

acetaminophen. The announcement stated that there is a lack of substantial evidence that the drug is effective as a fixed combination for its various claims, a lack of evidence that the claimed benefits outweigh the risks of administration of a phenothiazine derivative for symptoms related to the common cold, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug application for the drug. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. There has been no response.

Therefore, notice is given to Smith, Kline and French Laboratories, 1500 Spring Garden Street, Philadelphia, PA 19101, holder of NDA 12-467 for Coplex Liquid, 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 said 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 lack of substantial evidence that the drug will have the effects its purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the 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withdrawing such approval, an opportunity for a hearing to show why approval of the new drug application should not be withdrawn.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, un-

less 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 application and from the reasons and factual analysis in the request for a 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. 7, 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. 72-2132 Filed 2-11-72; 8:50 am]

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

**PARKE, DAVIS AND CO.**

**Tetraethylammonium Chloride Injection; Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application**

In a notice (DESI 6205) published in the FEDERAL REGISTER of October 15, 1970 (35 F.R. 16195) 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 and lacking substantial evidence of effectiveness 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 6-205; Etamon Chloride Sterile Vial containing Tetraethylammonium chloride; Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232.

Therefore, notice is given to Parke, Davis & Co., 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 an 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 application 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.72-2137 Filed 2-11-72;8:51 am]

[Docket No. FDC-D-417; NDA 11-577]

#### UPJOHN CO.

#### Ectylurea for Oral Use; Notice of Withdrawal of Approval of New Drug Application

In the FEDERAL REGISTER of June 25, 1970 (35 F.R. 10394), the Commissioner of Food and Drugs announced (DESI 6566) 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:

Levanil Tablets containing ectylurea; The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002 (NDA 11-577).

The announcement stated that the drug was regarded as either lacking substantial evidence of effectiveness or possibly effective for the various 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 for the possibly effective indications. No such data have been

received and the holder of said new drug application has requested withdrawal of approval of its new drug 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 finding, approval of new drug application No. 11-577, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (2-12-72).

Dated: February 3, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-2134 Filed 2-11-72;8:50 am]

[Docket No. FDC-D-348; NDA 9-922]

#### VITAMIX PHARMACEUTICALS INC.

#### Pyrilamine Maleate—Dextroamphetamine Hydrochloride Injection; Notice of Withdrawal of Approval of New Drug Application

On July 23, 1971, there was published in the FEDERAL REGISTER (36 F.R. 13697) a notice of opportunity for hearing (DESI 9922) 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 new drug applications NDA 9-922, Dexa-Pyramine Injection; Vitamix Pharmaceuticals, Inc., Division Wynn Pharmaceuticals, Inc., 2900 North 17th Street, Philadelphia, PA 19132, in the absence of substantial evidence that the drug is effective as a fixed combination for the conditions of use recommended in its labeling.

Neither the holder of the new drug application nor any other interested person has 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.

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 evi-

dence that Dexa-Pyramine Injection 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 new drug application, and all amendments and supplements thereto, is withdrawn effective on the date of publication of this document (2-12-72).

Dated: January 28, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-2139 Filed 2-11-72;8:51 am]

[Docket No. FDC-D-352; NDA 10-522, etc.]

#### WILSON LABORATORIES ET AL.

#### Trypsin or Chymotrypsin Injection and Ointment; Notice of Withdrawal of Approval of New Drug Applications

On August 28, 1971, there was published in the FEDERAL REGISTER (36 F.R. 17371) a notice of opportunity for hearing 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 new drug applications listed below in the absence of substantial evidence that the drugs have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

NDA No.	Drug name	NDA holder
11-882	Chymotrypsin Injection.	The Wilson Laboratories, Division of Wilson Pharmaceutical and Chemical Corp., 4221 South Western Ave., Chicago, IL. 60609.
11-883	Trypsin Injection...	Do.
12-743	Chymotrypsin Injection.	North American Pharmacal, 6851 Chase Rd., Dearborn, MI. 48126. (The former holder was Chicago Pharmacal Inc., Division of Conal Pharmaceuticals.)
10-779	Enzeon (chymotrypsin) Injection.	Breon Laboratories, Inc., Division Sterling Drug, Inc., 90 Park Ave., New York, NY 10016.
10-522	Parenzyme Aqueous Injection containing trypsin.	National Drug Co., Division of Richardson-Merrell, Inc., 4663 Stanton Ave., Philadelphia, PA. 19144.
11-252	Parenzyme Ointment containing trypsin chymotrypsin and aminacrine hydrochloride.	Do.

The Wilson Laboratories, by letter of October 8, 1971, elected not to avail itself of the opportunity for a hearing concerning NDA Nos. 11-882 and 11-883, stating that marketing of the drugs had been discontinued.

Neither the holders of the other new drug applications listed above nor any other interested person have filed a written appearance of election as provided by said notice. The failure to file such