

[DESI 5213]

**CERTAIN COUGH 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. Hydrocodone bitartrate and homatropine methylbromide, marketed as Hycodan Syrup, Tablets, and Powder, by Endo Laboratories, Inc., 1000 Stewart Avenue, Garden City, Long Island, NY 11533 (NDA 5-213).

2. Dimethoxanate hydrochloride, marketed as Cothera Syrup, by Ayerst Laboratories, 685 Third Avenue, New York, NY 10017 (NDA 11-174).

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 probably effective for the temporary relief of cough.

**B. Marketing status.** 1. Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as probably effective may be continued for 12 months as described in paragraphs (c), (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).

2. Within 60 days from publication hereof in the FEDERAL REGISTER, the holder of any approved new drug applications for such drug is requested to submit a supplement to his application to provide for revised labeling as needed, which, taking into account the comments of the Academy, furnishes adequate information for safe and effective use of the drug; is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970 (21 CFR 3.74); and recommends use of the drug for the probably effective indication as follows:

**INDICATION**

**SYMPTOMATIC RELIEF OF COUGH**

The 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.

3. After 60 days following publication hereof in the FEDERAL REGISTER, any such drug on the market without an approved new drug application and shipped within the jurisdiction of the Federal Food, Drug, and Cosmetic Act should be labeled in accord with this 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 5213, 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-87),  
Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-80), 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: April 11, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-5979 Filed 4-19-72;8:47 am]

[DESI 7337]

**DRUGS CONTAINING OXYCODONE  
HYDROCHLORIDE, OXYCODONE  
TEREPHTHALATE, HOMATROPINE  
TEREPHTHALATE, ASPIRIN, PHEN-  
ACETIN, AND CAFFEINE; OXYCO-  
DONE HYDROCHLORIDE, OXYCO-  
DONE TEREPHTHALATE, HOMAT-  
ROPINE TEREPHTHALATE, AND  
PENTYLENETETRAZOL; OR MEPE-  
RIDINE HYDROCHLORIDE AND PRO-  
METHAZINE HYDROCHLORIDE**

**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. Percodan Tablets containing oxycodone hydrochloride, oxycodone terephthalate, homatropine terephthalate, aspirin, phenacetin, and caffeine; Endo Laboratories, Inc., 1000 Stewart Avenue, Garden City, Long Island, N.Y. 11530 (NDA 7-337).

2. Nucodan Tablets containing oxycodone hydrochloride, oxycodone terephthalate, homatropine terephthalate, and pentylenetetrazol; Endo Laboratories, Inc. (NDA 7-337).

3. Mepergan Capsules and Mepergan Fortis Capsules containing meperidine hydrochloride and promethazine hydrochloride; Wyeth Laboratories, Inc., Post Office Box 8299, Philadelphia, Pa. 19101 (NDA 11-730; see below).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness

Comments: Evidence is submitted that the anticholinergic agent (Bentyl) has antimotility effects in animals, but none to support the claim that it will inhibit the motility of neurally stimulated ("nervous") stomach in man, in the dosage provided. No controlled clinical trials of this mixture are available.

Indication: "Relieves indigestion distress as no plain antacid can."

Evaluation: Possibly effective.

Comments: No clinical evidence is submitted in support of this claim. There is much experience with the relief of abdominal fullness after eating by the ingestion of antacids, this relief being due to eructation of gas and to the more rapid emptying of the stomach. Presumably, the antacid mixture offered here will provide these same benefits. However, the addition of an anticholinergic agent to the mixture may actually decrease this action by delaying the emptying of the stomach, and the claim of superiority over plain antacids should be supported by evidence.

19. Belglyn Tablets containing belladonna alkaloids and dihydroxyaluminum aminoacetate.

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

Indication: Gastric hyperacidity.

Evaluation: Possibly effective.

Comments: Gastric hyperacidity is not a clinical entity and there is no known relationship between the gastric acid level and symptoms. The presence of a given level of gastric acidity does not call for therapy.

