

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 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.

e. *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 ephedrine; 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

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 and which contains an Indications section in accord with that described below. Such 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 to delete all claims for which substantial evidence of effectiveness is lacking as described in paragraph A. above and to be in accord with this notice. Failure to delete such indications and to 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. Labeling revised pursuant to this notice should take into account the comments of the Academy; furnish adequate information for safe and effective use of the drug; and recommend use of the drug (for the probably effective indications) as follows:

INDICATIONS

PROTOKYLOL HYDROCHLORIDE FOR INJECTION

For the symptomatic relief of acute and chronic bronchial asthma; and for bronchospasm associated with emphysema, chronic bronchitis, and bronchiectasis.

EPINEPHRINE SUSPENSION PARENTERAL

For the symptomatic treatment of bronchial asthma; urticaria; angio-edema; and hay fever.

4. 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 (c), (e), and (f) the marketing status of the drug labeled with those indications for which it is regarded as probably effective. For epinephrine suspension parenteral it is recommended that applicants discuss with the administration the kinds of clinical studies needed.

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 366, 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 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 2.120).

Dated: June 28, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10534 Filed 7-10-72; 8:49 am]

[DESI 6403]

CERTAIN PERIPHERAL VASODILATORS

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 peripheral vasodilator drugs:

1. Priscoline Hydrochloride Tablets and Injection, each containing tolazoline hydrochloride; Ciba Pharmaceutical Co., Division Ciba-Geigy Corp., 556 Morris Avenue, Summit, N.J. 07901 (NDA 6-403).

2. Priscoline Hydrochloride Lontabs, sustained release tablets containing tolazoline hydrochloride; Ciba Pharmaceutical Co. (NDA 11-770).

3. Vasodilan Injection and Tablets, each containing isoxsuprine hydrochloride; Mead Johnson Laboratories, Division of Mead Johnson & Co., 2404 Pennsylvania Street, Evansville, Ind. 47721 (NDA 11-832).

4. Arlidin Solution for Injection containing nylidrin hydrochloride; USV Pharmaceutical Corp., 1 Scarsdale Road, Tuckahoe, N.Y. 10707 (NDA 9-813).

5. Ildar Tablets containing azapetine phosphate; Roche Laboratories, Division of Hoffmann-La Roche Inc., 340 Kingsland Road, Nutley, N.J. 07110 (NDA 9-225).

6. Dibenzylamine Capsules containing phenoxybenzamine hydrochloride; Smith Kline & French Laboratories, 1500 Spring Garden Street, Philadelphia, Pa. 19101 (NDA 8-708).

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

1. Tolazoline hydrochloride lacks substantial evidence of effectiveness for spastic peripheral vascular disorders which may be associated with cerebrovascular accidents and with ulcers.

2. Nylidrin hydrochloride lacks substantial evidence of effectiveness for the treatment of cerebrovascular disorders such as cerebral arteriosclerosis; relief of pain, ache, spasm, intermittent claudication, paresthesias, numbness, coldness, increased walking ability, promotion of healing of trophic ulcers associated with livedo reticularis; all forms of peripheral vascular disease; and increasing blood flow in the brain and eye, with clinical application in cerebral arteriosclerosis and other ischemic disturbances of the brain and eye.

3. Isoxsuprine hydrochloride lacks substantial evidence of effectiveness as a cerebral vasodilator in the management of hypertensive and arteriosclerotic cerebral vascular disease, as a uterine relaxant in the management of dysmenorrhea and uterine spasm, for the symptomatic relief of vascular insufficiency associated with peripheral vascular disease, post-phlebotic conditions, acroparesthesia, frostbite syndrome, ulcers of the extremities, as a peripheral vasodilator in the management of diabetic arteriosclerosis, diabetic vascular disease, for arterial thromboembolic occlusion, and for use in premature labor.

4. All these drugs, tolazoline hydrochloride, isoxsuprine hydrochloride, nylidrin hydrochloride, azapetine phosphate, and phenoxybenzamine hydrochloride, are regarded as possibly effective for their labeled indications other than those described above.

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 6403, 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 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 2.120).

Dated: June 28, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10535 Filed 7-10-72; 8:49 am]

[DESI 9414]

CERTAIN STEROID COMBINATION PREPARATIONS 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:

A. *Prednisone in combination with other active components.* 1. Co-Deltra Tablets containing 2.5 mg. or 5.0 mg. prednisone, magnesium trisilicate and dried aluminum hydroxide gel; Merck, Sharp, & Dohme, Division Merck and Co., Inc., West Point, Pa. 19486 (NDA 10-371).

