

[DESI 10598]

**ANTIEMETIC COMBINATION  
PREPARATION****Drugs for Human Use; Drug Efficacy  
Study Implementation**

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Bendectin Tablets containing dicyclomine hydrochloride, doxylamine succinate, and pyridoxine hydrochloride; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, Ohio 45215 (NDA 10-598).

This drug is regarded as a new drug (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 report, as well as other available evidence, and concludes that this preparation is possibly effective for nausea and vomiting of pregnancy.

**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 six 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).

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 10598, 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 an-  
nouncement: Drug Efficacy Study Imple-  
mentation 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.72-10455 Filed 7-7-72;8:48 am]

[DESI 12152]

**CERTAIN ANTIHISTAMINE-CON-  
TAINING DRUG CONTAINING  
CHLORPHENIRAMINE MALEATE,  
PHENYLPROPANOLAMINE HYDRO-  
CHLORIDE, AND ISOPROPAMIDE  
IODIDE****Drugs for Human Use; Drug Efficacy  
Study Implementation**

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug for oral use:

Ornade Spansules (sustained release capsules) containing chlorpheniramine maleate, phenylpropanolamine hydrochloride, and isopropamide iodide; Smith, Kline & French Laboratories, 1500 Spring Garden Street, Philadelphia, Pa. 19101 (NDA 12-152).

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 report, as well as other available evidence, and concludes that:

1. This drug is possibly effective for relief of upper respiratory tract congestion and hypersecretion associated with vasomotor rhinitis and allergic rhinitis, and for prolonged effect.

2. The drug lacks substantial evidence of effectiveness for relief of nasal congestion and hypersecretion associated with: the common cold; sinusitis (acute, subacute and chronic); influenza; and postnasal drip.

**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 which a drug is classified in paragraph A. 2. 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. 2. above. Failure to delete such indications and put the revised labeling into use within 60

ditions 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, an abbreviated supplement for updating information, and adequate data to show the biologic availability of the drug in the formulation which is marketed as described in paragraphs (a) (1) (i), (ii), and (iii) of the notice of July 14, 1970. Clinical trials which have established effectiveness of the drug may also serve to establish the bioavailability of the drug if such trials were conducted on the currently marketed formulation.

b. For any person who does not hold an approved or effective new-drug application, the submission of an abbreviated new-drug application to include biologic availability of the drug in the formulation which is or is intended to be marketed, as described in paragraph (a) (3) (ii) 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 the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12462, 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 report: Drug  
Efficacy Study Information Control (BD-  
67), Bureau of Drugs.

All other communications regarding this an-  
nouncement: Drug Efficacy Study Imple-  
mentation 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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