NOTICES

None of the applicants to which this consolidated decision relates has satisfied the requirements set forth above. Therefore, the denial 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 order denying the request 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. 72-00098-33-40700. Applicant: Washington University, School of Medicine, Mallinckrodt Institute of Radiology, 510 South Kingshighway, St. Louis, Mo. 63110. Article: Radiation unit. Date of denial without prejudice to resubmission: April 12, 1972.


AMPHYLLINE PREPARATIONS

1. Nethaphyll regular strength capsules and nethaphyll half strength capsules containing amiphylline, ephedrine hydrochloride, and ephedrine sulfate; Cole Pharmacal Co., Inc. (NDA 3-523).

2. Am_phylline liquid containing theophylline sodium salicylate, sodium phenobarbital, and ephedrine hydrochloride; Cole Pharmacal Co., Inc. (NDA 3-523).

3. Artemyn sublingual tablets (now marketed as Iso-Army) containing theophylline, phenobarbital, and ephedrine hydrochloride; Cole Pharmacal Co., Inc. (NDA 3-523).

4. Artemyn tablets and arsmyl scopolamine tablets containing theophylline, sodium phenobarbital, and ephedrine hydrochloride; Cole Pharmacal Co., Inc. (NDA 3-523).

5. Theoglycinate with racephedrine and ephedrine hydrochloride; Tilden Yates Laboratories, Inc., Fairfield Road, Wayne, N.J. 07470 (NDA 1-626).

6. Phephonine tablets (formerly Theophylline phenobarbital tablets) containing theophylline, phenobarbital, and ephedrine hydrochloride; Bratyn Pharmaceutical Co. (NDA 6-158).

7. Phephonine tablets containing theophylline, phenobarbital, and ephedrine hydrochloride; Bratyn Pharmaceutical Co. (NDA 6-158).

8. Artemyn liquid containing theophylline sodium salicylate, sodium phenobarbital, and ephedrine hydrochloride; Cole Pharmacal Co., Inc. (NDA 3-523).

9. Artemyn tablets containing theophylline sodium salicylate, sodium phenobarbital, and ephedrine hydrochloride; Cole Pharmacal Co., Inc. (NDA 3-523).

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

AMPHYLLINE PREPARATIONS

1. Nethaphyll regular strength capsules and nethaphyll half strength capsules containing amiphylline, ephedrine hydrochloride, and phenobarbital; Merrell-National Laboratories, Division of Richard Merrell, Inc., 115 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 glycate as the sole active ingredient are probably effective for bronchial asthma.

2. 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 sensations due to decongestion.

3. Lack substantial evidence of effectiveness as labeled for use in Cheyne-Stokes respiration and "bronchospastic type chronic hypertrophic pulmonary emphysema.

4. Other drugs listed in this announcement. a. These drugs lack substantial evidence of effectiveness as labeled for use in "pulmonary infections associated with bronchospasm," bronchitis 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, bronchectasia, 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. Such drugs, marketed without a supplement to his application, 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 a supplement to his application, its labeling should be revised if it includes those claims 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.

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: (2) the possibly effective indications for that drug may also be included in the labeling for 6 months.)

RECTAL SUPPOSITORIES CONTAINING THEOPHYLLINE SODIUM GLYCATE 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 DEST 2162, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 3500 Fishers Lane, Rockville, MD 20852.

Supplements (Identify with NDA number): 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. 72-11918 Filed 7-25-72; 8:46 am]

[DEST 11145; Docket No. FDC-D-325; NDA 11-146 et al.]

CERTAIN THIADIZIDES 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. Povane Tablets, containing benzthiadiazide; marketed by Chas. Pfizer & Co., 235 East 42d Street, New York, NY 10017 (NDA 12-128).

2. Esidrix Tablets, containing hydrochlorothiazide; marketed by Chas. Pfizer & Co., 235 East 42d Street, New York, NY 10017 (NDA 12-128).

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

4. Saluron Tablets, containing hydrochlorothiazide; 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).