

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]

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended, 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that: (1) New evidence of clinical experience, not contained in the new drug application or not available to the Commissioner until after the application was approved, evaluated together with the evidence available to him when the application was approved, reveals that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved. The use of gonadotropins of animal origin entails the risk of eliciting the formation of antibodies to their animal protein content so that allergic reactions may be produced by their use. Other drugs are available which are of benefit and involve less risk; and (2) new information, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, pursuant to the foregoing findings, approval of the above new drug application, and all amendments and supplements applying thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-6-72).

Dated: June 23, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10263 Filed 7-5-72; 8:48 am]

[DESI 6205; Docket No. FDC-D-425;
NDA 6-205]

PARKE, DAVIS & CO.

Tetraethylammonium Chloride Injection, Notice of Withdrawal of Approval of New Drug Application

A notice was published in the FEDERAL REGISTER of February 12, 1972 (37 F.R. 3201), extending to Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232 and to any interested person who may be adversely affected, an opportunity for hearing on the proposal of the Commissioner of Food and Drugs to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of NDA 6-205 for Etamon Chloride Steri-Vial (tetraethylammonium chloride). The basis of the proposed action was the lack of substantial evidence that the drug is effective for its labeled indications.

Neither the holder of the application nor any other person filed a written appearance of election within the 30 days provided by said notice. The failure to file such an appearance is construed as an election by such persons not to avail themselves of an opportunity for hearing. The Commissioner of Food and Drugs

pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that on the basis of new information before him with respect to the drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of new drug application No. 6-205 and all amendments and supplements thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-6-72).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10262 Filed 7-5-72; 8:48 am]

SCHERING A.G.

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 2B2801) has been filed by Schering A.G., 4619 Bergkamen, Postfach 15, Waldstrasse 14, West Germany, proposing that § 121.2602 *Octyltin stabilizers in vinyl chloride plastics* be amended; (1) By revising the specifications for the intermediate, di(*n*-octyl) tin dichloride, to allow for the presence of not more than 5 percent by weight total of higher (>C₈) alkyltin derivatives and (2) by providing for the use of di(*n*-octyl) tin oxide, the product of the intermediate di(*n*-octyl) tin dichloride, as an intermediate in the manufacture of octyltin stabilizers.

Dated: June 27, 1972.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc. 72-10265 Filed 7-5-72; 8:48 am]

[DESI 8089; Docket No. FDC-D-482; NDA 8-089]

WINTHROP LABORATORIES

Glycobiarsol With Chloroquine Phosphate; Notice of Withdrawal of Approval of New Drug Application

In an announcement (DESI 8089) published in the FEDERAL REGISTER of February 19, 1972 (37 F.R. 3779) the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Milibis with Aralen Phosphate Tablets (NDA 8-089) containing glycobiarsol and chloroquine phosphate. The announce-

ment stated that there is a lack of substantial evidence that the drug is effective as a fixed combination for its labeled indications, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug application providing for this drug. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. No such data have been received. Winthrop Laboratories, Div. of Sterling Drug, Inc., 90 Park Avenue, New York, N.Y. 10016, holder of the new drug application has voluntarily requested withdrawal of approval of their application, thereby waiving their opportunity for a hearing, stating that the drug is no longer marketed.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of the above new drug application, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-6-72).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10264 Filed 7-5-72; 8:48 am]

Office of the Secretary

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION; OCCUPATIONAL SAFETY AND HEALTH

Requests for Information on Certain Suspected Carcinogenic Substances

Section 20(a)(3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(3)) provides that the Secretary of Health, Education, and Welfare, on the basis of information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment. Section 22(c) of the act authorizes the National Institute for Occupational Safety and Health to develop recommended occupational safety and health standards and to perform all functions of the Secretary of Health, Education, and Welfare, under sections 20 and 21 of the act. The Institute is considering the development of criteria documents and recommended occupational health standards for a number of known and suspected carcinogenic substances including: