

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),

extending to Wyeth Laboratories, Inc., Post Office Box 8299, Philadelphia, Pa. 19101 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 12-663 for Spartase Tablets (potassium and magnesium aspartates). 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. 12-663 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.72-2002 Filed 2-9-72;8:53 am]

## ATOMIC ENERGY COMMISSION

[Docket No. 50-253]

### GULF ENERGY & ENVIRONMENTAL SYSTEMS CO.

#### Notice of Issuance of Amendment to Facility License

The Atomic Energy Commission (the Commission) has issued, effective as of the date of issuance, Amendment No. 5 to Facility License No. R-105 dated March 7, 1967. The license presently authorizes Gulf Energy & Environmental Systems Co. to possess, use and operate the Accelerator Pulsed Fast Critical Assembly (APFA-III) located at the Torrey Pines Mesa site near San Diego, Calif. The amendment extends the expiration date to January 31, 1974.

The Commission has found that the application for the amendment complies with the requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations

published in 10 CFR Ch. I. The Commission has made the findings required by the Act and the Commission's regulations which are set forth in the amendment, and has concluded that the issuance of the amendment will not be inimical to the common defense and security or to health and safety of the public. The Commission has also found that prior public notice of this amendment is not required since the amendment does not present significant hazards considerations different from those previously evaluated.

Within fifteen (15) days from the date of publication of the notice in the FEDERAL REGISTER, the applicant may file a request for a hearing and any person whose interest may be affected by this proceeding may file a petition for leave to intervene. Requests for a hearing and petitions to intervene shall be filed in accordance with the Commission's rules of practice in 10 CFR Part 2. If a request for a hearing or a petition for leave to intervene is filed within the time prescribed in this notice, the Commission will issue a notice of hearing or an appropriate order.

For further details with respect to this amendment, see (1) the licensee's application for license amendment dated December 15, 1971, and (2) the amendment to facility license, which are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. A copy of the amendment may be obtained upon request sent to the Atomic Energy Commission, Washington, D.C. 20545, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Md., this 27th day of January 1972.

For the Atomic Energy Commission.

DONALD J. SKOVHOLT,  
Assistant Director for Reactor  
Operations, Division of Reactor  
Licensing.

[FR Doc.72-1998 Filed 2-9-72;8:53 am]

[Docket No. 50-192]

## UNIVERSITY OF TEXAS

### Notice of Issuance of Facility License Amendment

The Atomic Energy Commission (the Commission) has issued, effective as of the date of issuance, Amendment No. 8 to Facility License No. R-92 dated February 20, 1968. The license authorizes The University of Texas to possess, use and operate a TRIGA Mark I nuclear reactor located on the University's campus at Austin, Tex., at power levels up to 250 kilowatts (thermal). The amendment extends the expiration date of the license from February 12, 1972, to February 12, 1976, in accordance with the University's application dated January 11, 1972.

The Commission has found that the application for the amendment dated January 11, 1972, complies with the requirements of the Atomic Energy Act of

1954, as amended (the Act), and the Commission's regulations published in 10 CFR Ch. I. The Commission has made the findings required by the Act and the Commission's regulations and has concluded that the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public. The Commission has also found that prior public notice of this amendment is not required since the amendment does not involve significant hazards considerations different from those previously evaluated.

Within 15 days from the date of publication of the notice in the FEDERAL REGISTER, the applicant may file a request for a hearing and any person whose interest may be affected by this proceeding may file a petition for leave to intervene. Requests for a hearing and petitions to intervene shall be filed in accordance with the Commission's rules of practice in 10 CFR Part 2. If a request for a hearing or a petition for leave to intervene is filed within the time prescribed in this notice, the Commission will issue a notice of hearing or an appropriate order.

For further details with respect to this amendment, see (1) the licensee's application for license amendment dated January 11, 1972, and (2) the amendment to the facility license, both of which are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. A copy of item (2) above may be obtained upon request sent to the U.S. Atomic Energy Commission, Washington, DC 20545, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Md., this 27th day of January 1972.

For the Atomic Energy Commission.

DONALD J. SKOVHOLT,  
Assistant Director for Reactor  
Operations, Division of Reactor  
Licensing.

[FR Doc.72-1915 Filed 2-9-72;8:47 am]

[Docket No. 50-271]

## VERMONT YANKEE NUCLEAR POWER CORP.

### Order Setting Dates for Further Sessions of Evidentiary Hearings

In the matter of Vermont Yankee Nuclear Power Corp. (Vermont Yankee Nuclear Power Station), Docket No. 50-271.

At an evidentiary session of hearings convened on January 31 and February 1, 1972, consideration was given to requests by Applicant for further sessions of hearings. Applicant requested two sessions each of 2 weeks duration in March and April. After a consideration of schedules, the Atomic Safety and Licensing Board has granted the request of Applicant by providing for two sessions of 1 week each, contemplating more than the usual hours of hearing for each day's session. In addition, Applicant requested that a