

Ill. 60606, has withdrawn its petition (FAP 1A2688), notice of which was published in the FEDERAL REGISTER of June 22, 1971 (36 F.R. 11875), proposing the issuance of a food additive regulation (21 CFR Part 121) to provide for the safe use of glycine as a flavor-masking agent for saccharin in sugar substitutes for table use.

Dated: January 27, 1972.

VIRGIL O. WODICKA,
Director,
Bureau of Foods.

[FR Doc.72-1962 Filed 2-9-72; 8:52 am]

[Docket No. FDC-D-269; various NDAs]

REXALL DRUG CO.

New-Drug Application; Notice of Withdrawal of Approval

A notice of opportunity for hearing was published in the FEDERAL REGISTER of January 13, 1971 (36 F.R. 454), on a proposal to issue an order under the provision of section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of new-drug application No. 9-430 and all amendments and supplements thereto held by Rexall Drug Co., 3901 North Kingshighway, St. Louis, Missouri 63115, for the drug R.D. Reserpine Tablets.

Rexall Drug Co. filed a letter requesting an extension of the time permitted to request a hearing and requested further information on the new-drug application. Subsequently, the firm filed a letter stating they had not distributed reserpine tablets under NDA 9-430 for a number of years, were voluntarily recalling the application and thereby waived opportunity for a hearing.

Therefore, 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 the Commissioner of Food and Drugs (21 CFR 2.120), approval of new-drug application No. 9-430, including all amendments and supplements thereto, is hereby withdrawn on the grounds that the applicant has failed to make reports under section 505(j) of the Act (21 U.S.C. 355(j)) and §§ 130.13 and 130.35 (e) and (f) of the new-drug regulations (21 CFR 130.13 and 130.35).

This order shall become effective on its date of publication in the FEDERAL REGISTER (2-10-72).

Dated: January 28, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-1961 Filed 2-9-72; 8:52 am]

[DESI 8530; Docket No. FDC-D-141; NDA Nos. 10-613 and 8-530]

WINTHROP PRODUCTS, INC., AND WINTHROP LABORATORIES

Alevaire; Notice of Reconsideration of Requests for Hearing

On September 11, 1971, there was published in the FEDERAL REGISTER (36 F.R.

18336) a final order denying requests for hearing and withdrawing approvals of new-drug applications Nos. 10-613 and 8-530 on the grounds that there is a lack of substantial evidence that the drug, Alevaire, is effective for its recommended uses.

After preparation of the order, but prior to its publication in the FEDERAL REGISTER, additional data in support of requests for hearing were submitted to the Food and Drug Administration. Due to inadvertence, these data were not considered prior to publication of the final order.

Sterling Drug, Inc., Winthrop Products, Inc., and Breon Laboratories, Inc. petitioned for judicial review of the order in the U.S. Court of Appeals for the Second Circuit. On January 11, 1972, the court, upon application of the Secretary of Health, Education, and Welfare and the Commissioner of Food and Drugs, set aside the order and remanded the proceedings to the Food and Drug Administration for reconsideration of the requests for hearing in light of the data not considered.

Therefore, the Commissioner, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505 (f) and (h), 52 Stat. 1052, as amended; 21 U.S.C. 355 (f) and (h)) and under authority delegated to him (21 CFR 2.120), hereby gives notice that the order denying a hearing and withdrawing approvals of new-drug applications for Alevaire is set aside to allow reconsideration of the requests for hearing and approvals of such applications are reinstated.

Dated: February 2, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-1963 Filed 2-9-72; 8:52 am]

[Docket No. FDC-D-416; NDA No. 6-813]

CARAMIPHEN HYDROCHLORIDE

Certain Antiparkinson Drug; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

In a notice (DESI 6813) published in the FEDERAL REGISTER of August 26, 1970 (35 F.R. 13601) 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 the drug described below, stating that the drug is regarded as possibly effective for the various labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drug has been submitted within the period provided.

NDA 6-813; Panparnit Tablets containing 12.5 or 50 milligrams caramiphen hydrochloride; Gelgy Chemical Corp., Saw Mill River Road, Ardsley, N.Y. 10502.

Therefore, notice is given to Gelgy Chemical Corp., and to any interested person who may be adversely affected,

that the Commissioner proposes 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 listed new drug application and all amendments and supplements thereto on the grounds that new information before him with respect to the drug, 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 all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the applicant, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new drug application should not be withdrawn. Any related drug for human use not the subject of an approved new drug application, may be affected by this action.

Within 30 days after publication hereof in the FEDERAL REGISTER, such persons are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or
2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the new drug application. Failure of such persons to file a written appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

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 applications 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: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-1999 Filed 2-9-72;8:53 am]

[DESI 11498; Docket No. FDC-D-427;
NDA No. 11-498]

CIBA PHARMACEUTICAL CO.

Domiphen Bromide-Benzocaine Lozenges; Notice of Withdrawal of Approval of New Drug Application

In an announcement (DESI 11498) published in the FEDERAL REGISTER on March 28, 1970 (35 F.R. 5278), 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 Bradosol Lozenges (NDA 11-498) containing domiphen bromide and benzocaine; Ciba Pharmaceutical Co., 556 Morris Avenue, Summit, N.J. 07901. The announcement stated that there is a lack of substantial evidence that the drug will have the effects it purports or is represented to have under the conditions of use recommended in its labeling.

Ciba Pharmaceutical Co., holder of NDA 11-498 Bradosol Lozenges has requested withdrawal of approval of their new drug application and thereby waived their opportunity for a hearing, stating that marketing of the drug was discontinued in January 1970.

The Commissioner of Food and Drugs, pursuant to the 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 the authority delegated to him (21 CFR 2.120) finds 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, 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 its labeling.

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

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2000 Filed 2-9-72;8:53 am]

[Docket No. FDC-D-419; NDA No. 6-969]

ENDO LABORATORIES, INC.

Arsthinol Tablets; Notice of Withdrawal of Approval of New Drug Application

In the FEDERAL REGISTER of May 22, 1971 (36 F.R. 9342), the Commissioner announced (DESI 6969) his conclusions pursuant to evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, concerning the following drug for oral use:

NDA 6-969; Balarsen Tablets containing arsthinol; Endo Laboratories, Inc., 1000 Stewart Avenue, Garden City, Long Island, N.Y. 11533.

The announcement stated that the drug was regarded as possibly effective for the labeled indications. Six months from the date of that publication were allowed for the holder of the application and any person marketing such drug without approval to obtain and submit data providing substantial evidence of effectiveness of the drug. No such data have been received and the holder of said new drug application has stated that marketing of the drug was discontinued in 1966, requested withdrawal of approval of the application and thereby has waived opportunity for a hearing.

The Commissioner of Food and Drugs, pursuant to the 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 said 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 findings, approval of the above-listed new drug application (NDA 6-969), and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER.

Dated: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2001 Filed 2-9-72;8:53 am]

[DESI 4]

HYDROXYAMPHETAMINE HYDROBROMIDE

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

In a notice [DESI 4] published in the FEDERAL REGISTER of June 23, 1970 (35 F.R. 10237), 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 concerning Paredrine (hydroxyamphetamine hydrobromide) 1 percent with Boric Acid ophthalmic solution; Smith Kline and French Laboratories, 1500 Spring Garden Street, Philadelphia, Pa. 19101 (NDA 0-004). The announcement stated that this drug was regarded as effective for use in the production of mydriasis; and possibly effective when used adjunctively to help induce a rapid and satisfactory cycloplegia.

The indication for which the drug was regarded as possibly effective was allowed to be used for 6 months following the publication date (June 30, 1970) of the announcement to allow additional time for submission of data supporting the efficacy of the drug for this indication.

The time for submission of additional evidence has expired, and no additional evidence has been submitted in support of the possibly effective indication. Smith Kline and French Laboratories has supplemented their new drug application to delete any indication other than the effective indication.

Accordingly, the Commissioner of Food and Drugs finds that there is a lack of substantial evidence that hydroxyamphetamine hydrobromide is effective when used adjunctively to help induce a rapid and satisfactory cycloplegia. Therefore, this indication is no longer acceptable in labeling.

Any such preparation on the market with labeling bearing indications for which substantial evidence of effectiveness is lacking may be subject to regulatory proceedings.

This notice is issued pursuant to 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: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2003 Filed 2-9-72;8:54 am]

[Docket No. FDC-D-342; NDA 12-663]

WYETH LABORATORIES

Spartase Tablets; Notice of Withdrawal of Approval of New Drug Application

A notice was published in the FEDERAL REGISTER of July 23, 1971 (36 F.R. 13696),