



# Notices

## DEPARTMENT OF STATE

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

Register of Voluntary Foreign Aid  
Agencies

In accordance with the regulations of the Agency for International Development concerning Registration of Agencies for Voluntary Foreign Aid (A.I.D. Regulation 3) 22 CFR, Part 203, promulgated pursuant to section 621 of the Foreign Assistance Act of 1961, as amended, notice is hereby given that a certificate of registration as a voluntary foreign aid agency has been issued by the Advisory Committee on Voluntary Foreign Aid of the Agency for International Development to the following agency:

Americans for Children's Relief, Inc., 49  
Greenwich Avenue, Greenwich, Conn.  
06830.

Dated: June 23, 1970.

HARRIET S. CROWLEY,  
Director,

Office for Private Overseas Programs.

[F.R. Doc. 70-8330; Filed, June 30, 1970;  
8:47 a.m.]

## DEPARTMENT OF THE INTERIOR

National Park Service

[Order No. 56]

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 F.R. 4591) is hereby revoked.

(Act of July 19, 1952; 66 Stat. 781)

Dated: June 19, 1970.

HARTHON L. BILL,  
Acting Director,  
National Park Service.

[F.R. Doc. 70-8318; Filed, June 30, 1970;  
8:48 a.m.]

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 0172 NV]

### 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. K & 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 ton.
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-hydroxyphenylarsonic acid.

The Academy classified these premixes as probably effective for faster gains and 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 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, 5600 Fishers Lane, Rockville, Md. 20852.

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

report. Any other interested person may obtain a copy by writing to the Food and Drug Administration, Press Relation Staff, 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 512, 52 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.

[F.R. Doc. 70-8313; Filed, June 30, 1970;  
8:46 a.m.]

[DESI 0024 NV]

### CERTAIN DIHYDROSTREPTOMYCIN AND STREPTOMYCIN CONTAINING DRUGS

#### Drugs for Veterinary Use; Drug Efficacy Study Implementation

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

1. Dihydrostreptomycin Sulfate Crystalline Solution; each cubic centimeter contains 400 milligrams dihydrostreptomycin base (as dihydrostreptomycin sulfate); by Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017.

2. Crystalline 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., 8514 Roosevelt Boulevard, Philadelphia, Pa. 19114.

4. Dihydrostreptomycin Sulfate Injection; each cubic centimeter contains 500, 400, or 250 milligrams of 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 250 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 125 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); by Chas. Pfizer & Co., Inc.

The Academy evaluated these products as probably effective for the 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. Irritation resulting from subcutaneous use of the 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 diseases to be treated as those caused by pathogens sensitive to streptomycin or dihydrostreptomycin. 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 micro-organisms.

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.

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 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 (1) to inform the holders of new animal drug applications 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.

Holders of new animal drug applications 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 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, 5600 Fishers Lane, Rockville, Md. 20852.

The holders of the new animal drug applications for the listed drugs have been mailed a copy of the NAS-NRC report. Any other interested person may obtain a copy by writing to the Food and Drug Administration, Press Relations Staff, 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 512, 52 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.

[F.R. Doc. 70-8311; Filed, June 30, 1970;  
8:45 a.m.]

[DESI 50125]

### 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

2. Bicillin P-A-B Aqueous Suspension (NDA 50-138); Wyeth Laboratories, Inc., Post Office Box 8299, Philadelphia, Pa. 19101.

B. Procaine Penicillin G with Sodium or Potassium Penicillin G for Injection, marketed as:

1. Abocillin 800 M for Suspension (NDA 60-019); Abbott Laboratories, 14th and Sheridan Road, North Chicago, Ill. 60064.

2a. Duracillin Fortified Powder for Aqueous Suspension (NDA 60-015); and  
b. Duracillin F.A. Powder for Aqueous Suspension (NDA 60-015); Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206.

3. Pen Produral for Aqueous Injection (NDA 60-204); Merck Sharp & Dohme Division, Merck and Co., Inc., West Point, Pa. 19486.

4. Pronapen for Aqueous Injection (NDA 60-021); Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017.