

None of the applicants to which this consolidated decision relates has satisfied the requirements set forth above, therefore, the prior denials without prejudice have the effect of a final decision denying their respective applications.

Section 701.8 further provides:

*** the Deputy Assistant Secretary shall transmit a summary of the prior denial without prejudice to resubmission to the FEDERAL REGISTER for publication, to the Commissioner of Customs, and to the applicant.

Each of the prior denials without prejudice to resubmission to which this consolidated decision relates was based on the failure of the respective applicants to submit the required documentation, including a completely executed application form, in sufficient detail to allow the issue of "scientific equivalency" to be determined by the Deputy Assistant Secretary.

Docket No. 70-00575-01-77030. Applicant: University of Wisconsin-Parkside, Woods Road, Kenosha, Wis. 53140. Article: NMR Spectrometer, Model JNM-MH-60-II. Date of denial without prejudice to resubmission: April 11, 1972.

Docket No. 70-00576-33-43780. Applicant: Presbyterian-St. Luke's Hospital, 1753 West Congress Parkway, Chicago, IL 60612. Article: Incubator slide containing MacConkeys nutrient agar. Date of denial without prejudice to resubmission: April 5, 1972.

Docket No. 71-00331-65-25300. Applicant: University of Chicago, Operator of Argonne National Laboratory, 9700 South Cass Avenue, Argonne, IL 60439. Article: Electrical discharge machine, Model DL-5. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 71-00434-33-46040. Applicant: Tufts University, Department of Pathology, 136 Harrison Avenue, Boston, MA 02111. Article: Electron microscope, JEM-100B. Date of denial without prejudice to resubmission: April 5, 1972.

Docket No. 71-00605-01-10520. Applicant: Federal Bureau of Investigation, U.S. Department of Justice. Article: Vapor Trace Analyzer, Model 103A. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 71-00614-65-72000. Applicant: Michigan State University, East Lansing, Mich. 48823. Article: Single drive unit for Weissenberg Rheogoniometer. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 71-00623-01-77030. Applicant: University of Vermont, Department of Chemistry, Burlington, Vt. 05401. Article: NMR Spectrometer System; Model JNM-MH-100. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 72-00011-01-77030. Applicant: University of California, Department of Chemistry, Division of Natural Sciences, Santa Cruz, Calif. 95060. Article: NMR Spectrometer Model JNM-PS-100. Date of denial without prejudice to resubmission: April 11, 1972.

Docket No. 72-00034-99-66700. Applicant: Thomas S. Clarkson Memorial College of Technology, Potsdam, N.Y. 13676. Article: Teleprinter projector, Model 2510T. Date of denial without prejudice to resubmission: April 5, 1972.

Docket No. 72-00053-99-46040. Applicant: State University of New York, Department of Anatomy, Stony Brook, N.Y. 11790. Article: Electron microscope, Model HU-12. Date of denial without prejudice to resubmission: April 5, 1972.

Docket No. 72-00061-33-43780. Applicant: County of Sacramento Medical Center, 2315 Stockton Boulevard, Sacramento, CA 95817. Article: Isotron stand. Date of denial without prejudice to resubmission: April 5, 1972.

Docket No. 72-00068-33-46500. Applicant: Temple University, School of Dentistry, Department of Pathology, 3223 North Broad Street, Philadelphia, PA 19140. Article: Ultramicrotome, Model OM U2. Date of denial without prejudice to resubmission: April 3, 1972.

Docket No. 72-00076-33-77040. Applicant: Galesburg State Research Hospital, Research Division, 1801 North Seminary Street, Galesburg, IL 61401. Article: Gas chromatograph—mass spectrometer, Model CH 7. Date of denial without prejudice to resubmission: April 3, 1972.

Docket No. 72-00081-91-80300. Applicant: University of Alaska. Geophysical Institute, College, Alaska 99701. Article: Temperature recorder. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 72-00094-33-54500. Applicant: University of Michigan, Department of Ophthalmology, Ann Arbor, Mich. 48104. Article: Tubinger perimeter. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 72-00098-33-40700. Applicant: Washington University, School of Medicine, Mallinckrodt Institute of Radiology, 510 South Kingshighway, St. Louis, MO 63110. Article: Irradiation unit. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 72-00105-33-40700. Applicant: Kensington Hospital, 136 West Diamond Street, Philadelphia, PA 19122. Article: Irradiator model RW-1, one probe. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 72-00107-01-77030. Applicant: Sangamon State University, Chemistry Department, Springfield, Ill. 62703. Article: NMR spectrometer, JNM-MH-100. Date of denial without prejudice to resubmission: April 12, 1972.