2. Predsem Tablets containing prednisone, calcium pantothenate, dried aluminum hydroxide gel and magnesium trisilicate; The S.E. Massengill Co., 527 Fifth Street, Bristol, Tenn. 37620 (NDA 11-022).

B. *Prednisolone in combination with other active components.* 1. Ataraxoid Tablets containing 2.5 mg. or 5.0 mg. prednisolone and hydroxyzine hydrochloride; Chas. Pfizer and Co., Inc., 235 East 42d Street, New York, N.Y. 10017 (NDA 10-636).

2. Cordex Tablets and Cordex-Forte Tablets containing prednisolone and aspirin (NDA 10-185); and

3. Cordex (Buffered) Tablets and Cordex-Forte (Buffered) Tablets contain-

ing prednisolone, aspirin and calcium carbonate (NDA 10-185); The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002.

4. Co-Hydeltra Tablets containing 2.5 mg. or 5.0 mg. prednisolone, magnesium trisilicate and dried aluminum hydroxide gel; Merck Sharp & Dohme (NDA 10-372).

5. Deltacortril-APC Tablets containing prednisolone, aspirin, phenacetin and caffeine; Chas. Pfizer and Co., Inc. (NDA 10-774).

C. *Methylprednisolone in combination with other active components.* 1. Medaprin Tablets and Medadent Tablets containing methylprednisolone, aspirin and calcium carbonate (NDA 11-632); and

2. Cordex Improved Tablets and Cordex-Forte Improved Tablets containing methylprednisolone and aspirin (NDA 11-455); The Upjohn Co.

D. *Dexamethasone in combination with other active components.* 1. Decagesic Tablets containing dexamethasone, aspirin and dried aluminum hydroxide gel; Merck Sharp & Dohme (NDA 12-187).

2. Delenar Tablets containing dexamethasone, orphenadrine hydrochloride and aluminum aspirin; Schering Corp., 1011 Morris Avenue, Union, N.J. 07083 (NDA 12-092).

3. Dronactin Tablets containing dexamethasone and cyproheptadine hydrochloride, Merck Sharp & Dohme (NDA 13-084).

E. *Cortison acetate in combination with other active components.* 1. Salcort Tablets containing cortisone acetate, sodium salicylate, dried aluminum hydroxide gel, calcium ascorbate and calcium carbonate; The S. E. Massengill Co. (NDA 9-414).

Notices published in the FEDERAL REGISTER of August 4, 1971 (36 F.R. 14342), and February 8, 1972 (37 F.R. 2851), withdrew approval of NDA 11-022 Predsem Tablets and NDA 10-372 Co-Hydeltra Tablets, respectively, on the grounds that the applicants had failed to make reports under section 505(j) of the act (21 U.S.C. 355(j)) and § 130.13 or § 130.35 (e) and (f) of the new-drug regulations (21 CFR 130.13 and 130.35).

The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that there is a lack of substantial evidence, within the meaning of the Federal Food, Drug, and Cosmetic Act, that these fixed combination drugs will have the effects that they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling and that each component of such drugs contributes to the total effects claimed.

Accordingly, except for those applications for which approval has already been withdrawn (NDA 11-022; NDA 10-372), the Commissioner of Food and Drugs intends to initiate proceedings to withdraw approval of the above-listed new-drug applications. Any related drug for human use, not the subject of an approved new-drug application, may be affected by this action.

Prior to initiating such action, however, the Commissioner invites the holders of the new-drug applications for these drugs and any interested person who might be adversely affected by their removal from the market, to submit pertinent data bearing on the proposal within 30 days after publication hereof in the FEDERAL REGISTER. To be acceptable for consideration in support of the effectiveness of a drug, any such data must be previously submitted, well organized, and include data from adequate and well controlled clinical investigations (identified for ready review) as described in section 130.12(a)(5) of the regulations published as a final order 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 the approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

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 9414, 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-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 the 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 30, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10536 Filed 7-10-72; 8:49 am]

[Docket No. FDC-D-379; NDA's 4-687, etc.]

MERCK, SHARP & DOHME AND SCHERING CORP.

Poorly Absorbed Sulfonamides for Oral or Rectal Use, Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New- Drug Applications

In the FEDERAL REGISTER of September 19, 1970 (35 F.R. 14666), the Food and Drug Administration announced (DESI 5803) its conclusions pursuant to evaluation by the National Academy of Sciences-National Research Council, Drug Efficacy Study Group concerning the following drugs:

1. Cremothalidine (phthalylsulfathiazole) Suspension and Sulfathalidine (phthalylsulfathiazole) Tablets (NDA 5-803); Merck, Sharp & Dohme, Division of Merck and Co., Inc., West Point, Pa. 19486.

