

which substantial evidence of effectiveness is lacking as described in paragraph 4.3. of this announcement. An order withdrawing approval of the applications will not issue if such applications are supplemented, in accord with this notice, to delete such indication. Any related drug for human use, not the subject of an approved new drug application, offered for the indication for which substantial evidence of effectiveness is lacking may be affected by this action.

2. In accordance with the provisions of section 505 of the Act (21 U.S.C. 355), and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the holders of any such applications, and any interested person who would be adversely affected by such an order, an opportunity for a hearing to show why such indications should not be deleted from labeling. A request for a hearing must be filed within 30 days after the date of publication of this notice in the FEDERAL REGISTER.

3. A request for a hearing may not rest upon mere allegations or denials but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing, together with a well organized and full factual analysis of the clinical and other investigational data that the objector is prepared to prove in a hearing. Any data submitted in response to this notice must be previously unsubmitted and include data from adequate and well controlled clinical investigations (identified for ready review) as described in § 130.12(a) (5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

4. If a hearing is requested and is justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue a written notice of the time and place at which the hearing will commence.

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 12301, 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.
Request for Hearing (Identify with Docket Number): Hearing Clerk, Office of General Counsel (GC-1), Room 6-88, Parklawn Building.
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.

Received requests for a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

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 29, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10538 Filed 7-10-72; 8:49 am]

[DESI 12595]

COLISTIN SULFATE FOR ORAL SUSPENSION

Drugs for Human Use; Drug Efficacy Study Implementation; Follow-Up Notice

In a notice (DESI 12595) published in the FEDERAL REGISTER of July 17, 1971 (36 F.R. 13284), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Colymycin S Oral Suspension containing colistin sulfate, marketed by Warner-Chilcott Laboratories, Division of Warner-Lambert Pharmaceutical Co., 201 Tabor Road, Morris Plains, N.J. 07950 (NDA 50-355).

The notice stated that the drug was regarded as probably effective and possibly effective for its various labeled indications.

Based upon further review and evaluation of additional studies, the Commissioner finds it appropriate to amend the announcement of July 17, 1971 by:

1. Changing the effectiveness classification of the probably effective indications to effective, and restating them as follows:

INDICATIONS

Diarrhea in infants and children, caused by susceptible strains of enteropathogenic *E. coli*.

Gastroenteritis due to *Shigella* organisms. Clinical response may vary, due to the absence of tissue levels in the bowel wall.

2. Reclassifying the possibly effective indications to lacking substantial evidence of effectiveness in that no new evidence of effectiveness has been received pursuant to the July 17, 1971 announcement.

Batches of such drugs with labeling bearing indications for which substantial evidence of effectiveness is lacking are no longer acceptable for certification or release.

Any person who will be adversely affected by the deletion from labeling of

the indications for which the drug has been reclassified from possibly effective to lacking substantial evidence of effectiveness may, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, petition for the issuance of a regulation providing for other certification of the drug for such indications. The petition must be supported by a full factual and well documented medical analysis which shows reasonable grounds for the issuance of such regulation.

A petition for issuance of said regulation should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463 as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 29, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10539 Filed 7-10-72; 8:49 am]

[DESI 11730; Docket No. FDC-D-440; NDA 11-730]

MEPERIDINE HYDROCHLORIDE AND PROMETHAZINE HYDROCHLORIDE FOR PARENTERAL USE

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:

Mepergan Injection containing meperidine hydrochloride and promethazine hydrochloride; marketed by Wyeth Laboratories, Inc., Post Office Box 8299, Philadelphia, Pa. 19101 (NDA 11-730).

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

1. The drug is effective as a preanesthetic medication and for use as an adjunct to local or general anesthesia.

2. The drug is possibly effective for the analgesic claims made for it, and for use as an antiemetic.

3. The drug lacks substantial evidence of effectiveness of amnesic action.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve new drug applications and supplements to pre-

viously approved new drug applications under conditions described herein.

1. *Form of drug.* Meperidine hydrochloride and promethazine hydrochloride preparations are in solution form suitable for parenteral administration.

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

b. The drug is labeled to comply with all requirements of the Act and regulations. The labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970 (35 F.R. 2656), and where applicable, the Academy's comments. The "Indications" section is as follows:

INDICATIONS

Preanesthetic medication.
As an adjunct to local or general anesthesia.

(The possibly effective indications may also be included for 6 months.)

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, a supplement for updating information, and adequate data to assure 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 serve also 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 a full new drug application, including adequate data to show the biologic availability of the drug in the formulation which is or is intended to be marketed, as described in paragraph (a)(3)(iii) 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.

d. For indications for which the drug has been classified as possibly effective (not included in the "Indications" section above), continued use as described in paragraphs (d), (e), and (f) of that notice.

c. *Opportunity for a hearing.* 1. The Commissioner of Food and Drugs proposes to issue an order under the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of all new-drug applications and all amendments and supplements thereto providing for the indications for which substantial evidence of effectiveness is lacking as described in paragraph

A. 3 of this announcement. An order withdrawing approval of the applications will not issue if such applications are supplemented, in accord with this notice, to delete such indications. Any related drug for human use, not the subject of an approved new drug application, offered for the indications for which substantial evidence of effectiveness is lacking may be affected by this action.

2. In accordance with the provisions of section 505 of the Act (21 U.S.C. 355), and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the holders of any such applications, and any interested person who would be adversely affected by such an order, an opportunity for a hearing to show why such indications should not be deleted from labeling. A request for a hearing must be filed within 30 days after the date of publication of this notice in the FEDERAL REGISTER.

3. A request for a hearing may not rest upon mere allegations or denials but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing, together with a well organized and full factual analysis of the clinical and other investigational data that the objector is prepared to prove in a hearing. Any data submitted in response to this notice must be previously unsubmitted and include data from adequate and well controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

4. If a hearing is requested and is justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue a written notice of the time and place at which the hearing will commence.

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 11730, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 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.

Request for Hearing (Identify with Docket Number): Hearing Clerk, Office of General Counsel (GC-1), Room 6-88, Parklawn Building.

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.

Received requests for a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

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 28, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10537 Filed 7-10-72; 8:49 am]

[DESI 366]

PARENTERAL BRONCHODILATORS

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 parenteral bronchodilators:

1. Caytine Injection, containing protokylol hydrochloride; Lakeside Laboratories, Division of Colgate-Palmolive Co., 1707 East North Avenue, Milwaukee, Wis. 53203 (NDA 11-469).

2. Sus-Phrine Suspension, containing epinephrine; Cooper Laboratories, Inc., 546 Bedford Road, Bedford Hills, N.Y. 10507 (NDA 7-942).

3. Adrenalin in Oil for injection, containing ephrinphrine; Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232 (NDA 0-366).

4. Epinephrine Suspension; Endo Laboratories, Inc., 1000 Stewart Avenue, Garden City, N.Y. 11533 (NDA 1-225).

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 conclude that:

1. Protokylol hydrochloride for injection is probably effective for the symptomatic relief of acute and chronic bronchial asthma and for bronchospasm associated with emphysema, chronic bronchitis, and bronchiectasis.

2. Epinephrine suspension parenteral is probably effective for the treatment of bronchial asthma; urticaria; angioedema; and hay fever. In the case of the oil suspension, a question of safety as well as efficacy is involved.

3. Protokylol hydrochloride for injection lacks substantial evidence of effectiveness for use in the treatment of pulmonary fibrosis.

B. *Marketing status.* 1. Within 60 days of the date of publication of this announcement in the FEDERAL REGISTER, the holder of any previously approved new drug application for a drug which is classified in paragraph A above as