Docket No. 72-00126-33-71200. Applicant: University of Chicago, 950 East 59th Street, Chicago, IL 60637. Article: Freezer-Dryer, FT-1. Date of denial without prejudice to resubmission: April 12, 1972.

SETH M. BODNER,

Director,

Office of Imports Programs.

[FR Doc.72-11536 Filed 7-25-72;8:47 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 1626]

CERTAIN PREPARATIONS CONTAINING XANTHINE DERIVATIVES

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs:

OXTRIPHYLLINE PREPARATIONS

1. Cholel tablets containing oxtriphylline; Warner-Chilcott Laboratories Division, Warner Lambert Pharmaceutical Co., 210 Tabor Road, Morris Plains, N.J. 07950 (NDA 9-268).

2. Cholorace tablets containing oxtriphylline, racephedrine hydrochloride, and pentobarbital; Warner-Chilcott Laboratories (NDA 10-888).

DYPHYLLINE PREPARATIONS

1. Neothylline tablets containing dyphylline; Lemmon Pharmacal Co., Cat-hill and Lonely Roads, Sellersville, Pa. 18960 (NDA 7-794).

2. Neothylline Intramuscular containing dyphylline; Lemmon Pharmacal Co. (NDA 9-088).

AMINOPHYLLINE PREPARATIONS

1. Aminophyllin tablets containing aminophylline; G. D. Searle & Co., Post Office Box 5110, Chicago, Ill. 60680 (NDA 2-386).

2. Aminophyllin enteric coated tablets containing aminophylline; G. D. Searle & Co. (NDA 2-385).

3. Aminophyllin with phenobarbital tablets containing aminophylline and phenobarbital; G. D. Searle & Co. (NDA 3-832).

4. Aminophylline tablets; Cole Pharmacal Co., Inc., 3721 Laclede Avenue, St. Louis, Mo. 63108 (NDA 4-096).

5. Aminophylline with phenobarbital tablets; Cole Pharmacal Co., Inc. (NDA 4-096).

6. Amodrone tablets containing aminophylline, phenobarbital and racephedrine hydrochloride; G. D. Searle & Co. (NDA 2-384).

THEOPHYLLINE AND THEOPHYLLINE SODIUM GLYCINATE PREPARATIONS

1. Synophylate tablets, elixir, and suppositories containing theophylline sodium glycinate; The Central Pharmacal Co., 116-128 East Third Street, Seymour, Ind. 47274 (NDA 6-333).

2. Synophylate with phenobarbital tablets containing theophylline sodium glycinate and phenobarbital; The Central Pharmacal Co. (NDA 6-333).

3. Theoglycinate tablets and syrup containing theophylline sodium glycinate; Brayten Pharmaceutical Co.,

1715 West 38th Street, Chattanooga, Tenn. 37409 (NDA 6-158).

4. Theoglycinate with phenobarbital tablets containing theophylline sodium glycinate and phenobarbital; Brayten Pharmaceutical Co. (NDA 6-158).

5. Theoglycinate with racebookrine and phenobarbital tablets containing theophylline sodium glycinate, phenobarbital, and racebookrine hydrochloride; Brayten Pharmaceutical Co. (NDA 6-158).

6. Phedorine tablets (formerly Theophedrine with phenobarbital tablets) containing theophylline, phenobarbital, and ephedrine hydrochloride; Tilden-Yates Laboratories, Inc., Fairfield Road, Wayne, N.J. 07470 (NDA 1-626).

7. Asminyl tablets and asminyl slosol pink tablets containing theophylline, sodium phenobarbital, and ephedrine sulfate; Cole Pharmacal Co., Inc. (NDA 3-523).

8. Asminyl liquid containing theophylline sodium salicylate, sodium butabarbital, and ephedrine sulfate; Cole Pharmacal Co., Inc. (NDA 3-523).

9. Arteminyl sublingual tablets (now marketed as Iso-Asminyl) containing theophylline, sodium phenobarbital, isoproterenol hydrochloride, and ephedrine sulfate; Cole Pharmacal Co., Inc. (NDA 3-523).

10. Marax syrup containing theophylline, hydroxyzine hydrochloride, and ephedrine sulfate; J. B. Roerig Division, Pfizer Pharmaceuticals, 235 East 42d Street, New York, NY 10017 (NDA 12-879).

11. Marax tablets containing theophylline, hydroxyzine hydrochloride, and ephedrine sulfate; J. B. Roerig Division, Pfizer Pharmaceuticals (NDA 11-768).

