Laboratories, 14th and Sheridan Road, North Chicago, Ill. 60064.
   2a. Duracillin Fortified Powder for Aqueous Suspension (NDA 60-015) and
   2b. Duracillin F.A. Powder for Aqueous Suspension (NDA 60-015); Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206.
   3. Pen Prudential for Aqueous Injection (NDA 60-204); Merck Sharp & Dohme Division, Merck and Co., Inc., West Point, Pa. 19486.
   4. Promacen for Aqueous Injection (NDA 60-021); Chas. Pfizer & Co., Inc., 253 East 42nd Street, New York, N.Y. 10017.