CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

84279

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: [redacted]

DATE APPROVAL LETTER ISSUED: NOV 23 1976

TO: Press Relations Staff (HFI-40)

FROM:
- [x] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this ORIGINAL ABBREVIATED approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [x] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [x] HUMAN
- [ ] VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG:

[redacted]

DOSAGE FORM: [redacted]

HOW DISPENSED
- [x] RX
- [ ] OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

[redacted]

NAME OF APPLICANT (Include City and State)

[redacted]

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

[redacted]

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: /S/ DATE:

FORM APPROVED BY

NAME: J L M DATE:

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

Dated: July 11, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-11720 Filed 7-27-72;8:48 am]

[DESI 12177]

COMBINATION DRUG CONTAINING METHSCOPOLAMINE RESIN AND METHAQUALONE RESIN

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following anticholinergic-sedative drug:

Dimethacol Capsules containing methscopolamine resin and methaqualone resin (formerly called Akalon-T '5' Capsules and Akalon-T '10' Capsules); Strasenburgh Laboratories, Division Pennwalt Corp., 755 Jefferson Road, Rochester, N.Y. 14623 (NDA 12-177).

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 report, as well as other available evidence, and concludes that this combination drug is possibly effective for its labeled indications.

B. *Marketing status.* Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as possibly effective may be continued for 6 months as described in paragraphs (d), (e), and (f) of the notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273).

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12177, 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: July 11, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-11721 Filed 7-27-72;8:48 am]

[DESI 12383]

COMBINATION PREPARATION CONTAINING PROBENECID AND COLCHICINE

Drugs for Human Use; Drug Efficacy Study Implementation

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

ColBenemid Tablets containing probenecid and colchicine; Merck Sharp & Dohme, West Point, Pa. 19486 (NDA 12-383).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drug without approval.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that probenecid with colchicine is effective for the treatment of chronic gouty arthritis when complicated by frequent, recurrent, acute attacks of gout.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new-drug applications and abbreviated supplements to previously approved new-drug applications under conditions described herein.

1. *Form of drug.* Probenecid with colchicine preparations are in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The "Indications" section is as follows:

INDICATIONS

For the treatment of chronic gouty arthritis when complicated by frequent, recurrent acute attacks of gout.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), as follows:

a. For holders of "deemed approved" new-drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and an abbreviated supplement for updating information as described in paragraphs (a)(1) (i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new-drug application, the submission of an abbreviated new-drug application as described in paragraph (a)(3)(i) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12383, 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 abbreviated new-drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

Request 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: July 11, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-11723 Filed 7-27-72;8:48 am]

[DESI 5307]

PARENTERAL MERCURIAL DIURETICS

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 mercurial diuretics for parenteral use:

1. Cumertilin Injectable, containing mercumatilin; Endo Laboratories, Inc., subsidiary of E. I. du Pont de Nemours & Co., Inc., 1000 Stewart Avenue, Garden City, N.Y. 11530 (NDA 7-519).

2. Thiomerin Injection and Thiomerin Lyophilized Powder for Injection, containing sodium mercaptomerin; Wyeth Laboratories, Division American Home Products Corp., Post Office Box 8299, Philadelphia, Pa. 19101 (NDA 8-050).

3. Mercuhydrin Injection, containing meralluride; Lakeside Laboratories, Inc.,