2. Sulfasuxidine (succinylsulfathiazole) Tablets and Powder (NDA 4-687); Merck, Sharp & Dohme.

3. Thalamyd (phthalylsulfacetamide) Tablets and Phthalylsulfacetamide Sodium Powder¹ (NDA 6-593); Schering Corp., 60 Orange Street, Bloomfield, N.J. 07003.

The announcement stated that the drugs lacked substantial evidence of effectiveness for ileitis and were regarded as possibly effective for their other indications. Six months were allowed for obtaining and submitting substantial evidence of effectiveness for the possibly effective indications. In that such evidence has not been received the drugs have been reclassified as lacking substantial evidence of effectiveness for all of their labeled indications.

Therefore, notice is given to Merck, Sharp & Dohme and to Schering Corp. and to any interested person who may be adversely affected, that the Commissioner of Food and Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the above-named new-drug applications (with respect to NDA 4-687, only that portion providing for Sulfasuxidine Tablets and Powder), and all amendments and supplements applying thereto, on the grounds that new information before the Commissioner with respect to the drugs, evaluated together with the evidence available to him when the applications were approved, shows there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

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 applicants, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new-drug applications should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER such persons are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or
2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing the Commissioner without further notice will enter a final order withdrawing approval of the new-drug applications. Failure of such persons to file a written

appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public unless the respondent specifies otherwise in his appearance.

If such persons elect to avail themselves of the opportunity for a hearing they must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new-drug application should not be withdrawn, together with a well-organized and full factual analysis of the clinical and other investigational data they are prepared to prove in support of their opposition. 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. When it clearly appears from the data in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, the Commissioner will enter an order on these data, making findings and conclusions on such data.

If a hearing is requested and justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence (35 F.R. 7250, May 8, 1970; 35 F.R. 16631, October 27, 1970).

Received requests for a hearing and/or elections not to request 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 (sec. 505, 52 Stat. 1052-53, as amended: 21 U.S.C. 355) and under the authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 29, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10540 Filed 7-10-72; 8:49 am]

Office of the Secretary

PUBLIC HEALTH SERVICE AND FOOD AND DRUG ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part 6 (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health, Education, and Welfare (35 F.R. 3685-92, dated February 25, 1970) is amended to reflect the

deletion of paragraph (i) Office of the Assistant Commissioner for Program Coordination; the revision of paragraph (f) Office of the Assistant Commissioner for Administration, paragraph (f-2) Division of General Services, and paragraph (f-3) Division of Management Systems; and the establishment of an ADP Systems Policy and Operations Center, paragraph (f-5). These changes result from the disestablishment of the Office of the Assistant Commissioner for Program Coordination.

Section 6B is amended as follows:

SEC. 6B Organization. * * *

(f) Office of the Assistant Commissioner for Administration. Serves as principal advisor to the Commissioner on all phases of management inherent in the operations of FDA.

Responsible for the effective utilization of all management resources and the implementation of operating programs by coordinating the funding, manpower, facilities, and equipment needs of the Agency.

Provides leadership and direction to administrative management including budget, finance, personnel, organization, methods, procurement and property, records, and similar supporting activities.

Assures that conduct of these efforts effectively supports program operations.

Develops policy and procedures necessary to maintain the integrity of trade secrets and other privileged information submitted by industry to FDA; formulates Agency-wide security policy and investigates and recommends action concerning security problems.

Develops data systems policy and procedures necessary to coordinate all FDA information and data retrieval systems and ADP equipment; operates FDA's central computer facility; and provides systems analysis and programming services.

(f-2) Division of General Services. Provides leadership and guidance to headquarters staff officers, headquarters operating activities, and District offices for all general services programs, including procurement, contracts, administrative aspects of grants and fellowships, personal property management and accountability, real property management, space management and utilization, construction and engineering services, communications, printing and reproduction, and mails and files.

Responsible for maintaining effective liaison with the Government Printing Office, and for the centralized clearance and coordination of all printing and publication services.

Coordinates the development of Agency-wide policies and procedures for such services and plans; executes, evaluates, and adjusts efforts in these activities.

(f-3) Division of Management Systems. Provides assistance in organization and operations analysis; planning and evaluation; effective and economical use of resources; and analysis, design, and maintenance of operating systems and procedures.

¹ Powder not reviewed by Academy.