AMBUPHYLLINE PREPARATIONS

1. Nethaphyl regular strength capsules and nethaphyl half strength capsules containing ambuphylline, ephedrine hydrochloride, and phenobarbital; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, Ohio 45215 (NDA 6-359).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that:

1. *Rectal suppositories containing theophylline sodium glycinate as the sole active ingredient.* a. Are probably effective for bronchial asthma.

b. Are possibly effective as labeled for use in status asthmaticus, congestive heart failure, or as a diuretic in congestive heart failure, paroxysmal cardiac dyspnea, coronary artery diseases and angina, allaying pruritis, and relieving sensitization dermatoses.

c. Lack substantial evidence of effectiveness as labeled for use in Cheyne-Stokes respiration and "bronchospastic

type chronic hypertrophic pulmonary emphysema."

2. *Other drugs listed in this announcement.* a. These drugs lack substantial evidence of effectiveness as labeled for use in "pulmonary infections associated with bronchospasm," dyspnea induced by exertion and cough, Cheyne-Stokes respiration, status asthmaticus, "bronchospastic type of chronic hypertrophic pulmonary emphysema," "other pulmonary disorders," or as a sedative.

b. These drugs are possibly effective as labeled for use in bronchial asthma; bronchitis, bronchiectasis, and emphysema in which bronchospasm is present; paroxysmal cardiac or nocturnal dyspnea; biliary colic, renal colic; hay fever; congestive heart failure or as a diuretic in congestive heart failure, premenstrual fluid retention and drug induced edema; coronary artery disease and angina pectoris; allaying pruritis and in relieving sensitization dermatoses; pulmonary edema due to cardiac decompensation; the relief of bronchospasm; nasal allergy; or for use as respiratory center stimulants and expectorants.

B. *Marketing status.* 1. Within 60 days of the date of publication of this announcement in the FEDERAL REGISTER, the holder of any approved new drug application for which a drug is classified in paragraph A above as lacking substantial evidence of effectiveness is requested to submit a supplement to his application, as needed, to provide for revised labeling which deletes those indications for which substantial evidence of effectiveness is lacking. Such a supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new drug regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time, and the revised labeling should be put into use within the 60-day period. Failure to do so may result in a proposal to withdraw approval of the new drug application.

2. If any such preparation is on the market without an approved new-drug application, its labeling should be revised if it includes those claims for which substantial evidence of effectiveness is lacking as described in paragraph A above. Failure to delete such indications and put the revised labeling into use within 60 days after the date of publication hereof in the FEDERAL REGISTER may cause the drug to be subject to regulatory proceedings.

3. Labeling revised pursuant to this notice should take into account the comments of the Academy; furnish adequate information for safe and effective use of the drug; and recommend use of the drug having a probably effective indication as follows: (The possibly effective indications for that drug may also be included in the labeling for 6 months.)

RECTAL SUPPOSITORIES CONTAINING THEOPHYLLINE SODIUM GLYCINATE

INDICATION

Bronchial Asthma.

4. The notice "Conditions for Marketing New Drugs Evaluated in the Drug

Efficacy Study" published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273), describes in paragraphs (c), (d), (e), and (f) the marketing status of a drug labeled with those indications for which it is regarded as probably effective and possibly effective.

A copy of the Academy's report has been furnished to each firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 1626, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852:

Supplements (Identify with NDA number):
Office of Scientific Evaluation (BD-100),
Bureau of Drugs.

Original new-drug applications: Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

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 the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 28, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-11518 Filed 7-25-72; 8:46 am]

[DESI 11145; Docket No. FDC-D-322; NDA 11-145 et al.]

CERTAIN THIAZIDES

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following single entity thiazide drugs:

1. Fovane Tablets, containing benzthiazide; marketed by Chas. Pfizer and Co., 235 East 42d Street, New York, NY 10017 (NDA 12-128).

2. Esidrix Tablets, containing hydrochlorothiazide; marketed by Ciba Pharmaceutical Co., 556 Morris Avenue, Summit, NJ 07901 (NDA 11-793).

3. Exna Tablets, containing benzthiazide; marketed by A. H. Robins Co., 1407 Cummings Drive, Richmond, VA 23220 (NDA 12-489).

4. Saluron Tablets, containing hydroflumethiazide; marketed by Bristol Laboratories, Division of Bristol-Myers Co., Thompson Road, Post Office Box 657, Syracuse, NY 13201 (NDA 11-949).

5. Renese Tablets, containing polythiazide; Chas. Pfizer & Co. (NDA 12-845).