

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 glycohiarsol; 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 glycohiarsol 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.

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[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