

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a written appearance requesting the hearing, giving the reasons why approval of the new drug application should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their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).

NOTICES

[DESI 8278]

PHENTOLAMINE MESYLATE FOR INJECTABLE USE AND PHENTOLAMINE HYDROCHLORIDE FOR ORAL USE**Drugs for Human Use; Drug Efficacy Study Implementation Followup Notice**

In a notice published in the FEDERAL REGISTER of April 6, 1971 (36 F.R. 6531), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs marketed by Ciba Pharmaceutical Co., division of Ciba-Geigy Corp., 556 Morris Avenue, Summit, NJ 07901:

1. Regitine Lyophilized Powder for Injection containing phentolamine mesylate, and

2. Regitine Tablets containing phentolamine hydrochloride (NDA 8-278).

The notice stated that the drugs were regarded as effective, probably effective, and possibly effective for their various labeled indications. The indications classified as probably effective and possibly effective have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drug has been submitted pursuant to the notice of April 6, 1971. Ciba Pharmaceutical Co., holder of the only new drug application for these drugs supplemented the application to delete from labeling all indications other than those regarded as effective and the supplements have been approved.

Any such preparations, for human use, introduced into interstate commerce after 60 days following publication of this notice in the FEDERAL REGISTER with labeling bearing indications for which the drugs lack substantial evidence of effectiveness, may be subject to regulatory proceedings.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 23, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10254 Filed 7-5-72; 8:47 am]

[Docket No. FDC-D-485]

DIAMOND LABORATORIES, INC.**Cilopen Powder; Notice of Drug Deemed Adulterated**

In an announcement in the FEDERAL REGISTER of July 17, 1970 (35 F.R. 11533, DESI 0072NV), the Commissioner of Food and Drugs announced the conclusions of the Food and Drug Administration following evaluation of a report

received from the National Academy of Sciences—National Research Council Drug Efficacy Study Group, on Cilopen Powder. Said announcement provided Diamond Laboratories, Inc., 2538 Southeast 43d Street, Des Moines, Iowa 50303, and all interested parties a 6-month period in which to submit new animal drug applications.

Diamond Laboratories, Inc. did not submit a new animal drug application for the above named product within the 6-month period.

On the basis of the foregoing and the information before him the Commissioner concludes that Cilopen Powder is adulterated within the meaning of section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act in that it is not the subject of an approved new animal drug application pursuant to section 512 of the act. Therefore, notice is given to Diamond Laboratories, Inc., and all other interested persons that all stocks of said drug within the jurisdiction of the Federal Food, Drug, and Cosmetic Act are deemed adulterated within the meaning of the act and are subject to appropriate regulatory action.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 501(a)(5), 512, 52 Stat. 1049 as amended, 82 Stat. 343-51; 21 U.S.C. 351(a)(5), 360b) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10261 Filed 7-5-72; 8:48 am]

[DESI 5590; Docket No. FDC-D-380;
NDA 5-590]

PARKE, DAVIS & CO.**Synapoidin Steri-Vial; Notice of Withdrawal of Approval of New Drug Application**

On October 27, 1971, there was published in the FEDERAL REGISTER (36 F.R. 20619) a notice of opportunity for hearing (DESI 5590) in which the Commissioner of Food and Drugs proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the following new drug application on the basis that the drug is not shown to be safe for use and that substantial evidence of effectiveness is lacking.

NDA 5-590, Synapoidin Steri-Vial containing pituitary-chorionic gonadotropins; Parke, Davis & Co., Joseph Campau Avenue at the River, Detroit, Mich. 48232.

Neither Parke, Davis & Co. nor any other interested person have filed a written appearance of election as provided by said notice. The failure to file such an appearance is construed as an election by such persons not to avail themselves of the opportunity for a hearing.

2. Achromycin ophthalmic oil suspension containing tetracycline hydrochloride; Lederle Laboratories Division, American Cyanamid Co., Pearl River, N.Y. 10965 (NDA 50-268).

3. Achromycin ophthalmic sterilized powder for solution containing tetracycline hydrochloride, sodium chloride, and sodium borate; Lederle Laboratories (NDA 50-267).

4. Achromycin eye and ear ointment containing tetracycline hydrochloride; Lederle Laboratories (NDA 50-266).

5. Aureomycin ophthalmic sterilized powder for solution containing chlortetracycline hydrochloride, sodium borate, and sodium chloride; Lederle Laboratories (NDA 50-254).

6. Aueromycin ophthalmic ointment containing chlortetracycline hydrochloride, Lederle Laboratories (NDA 50-404).

The notice stated that the drugs were regarded as effective and possibly effective for their labeled indications.

The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness has been submitted pursuant to the notice of July 17, 1971.

Batches of such drugs with labeling bearing indications for which substantial evidence of effectiveness is lacking are no longer acceptable for certification or release.

Any person who will be adversely affected by the deletion from labeling of the indications for which the drugs have been reclassified from possibly effective to lacking substantial evidence of effectiveness may, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, petition for the issuance of a regulation providing for other certification of the drug for such indications. The petition must be supported by a full factual and well documented medical analysis which shows reasonable grounds for the issuance of such regulation.

A petition for issuance of said regulation 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.

This notice is issued 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 of Food and Drugs (21 CFR 2.120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner for
Compliance.

[FR Doc.72-10255 Filed 7-5-72; 8:47 am]