

Sept. 30, 1969). Although several of the improprieties and violations occurred within 1 year of the designation order, that order did not include a notice of apparent liability for a monetary forfeiture.

3. We believe that the public interest would best be served in this proceeding by our amending the designation order released September 30, 1969, to include a notice of apparent liability. The effect of this amendment will be to afford the Hearing Examiner and the Commission maximum flexibility in determining the appropriate sanction applicable to Mrs. Murphy if after the hearing any sanction is deemed to be warranted. It appears that Mrs. Murphy may be subject to a monetary forfeiture, totaling up to \$10,000 for operating her transmitter on an unauthorized site from July 31, to August 25, 1969. In Issue 3, Mrs. Murphy is specifically charged with this violation in contravention of section 319(a) of the Communications Act and §§ 1.533(a) (1) and 1.571 of the Commission's rules. We point out, in accord with WPPY Radio Broadcasters, Inc., FCC 70-650, released June 24, 1970, where we indicated that inclusion of a forfeiture notice would henceforth be a routine or standard procedure in hearings involving revocation or denial of renewal for alleged violations which also come within the purview of section 503(b) of the Act, that inclusion of the notice of apparent liability herein is not to be taken as in any way indicating what the initial or final disposition of the case should be. That judgment is of course to be made on the particular facts of this case.

4. *Accordingly, it is ordered*, That the petition for addition of a "Forfeiture Issue" filed May 26, 1970, by Cathryn C. Murphy is granted to the extent indicated herein; and the designation order (FCC 69-1025, released Sept. 30, 1970) is amended to include the following language which will serve as a notice of apparent liability for a monetary forfeiture:

If the Hearing Examiner should determine, in light of the evidence adduced pursuant to the foregoing issues, that the hearing record does not warrant denial of the renewal application, he shall make findings of fact as to whether any willful or repeated violations of the Communications Act or our rules, as specified in the amended designation order, has occurred within 1 year of the issuance of the amendment to the designation order and, if so, shall recommend to the Commission whether a forfeiture should be issued against the licensee in the amount of \$10,000 or some lesser sum pursuant to section 503(b) of the Communications Act.

Adopted: July 8, 1970.

Released: July 13, 1970.

FEDERAL COMMUNICATIONS
COMMISSION,¹
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 70-9177; Filed, July 16, 1970;
8:49 a.m.]

¹ Commissioner Bartley absent.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 0061NV]

BACITRACIN WITH OR WITHOUT PENICILLIN

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. Fortracin-25; each pound contains feed grade bacitracin methylene disalicylate equivalent to 25.0 grams bacitracin (master standard); by S. B. Penick & Co., Antibiotic Feed Division, 100 Church Street, New York, N.Y. 10007.

2. Bio-Best, B-100W; each ounce contains 6.25 grams of bacitracin activity; by Premier Malt Products, Inc., 1037 West McKinley Avenue, Milwaukee, Wis. 53201.

3. Baciferm-10; each pound contains feed grade zinc bacitracin equivalent to 10.0 grams of bacitracin (master standard); by Commercial Solvents Corp., 1331 South First Street, Terre Haute, Ind. 47802.

4. Baciferm-25; each pound contains feed grade zinc bacitracin equivalent to 25.0 grams of bacitracin (master standard); by Commercial Solvents Corp.

5. Baciferm-50; each pound contains feed grade zinc bacitracin equivalent to 40.0 grams bacitracin (master standard); by Commercial Solvents Corp.

6. Baciferm PB-10; each pound contains feed grade zinc bacitracin equivalent to 7.5 grams of bacitracin (master standard) and 2.5 grams of penicillin G master standard as procaine penicillin; by Commercial Solvents Corp.

7. Baciferm PB-25; each pound contains feed grade zinc bacitracin equivalent to 18.75 grams of bacitracin (master standard) and 6.25 grams of penicillin G master standard as procaine penicillin; by Commercial Solvents Corp.

8. Baciferm PB-50; each pound contains feed grade zinc bacitracin equivalent to 37.5 grams of bacitracin (master standard) and 12.5 grams of penicillin G master standard as procaine penicillin; by Commercial Solvents Corp.

9. Baciferm Soluble-50; each pound contains 50 grams of zinc bacitracin (master standard); by Commercial Solvents Corp.

10. Barker's Bartracin-50; each pound contains feed grade bacitracin methylene disalicylate equivalent to 50 grams of bacitracin (master standard); by Barker, Moore & Mein Co., Inc., Post Office Box 12, Lebanon, Pa. 17042.

11. Bartracin; each pound contains the equivalent of 10 grams of bacitracin activity (master standard) as bacitracin methylene disalicylate; by Barker, Moore & Mein Co., Inc.

12. Kemitracin-10; each pound contains 10 grams of bacitracin (from bac-

itracin methylene disalicylate); by Whitmoyer Laboratories, Inc., Myerstown, Pa. 17067.

