

If such persons elect to avail themselves of the opportunity for a hearing, they must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug application should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their opposition. 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 in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, 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 response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence (35 F.R. 7250, May 8, 1970; 35 F.R. 16631, Oct. 27, 1970).

Received requests for a hearing and/or elections not to request a hearing may be seen in the office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10253 Filed 7-5-72; 8:47 am]

[DESI 50417]

CERTAIN COMBINATION ANTIBIOTIC PREPARATIONS FOR OPHTHALMIC USE

Drugs for Human Use; Drug Efficacy Study Implementation; Classification and Labeling

In a notice (DESI 50417) published in the FEDERAL REGISTER of August 28, 1971 (36 F.R. 17372) the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs (other drugs were also included in that notice, and an order concerning them is published elsewhere in this issue of the FEDERAL REGISTER):

1. Preparations containing neomycin sulfate, polymyxin B sulfate, and gram-

cidin. a. Neo-polycin ophthalmic solution; the Dow Chemical Co., P.O. Box 10, Zionsville, Ind. 46077 (NDA 60-427).

b. Neosporin ophthalmic solution; Burroughs Wellcome & Co., 3030 Cornwallis Road, Research Triangle Park, N.C. 27709 (NDA 60-582).

2. Preparations containing bacitracin, neomycin sulfate, and polymyxin B sulfate. a. Mycitracin ophthalmic ointment; the Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49001 (NDA 61-048).

b. Polymyxin B-bacitracin-neomycin ophthalmic ointment; Pfizer Laboratories Division, Pfizer Inc., 235 East 42d Street, New York, N.Y. 10017 (NDA 60-281).

c. Neo-polycin ophthalmic ointment; the Dow Chemical Co. (NDA 60-647).

d. Bacitracin-neomycin-polymyxin B ophthalmic ointment; Biocraft Laboratories, Inc., 92 Route 46, East Paterson, N.J. 07407 (NDA 60-965).

3. Preparations containing zinc bacitracin, neomycin sulfate, and polymyxin B sulfate. a. Neosporin ophthalmic ointment; Burroughs Wellcome & Co. (NDA 50-417).

b. Polymyxin B-bacitracin-neomycin ophthalmic ointment; Day-Baldwin, Inc., 1460 Chestnut Avenue, Hillside, N.J. 07205 (NDA 61-078).

c. Bacitracin-polymyxin-neomycin ophthalmic ointment; Kasco Laboratories, Inc., Hicksville, N.Y. 11820 (NDA 60-764).

The notice stated that the drugs were regarded as possibly effective for their labeled indications related to use in superficial ocular infections and lacking substantial evidence of effectiveness for their other labeled indications.

Based upon a reevaluation of the preparations listed above, the Commissioner finds it appropriate to amend the announcement of August 28, 1971, by:

1. Changing the evaluation from possibly effective to effective for indications related to use in superficial ocular infections.

2. Setting forth labeling guidelines.

The labeling guidelines are as follows:

DESCRIPTION

(Descriptive information to be included by the manufacturer or distributor should be confined to an appropriate description of the physical and chemical properties of the drug and formulation.)

ACTIONS

As appropriate to the particular preparation:

Bacitracin, an antibiotic substance derived from cultures of *Bacillus subtilis* (Tracey), exerts antibacterial action in vitro against a variety of gram-positive and a few gram-negative organisms.

Neomycin, isolated from *Streptomyces fradiae*, has antibacterial activity in vitro against a wide range of gram-negative and gram-positive organisms, with effectiveness against many strains of *Proteus*.

Polymyxin B is one of a group of closely related substances produced by various strains of *Bacillus polymyxa*. Its activity is sharply restricted to gram-negative bacteria, including many strains of *Pseudomonas aeruginosa*.

Gramicidin has particular action in vitro against certain gram-positive bacteria.

INDICATIONS

This product is indicated in the short term treatment of superficial external ocular infections caused by organisms susceptible to one or more of the antibiotics contained therein.

CONTRAINDICATIONS

This product is contraindicated in those persons who have shown sensitivity to any of its components.

WARNINGS

Prolonged use may result in overgrowth of nonsusceptible organisms.

PRECAUTIONS

Culture and susceptibility testing should be performed during treatment.

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, gentamycin, streptomycin, and possibly gentamicin.

ADVERSE REACTIONS

Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin.

DOSAGE AND ADMINISTRATION

(To be provided by the manufacturer or distributor as appropriate to the particular preparation.)

Batches of such drugs for which certification or release is requested should provide for labeling information in accord with the guidelines set forth above.

This notice is issued pursuant to the 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 the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10246 Filed 7-5-72; 8:46 am]

[DESI 50254]

CERTAIN OPHTHALMIC AND/OR OTIC PREPARATIONS CONTAINING TETRACYCLINE HYDROCHLORIDE OR CHLORTETRACYCLINE HYDROCHLORIDE

Drugs for Human Use; Drug Efficacy Study Implementation; Follow-Up Notice

In a notice (DESI 50254) published in the FEDERAL REGISTER of July 17, 1971 (36 F.R. 13284), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following ophthalmic and/or otic preparations.

1. Tetracycline hydrochloride eye and ear ointment; Day-Baldwin, Inc., 1460 Chestnut Avenue, Hillside, N.J. 07205 (NDA 60-316).