

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),