

plication, the submission of an abbreviated new-drug application, as described in paragraph (a)(3)(1) 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 each firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 8709, 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.

Requests for the Academy's Reports: 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 27, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10454 Filed 7-7-72;8:48 am]

[DESI 7864]

CERTAIN VAGINAL PREPARATIONS

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:

1. Milibis Suppositories; containing glycolbialsol; marketed by Winthrop Laboratories, Division of Sterling Drug, Inc., 90 Park Avenue, New York, New York 10016 (NDA 7-354).

2. Broxolin Vaginal Cream; containing glycolbialsol marketed by Broon Laboratories Inc., subsidiary Sterling Drug, Inc., 90 Park Avenue, New York, New York 10016 (NDA 10-521).

3. Betadine Vaginal Gel; containing providone-iodine; marketed by The Purdue Frederick Co., 99-101 Saw Mill River Road, Yonkers, New York 10701 (NDA 11-754).

4. Redoderlein; containing viable Doderlein Bacilli; marketed by Fellows-Testagar, Inc., Division Fellows Medical Manufacturing Co., 12741 Capital Avenue, Oak Park, Michigan 48227 (NDA 12-730).

5. Balarsen Solution 1 percent and Vaginal Suppositories; containing arsthinol; marketed by Endo Laboratories Inc., 1000 Stewart Avenue, Garden City, Long Island, New York 11533 (NDA 10-612).

6. Balcort Solution and Vaginal Suppositories; containing arsthinol and hydrocortisone; marketed by Endo Laboratories Inc. (NDA 10-612).

7. Baculin Vaginal Tablets; containing diiodohydroxyquin, phenylmercuric acetate, sodium lauryl sulfate, lactose, potassium alum, and papain; marketed by Amfre-Grant, Inc., 924 Rogers Avenue, Brooklyn, New York 11226 (NDA 8-327).

8. Cenisert Tablets and Powder; containing aminacrine undecylenate, N-myristyl-3-hydroxybutylamine hydrochloride, methylbenzethonium chloride, and succinic acid; marketed by Central Pharmaceutical Co., 116-128 East Third Street, Seymour, Indiana 47274 (NDA 12-028).

9. Premarin H-C Vaginal Cream; containing conjugated estrogens and hydrocortisone acetate; marketed by Ayerst Laboratories, Division American Home Products Corp., 685 Third Avenue, New York, New York 10017 (NDA 11-074).

These drugs are regarded as new drugs. The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy reports and concludes that these drugs are possibly effective when labeled for treatment of trichomonal, monilial, or bacterial vaginitis; vaginitis of mixed etiology; non-specific vaginitis; mycotic infestation of the vagina; senile vaginitis; kraurosis vulvae; urethral caruncles; juvenile vaginitis; labial adhesions in children; or for the alteration of vaginal flora.

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).

The above-named holders of the new-drug applications for these drugs have been mailed a copy of the Academy's report. Communications forwarded in response to this announcement should be identified with the reference number DESI 7864, 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 27, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10451 Filed 7-7-72;8:47 am]

[DESI 8451]

COMBINATION DRUGS CONTAINING PAMABROM AND PYRILAMINE MALEATE FOR ORAL USE

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 containing pamabrom and pyrilamine maleate:

1. Neo Bromth Tablets; Brayten Pharmaceutical Co., 1715 West 38th Street, Chattanooga, Tenn. 37409 (NDA 8-451).

2. Neoparbrom Tablets; The Central Pharmaceutical Co., 116-128 East Third Street, Seymour, Ind. 47274 (NDA 8-613).

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 these drugs are:

1. Possibly effective for premenstrual tension.

2. Lacking substantial evidence of effectiveness for edema of pregnancy.

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 a drug 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. The notice Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), describes in paragraphs (d), (e), and (f) the marketing status of a drug labeled with those indications for which it is regarded as 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 8451, 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 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10453 Filed 7-7-72;8:48 am]

[DESI 50020]

NEOMYCIN PALMITATE-TRYPSIN-CHYMOTRYPSIN TOPICAL PREPARATION

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 prescription drug for topical application:

Biozyme Ointment containing neomycin palmitate and trypsin-chymotrypsin concentrate; Armour Pharmaceutical Co., Division, Armour and Co., Post Office Box 511, Kankakee, Ill. 69901.

The Food and Drug Administration concludes that the above listed combination drug for topical administration is possibly effective for the claimed indications for treatment of localized infections or for suppressive therapy in such conditions.

Preparations containing neomycin sulfate in combination with trypsin-chymo-

trypsin are subject to antibiotic certification procedures under section 507 of the Federal Food, Drug, and Cosmetic Act. To allow applicants to obtain and submit data to provide substantial evidence of the effectiveness of the drug in those conditions for which it has been evaluated as possibly effective, such drug labeled with those indications will continue to be accepted for release or certification by the Food and Drug Administration for a period of 6 months after publication of this announcement in the FEDERAL REGISTER.

To be acceptable for consideration in support of the effectiveness of a drug, any such data must be previously unsubmitted, well-organized, and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in section 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for the approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

At the end of the 6-month period, any such data will be evaluated to determine whether there is substantial evidence of effectiveness for such uses. After that evaluation, the conclusions concerning the drug will be published in the FEDERAL REGISTER. If no studies have been undertaken, or if the studies do not provide substantial evidence of effectiveness, such drug will not be eligible for release or certification.

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 50020 directed to the attention of the following appropriate office, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Amendments (Identify with NDA number) Division of Anti-Infective Drug Products (BD-140), Office of Scientific Evaluation, 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, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 27, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10458 Filed 7-7-72;8:48 am]

[DESI 7909]

PREPARATION CONTAINING CARBACRYLAMINE RESINS

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 for oral use:

Carbo-Resin Powder containing carbacrylamine resin; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 7-909).

The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that there is a lack of substantial evidence, within the meaning of the Federal Food, Drug, and Cosmetic Act, that this drug will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. The holder of the NDA has indicated that the preparation is no longer marketed.

A notice was published in the FEDERAL REGISTER of March 18, 1972 (37 F.R. 5711), withdrawing approval of NDA 7-909 on the grounds that reports required under section 505(j) of the Act and §§ 130.13 and 130.35 (e) and (f) of the new drug regulations (21 CFR 130.13 and 130.35) had not been submitted.

Accordingly, this notice is published to inform any person interested in similar or related products of the effectiveness classification of this article. If any related drug for human use, not the subject of an approved new drug application, is being marketed it may be affected by the above classification and be subject to appropriate action.

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 7909, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

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 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10452 Filed 7-7-72;8:47 am]