

should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their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

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 each of said drugs, evaluated together with the evidence available to him when each application was approved, that there is a lack of substantial evidence that each of the drugs 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 applications, and all amendments and supplements thereto, is withdrawn effective on the date of publication of this document (2-12-72).

Dated: February 2, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-2138 Filed 2-11-72; 8:51 am]

[DESI 6483]

BACITRACIN STERILE POWDER

Drugs for Human Use; Drug Efficacy Study Implementation; Classification and Labeling Amended

In a notice (DESI 6483) published in the FEDERAL REGISTER of June 24, 1970 (35 F.R. 10326), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following bacitracin drugs:

1. Bacitracin Sterile Powder; The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002 (NDA 6-483).

2. Bacitracin Sterile Powder; Chas. Pfizer and Co., Inc., 235 42d St., New York, N.Y. 10017 (NDA 60-282).

3. Bacitracin Sterile Powder; Philadelphia Laboratories, Inc., 9815 Roosevelt Boulevard, Philadelphia, Pa. 19114 (NDA 60-350).

The notice stated that the drug was regarded as probably effective, possibly effective, and lacking substantial evidence of effectiveness for the various labeled indications.

Based upon a reevaluation of these preparations, the Commissioner of Food and Drugs finds it appropriate to amend the announcement of June 24, 1970, by:

1. Changing the effectiveness classification of the following probably effective indication to effective: Intramuscularly for the treatment of infants with pneumonia and empyema caused by staphylococci shown to be sensitive to the drug.

2. Revising the labeling guidelines, as follows:

BACITRACIN STERILE POWDER FOR INTRAMUSCULAR USE ONLY

WARNING

Nephrotoxicity: Bacitracin in parenteral (intramuscular) therapy may cause renal failure due to tubular and glomerular necrosis. Its use should be restricted to infants with staphylococcal pneumonia and empyema when due to organisms shown to be susceptible to bacitracin. It should be used only where adequate laboratory facilities are available and when constant supervision of the patient is possible.

Renal function should be carefully determined prior to and daily during therapy. The recommended daily dose should not be exceeded and fluid intake and urinary output maintained at proper levels to avoid kidney toxicity. If renal toxicity occurs the drug should be discontinued. The concurrent use of other nephrotoxic drugs, particularly streptomycin, kanamycin, polymyxin B, polymyxin E (colistin), neomycin, and viomycin, should be avoided.

DESCRIPTION

(Descriptive information to be included by the manufacturer or distributor should be confined to an appropriate description of the physical and chemical properties of the drug and the formulation.)

ACTIONS

Bacitracin, an antibiotic substance derived from cultures of *Bacillus subtilis* (Tracey), exerts pronounced antibacterial action *in vitro* against a variety of gram-positive and a few gram-negative organisms. However, among systemic diseases, only staphylococcal infections qualify for consideration of bacitracin therapy. Bacitracin is assayed against a standard and its activity is expressed in units, 1 mg. having a potency of not less than 50 units.

Susceptibility plate testing: If the Kirby-Bauer method of disc susceptibility is used, a 10-unit bacitracin disc should give a zone of over 13 mm. when tested against a bacitracin-susceptible strain of *Staphylococcus aureus*. Absorption of bacitracin following intramuscular injection is rapid and complete. A dose of 200 or 300 units/kg. every 6 hours gives serum levels of 0.2 to 2 mcg./ml. in individuals with normal renal function. The drug is excreted slowly by glomerular filtration. It is widely distributed in all body organs and is demonstrable in ascitic and pleural fluids after intramuscular injection.

INDICATIONS

In accord with the statements in the "Warning Box," the use of intramuscular bacitracin is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug.

CONTRAINDICATIONS

This drug is contraindicated in those individuals with a history of previous hypersensitivity or toxic reaction to it.

PRECAUTIONS

See "Warning Box" for precautions in regard to kidney toxicity associated with intramuscular use of bacitracin.

Adequate fluid intake should be maintained orally, or if necessary, by parenteral method.

As with other antibiotics, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be instituted.

ADVERSE REACTIONS

Nephrotoxic reactions. Albuminuria. Cylinduria. Azotemia. Rising blood levels without any increase in dosage.

Other reactions. Nausea and vomiting. Pain at site of injection. Skin rashes.

DOSAGE AND ADMINISTRATION

TO BE ADMINISTERED INTRAMUSCULARLY ONLY

Infant dose: For infants under 2500 Gm.—900 units/kg./24 hours in 2-3 divided doses. For infants over 2500 Gm.—1,000 units/kg./24 hours, in 2-3 divided doses.

Preparation of solutions. (To be supplied by manufacturer or distributor.)

Storage conditions. (To be supplied by manufacturer or distributor.)

3. The remaining probably effective and possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of this drug has been submitted pursuant to the notice of June 24, 1970.

Batches of such drugs with labeling bearing indications for which substantial evidence of effectiveness is lacking are no longer acceptable for certification or release.

Any person who will be adversely affected by the deletion from labeling of the indications for which the drug has been reclassified from probably effective or possibly effective to lacking substantial evidence of effectiveness may, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, petition for the issuance of a regulation providing for other certification of the drug for such indications. The petition must be supported by a full factual and well documented medical analysis which shows reasonable grounds for the issuance of such regulations.

A petition for issuance of said regulation should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51 as amended, 59 Stat. 463 as amended; 21 U.S.C. 352, 357) 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. 72-2116 Filed 2-11-72; 8:48 am]