

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]