

[DESI 8709]

**CERTAIN PARENTERAL DRUGS
CONTAINING VERATRUM ALKALOIDS****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 antihypertensive drugs:

1. Veralba Injection containing protoveratrine A and B; the Dow Chemical Co., 1200 Madison Avenue, Indianapolis, Ind. 46225 (NDA 8-709).

2. Unitensin Aqueous containing cryptenamine acetates; Mallinckrodt Chemical Works, 3600 North Second Street, St. Louis, Mo. 63160 (NDA 8-814).

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 reports, as well as other available evidence, and concludes that these drugs are effective for short-term use in the treatment of hypertensive crises:

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.** These veratrum alkaloid preparations are aqueous solutions suitable for parenteral administration.

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

b. The drugs are labeled to comply with all requirements of the Act and regulations. Their labeling bears adequate information for safe and effective use and, where applicable, the Academy's comments. The "Indications" sections are as follows:

INDICATIONS

For short-term use in the treatment of hypertensive crises.

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 ap-

Comments: Controlled clinical data supporting the 12-hour action of this product have not been presented to the Panel.

25. **Chlorephrine Nyscaps** containing chlorpheniramine maleate and phenylephrine hydrochloride.

This drug has been evaluated by the Panel on Drugs Used in Allergy.

Indication: Nasal congestion due to hay fever.

Evaluation: Effective.

Comments: None.

Indication: Nasal congestion due to the common cold.

Evaluation: Possibly effective.

Comments: Adequate evidence supporting this claim has not been presented to the Panel. In addition, it is doubtful whether the antihistamine is of benefit for the relief of symptoms due to the common cold. Several carefully controlled studies, in which different antihistamines were tried, disclosed no alleviation of symptoms or shortening of the duration of symptoms of colds. When allergic rhinitis is mistaken for a cold, antihistamines may be of benefit; but allergic rhinitis is being treated in that instance, not an upper respiratory infection.

This indication was subsequently reevaluated as ineffective as a fixed combination with the following additional comments:

Indication: Relief of nasal congestion associated with colds.

There is no evidence that either drug in this combination will accomplish what is claimed. The dose of pseudoephedrine is less than optimal for many adults and it has not been proved to be beneficial for this indication. It has not been proved that the antihistamine contributes to the relief of cold symptoms which is provided by this combination. The majority of carefully controlled studies that have been performed with antihistamines disclosed no alleviation of symptoms or shortening of the duration of symptoms of colds.

Indication: Timed-release capsule.

Evaluation: Effective.

Comments: None.

26. **Vicks Tri-Span 12-Hour Decongestant Tablets** containing acetaminophen, pyrilamine maleate, caffeine, ephedrine sulfate, and phenylpropanolamine.

This drug has been evaluated by the Panel on Drugs Used in Allergy.

Indication: Symptomatic relief of nasal congestion due to colds.

Evaluation: Probably effective (subsequently reevaluated as ineffective as a fixed combination).

Comments: Although the acetaminophen and caffeine may provide some relief of "headache, achy feeling of colds," it is doubtful whether they contribute to the relief of nasal congestion, which appears to be the major indication for which this product is sold. The antihistamine may provide some benefit in cases of hay fever, but is probably not of use in colds. No supporting data, collected in a controlled fashion, have been presented to the Panel. It is doubtful whether the antihistamine is of benefit for the relief of nasal congestion due to the common cold. Several carefully controlled studies, in which different antihistamines were tried, disclosed no alleviation of symptoms or shortening of the duration of symptoms of colds. When allergic rhinitis is mistaken for a cold, antihistamines may be of benefit; but allergic rhinitis is being treated in that instance, not an upper respiratory infection.

Indication: 12-hour effect.

Evaluation: Possibly effective.

Comments: Controlled clinical data supporting this claim have not been presented to the Panel.

Indication: Symptomatic relief of nasal congestion due to hay fever.

Evaluation: Probably effective.

Comments: None.

27. **Ampar Timed Release Capsules** containing chlorpheniramine maleate and phenylephrine hydrochloride.

This drug has been evaluated by the Panel on Drugs Used in Allergy.

Indication: Nasal congestion due to hay fever.

Evaluation: Probably effective.

Comments: Adequate evidence supporting this claim has not been presented to the Panel.

Indication: Nasal congestion due to the common cold.

Evaluation: Possibly effective.

Comments: Adequate evidence supporting this claim has not been presented to the Panel. In addition, it is doubtful whether the antihistamine is of benefit for the relief of symptoms due to the common cold. Several carefully controlled studies, in which different antihistamines were tried, disclosed no alleviation of symptoms or shortening of the duration of symptoms of colds. When allergic rhinitis is mistaken for a cold, antihistamines may be of benefit; but allergic rhinitis is being treated in that instance, not an upper respiratory infection.

This indication was subsequently reevaluated as ineffective as a fixed combination with the following additional comments.

There is no evidence that either drug in this combination will accomplish what is claimed. The dose of pseudoephedrine is less than optimal for many adults and it has not been proved to be beneficial for this indication. It has not been proved that the antihistamine contributes to the relief of cold symptoms which is provided by this combination. The majority of carefully controlled studies that have been performed with antihistamines disclosed no alleviation of symptoms or shortening of the duration of symptoms of colds.

Indication: Time-released capsule.

Evaluation: Possibly effective.

Comments: No unequivocal data regarding this property have been submitted to the Panel.

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 1205, 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 120).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10445 Filed 7-7-72; 8:47 am]

NOTICES

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 Im-
plementation 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 glycolborsol; marked by Winthrop Laboratories, Division of Sterling Drug, Inc., 90 Park Avenue, New York, New York 10016 (NDA 7-864).

2. Broxolin Vaginal Cream; containing glycolborsol marketed by Broom 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 48237 (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. Cenaserit Tablets and Powder; containing aminacrine undecylenate, N-myristyl-3-hydroxybutylamine hydrochloride, methylbenzethonium chloride, and succinic acid; marketed by Central Pharmacal 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 Im-
plementation Project Office (BD-60), Bu-
reau 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 Pharmacal 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