Supplements (identify with NDA number): Md. DESI 8709, directed to the attention of 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 Implementation Project Office (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, 805, 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 2.129).

Dated: June 27, 1972.

SAM D. FINE, Associate Commissioner for Compliance.

NOTICES

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:


2. Broxolin Vaginal Cream; containing glycobilarsol marketed by Broom Laboratories Inc., subsidiary Sterling Drug, 90 Park Avenue, New York, New York 10016 (NDA 8–621).

3. Betadine Vaginal Gel; containing providone iodine; marketed by The Purdue Frederick Co., 92–181 Saw Mill River Road, Yonkers, New York 10701 (NDA 11–754).

4. Redoderlin; containing viable Doderlein Bacilli; marketed by Pollowatz-Tesilgar Inc., Division Pollowatz Medical Manufacturing Co., 12741 Capital Avenue, Oak Park, Michigan 48277 (NDA 12–730).

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

6. Bacolent Solution and Vaginal Suppositories; containing arsinthiol and hydrocorisone; 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 Amfere-Grant Inc., 524 Rogers Avenue, Brooklyn, New York 11206 (NDA 8–327).


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's reports and concludes that these drugs are effective when labeled for treatment of trichomonal, monilial, or bacterial vaginitis; vaginitis of mixed etiology; nonspecific vaginitis; mosaic infections of the vagina; senile vaginitis; kraurosis vulvae; uretral 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. Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as effective is requested to submit a supplement to this 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 § 199.9 (d) and (e) of the new-drug regulations (21 CFR 199.9 (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 60 days of the date of publication. 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

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Dated: June 27, 1972.

SAM D. FINE, Associate Commissioner for Compliance.

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