13. Kemitracin-50; each pound contains 50 grams feed grade bacitracin (from bacitracin methylene disalicylate); by Whitmoyer Laboratories, Inc.

14. Aquatracin; each pound contains 25 grams of bacitracin (from bacitracin methylene disalicylate); by Whitmoyer Laboratories, Inc.

15. Bio-Best B-10; each pound contains bacitracin the equivalent of not less than 10.0 grams bacitracin (master standard); by Premier Malt Products, Inc.

16. Bio-Best B-20; each pound contains bacitracin the equivalent of not less than 20.0 grams bacitracin (master standard); by Premier Malt Products, Inc.

17. Bio-Best B-25; each pound contains bacitracin the equivalent of not less than 25.0 grams bacitracin (master standard); by Premier Malt Products, Inc.

18. Bio-Best B-40; each pound contains bacitracin the equivalent of not less than 40.0 grams of bacitracin (master standard); by Premier Malt Products, Inc.

19. Bio-Best B-50; each pound contains bacitracin the equivalent of not less than 50.0 grams of bacitracin (master standard); by Premier Malt Products, Inc.

20. Bio-Best B-100; each pound contains not less than 100 grams of bacitracin (master standard); by Premier Malt Products, Inc.

21. Kem-Pen-10; each pound contains 7.5 grams bacitracin (from bacitracin methylene disalicylate) and 2.5 grams penicillin (from procaine penicillin); by Whitmoyer Laboratories, Inc.

The Academy evaluated these products as probably effective for the growth claims in poultry and probably not effective for the growth claim in swine or for the therapeutic claims. The Academy stated:

1. Claims made regarding "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of."

2. Each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)." If the disease cannot be so qualified the claim must be dropped.

3. The disease claims for these preparations must be restricted to diseases involving the gastrointestinal tract because of the chemical and pharmacologic properties of bacitracin.

4. Only by controlling pathogenic microorganisms may the use of this product aid in maintaining egg production and hatchability.

5. Claims for growth promotion or stimulation are disallowed and 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." This is applicable to use in poultry.

6. The references regarding swine growth are inadequate and more information is needed.

7. Each active ingredient in a preparation containing more than one drug must be effective, or contribute to the effectiveness of the preparation, to warrant acceptance as an active ingredient.

8. The manufacturer's label should warn that treated animals must actually consume enough medicated water or medicated feed to provide a therapeutic dose under the conditions that prevail. As a precaution, the label should state the desired oral dose per unit of animal weight per day for each species as a guide to effective use of the preparation in drinking water or feed.

9. For poultry, it is recommended that a minimum of 25 grams of bacitracin per ton of complete feed is necessary for improving rate of gain and/or feed efficiency.

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

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 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 manufacturers of 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 29, 1970.

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

[F.R. Doc. 70-9133; Filed, July 16, 1970;
8:45 a.m.]

[DESI 6034V]

CERTAIN DRUG PRODUCTS CONTAINING SULFAMETHAZINE

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 American Cyanamid Co., Agricultural Division, Post Office Box 400, Princeton, N.J. 08540:

1. Sodium Sulfamethazine Solution, 25 percent; contains 250 milligrams of sodium sulfamethazine per milliliter or 7.5 grams of sodium sulfamethazine per ounce.

2. Sulmet Soluble Powder; contains 99 percent of sodium sulfamethazine.

3. Sulmet Olets; each olet contains 2.5 grams or 5 grams of sulfomethazine.

4. Sulfamethazine Olets; each olet contains 15 grams of sulfamethazine.

5. Sulmet Drinking Water Solution 12.5 percent; contains 125 milligrams of sodium sulfamethazine per milliliter or 3.75 grams of sodium sulfamethazine per ounce.

The Academy evaluated these oral veterinary preparations as probably effective for infectious diseases caused by organisms sensitive to sulfamethazine. The Academy stated: (1) Each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)"; if the disease claim cannot be so qualified the claim must be dropped; (2) the claim for coccidiosis should be qualified by listing the species for each respective host; (3) claims made regarding "for prevention" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of"; (4) the labels should warn that treated animals must actually consume enough medicated water or medicated feed to provide a therapeutic dose under the conditions that prevail; as a precaution that labels should state the desired oral dose per unit of animal weight per day for each species as a guide to effective use of the preparations in drinking water or feed; (5) there is need for

documentation of blood and tissue concentrations of the drug when used at the recommended dosage levels in order to establish efficacy of the bacterial disease claims; and (6) evidence should be furnished to demonstrate that the olets disintegrate in the gastrointestinal tract of the medicated species to produce the desired therapeutic effect.

The Food and Drug Administration concurs with 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 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 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 may be marketed provided they are 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 hereof 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 holder of the new animal drug application for 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 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: July 6, 1970.

SAM D. FINE,
Acting Associate Commissioner
for Compliance.

[F.R. Doc. 70-9134; Filed, July 16, 1970;
8:45 a.m.]