

[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]