The label advises use of one tablet 1-2 hour after meals and at bedtime, not to exceed three or four tablets a day. The dose of dihydroxyaluminum aminoacetate (DAA), 0.5 g/tablet, may or may not be effective in a high percentage of instances. The content of 0.162 mg. of belladonna alkaloids is too small to have any pharmacologic effect, even if absorption from DAA were 100 percent.

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 1875, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-87), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-80), 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: April 14, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-5998 Filed 4-19-72;8:48 am]

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:

1. These combination drugs are possibly effective for moderate to moderately severe pain.

2. In addition, the drug containing oxycodone hydrochloride, oxycodone terephthalate, homatropine terephthalate, aspirin, phenacetin, and caffeine lacks substantial evidence of effectiveness as a fixed dose combination for antipyresis.

No new drug applications have been approved or are deemed approved for oral preparations containing meperidine hydrochloride with promethazine hydrochloride for oral use.

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 7337, 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-87), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-80), 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: April 5, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-5980 Filed 4-19-72; 8:47 am]

### ROHM AND HAAS CO.

#### Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 2B2783) has been filed by Rohm and Haas Co., Independence Mall West, Philadelphia, Pa. 19105, proposing that § 121.2597 *Polymer modifiers in semirigid and rigid vinyl chloride plastics* (21 CFR 121.2597) be amended in paragraph (b) (2) by revising the polymer content of the finished plastic food-contact article to include not more than 5 weight-percent of polymer units derived from polymers identified in paragraph (a) (1) of § 121.2597.

Dated: April 11, 1972.

VIRGIL O. WODICKA,  
Director, Bureau of Foods.

[FR Doc.72-5999 Filed 4-19-72; 8:48 am]

### VELSICOL CHEMICAL CORP.

#### Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 2B2782) has been filed by Velsicol Chemical Corp., 1725 K Street NW., Washington, DC 20006, proposing that § 121.2520 *Adhesives* (21 CFR 121.2520) be amended to provide for the safe use of neopentyl glycol dibenzoate as a component of adhesives intended for use in food-contact articles.

Dated: April 11, 1972.

VIRGIL O. WODICKA,  
Director, Bureau of Foods.

[FR Doc.72-5981 Filed 4-19-72; 8:47 am]

## DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

### COMBINED STATION/TOWER AT POCATELLO, IDAHO

#### Notice of Relocation and Reduction in Hours of Operation

Notice is hereby given that on April 20, 1972, the Pocatello Combined Station/Tower will be decommissioned and the flight service station functions will be relocated to Burley, Idaho, Flight Service Station. On or about May 11, 1972, pending publication of amended instrument approach procedures, operation of the Pocatello Airport Traffic Control Tower will be reduced to 16 hours each day, 7 a.m. to 11 p.m. local time. This information will be reflected in the FAA organization statement the next time it is issued.

(Sec. 313(a), 72 Stat. 752; 49 U.S.C. 1354)

Issued in Seattle, Wash., on April 12, 1972.

C. B. WALK, Jr.,  
Director, Northwest Region.

[FR Doc.72-5989 Filed 4-19-72; 8:46 am]

## ATOMIC ENERGY COMMISSION

[Docket No. 50-247]

### CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.

#### Notice of Availability of Applicant's Environmental Report and AEC Draft Detailed Statement

Pursuant to the National Environmental Policy Act of 1969 and the Atomic Energy Commission's regulations in Appendix D to 10 CFR Part 50, notice is hereby given that reports entitled "Applicant's Environmental Report—Operating License Stage, August 6, 1970," and "Applicant's Supplemental Environmental Reports No. 1 and Appendices Volumes Nos. 1 and 2," and Supplement No. 2 on the Indian Point Nuclear Generating Unit No. 2, September 9 and October 15, 1971, respectively" (collectively "the report"), submitted by Consolidated Edison Company of New York, Inc., are available for public inspection in the Commission's Public Document Room at 1717 H Street NW., Washington, DC, and in the Hendrick Hudson High School Library, Albany Post Road, Montrose, N.Y. 10548. The report is also being made available at the New York State Office of Planning Coordination, 488 Broadway, Albany, NY 12207, and the Metropolitan District Review Coordinator, Office of Planning Coordination, 1841 Broadway, New York, NY 10023.

This report discusses environmental considerations related to the proposed