

(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 A venue, 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 persons 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 unsubmitted, 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: