

should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their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 Pharnacal, 6851 Chase Rd., Dearborn, MI. 48126. (The former holder was Chicago Pharnacal 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

DESI 1010