

nounced his conclusions pursuant to the evaluation of two reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs containing conjugated estrogens with meproamate:

NDA 10-971; PMB-200 and PMB-400 tablets, marketed by Ayerst Laboratories, Division of American Home Products Corporation, 685 Third Avenue, New York, N.Y. 10017.

NDA 11-045; Milprem-200 and Milprem-400 tablets, marketed by Wallace Laboratories, Division of Carter-Wallace Inc., Half Acre Road, Cranbury, N.J. 08512.

The announcement stated that the Food and Drug Administration has considered the Academy reports, as well as other available evidence, and concludes there is a lack of substantial evidence that such fixed combination drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling and that each component of the combination drug contributes to the total effects claimed, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug applications. Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcements. No data providing substantial evidence of effectiveness were received pursuant to the announcement.

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner 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 listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug(s) will have all the effects purported or represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, Md. 20852.

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 hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he 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(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his 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 (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) for the labeling claims involved, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, 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. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the

hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. 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.

Requests for a hearing and/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 the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: November 14, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-20345 Filed 11-27-72; 8:47 am]

[DESI 9414; Docket No. FDC-D-528; NDA 9-414 etc.]

### CERTAIN STEROID COMBINATION PREPARATIONS FOR ORAL USE

#### Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

In an announcement (DESI 9414) published in the FEDERAL REGISTER of July 11, 1972 (37 F.R. 13566), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of 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).

#### 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, NY 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 containing prednisolone, aspirin, and calcium carbonate (NDA 10-185); The Upjohn Co., 7171 Portage Road, Kalamazoo, MI 49002.

4. 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, NJ 07083 (NDA 12-092).

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

**E. CORTISONE 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).

In addition to the drugs listed above, the following preparation, although not reviewed by the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, is regarded to be affected by the announcement of July 11, 1972:

Stero-Darvon with A.S.A. Tablets containing paramethasone acetate, propoxyphene hydrochloride, and aspirin; Eli Lilly and Co., Post Office Box 618, Indianapolis, IN 46206 (NDA 14-768).

The announcement stated that there is a lack of substantial evidence 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 and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug applications for the drugs. Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcement. Data submitted by Merck Sharp & Dohme concerning Decagesic Tablets (NDA 12-187) were evaluated and found not to provide substantial evidence of effectiveness. No other data were received.

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner 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 listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug(s) will have all the effects purported or represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

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 hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 8-88, 5600 Fishers Lane, Rockville, MD 20852, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he 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(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his 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 (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) for the labeling claims involved, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, 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. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. 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.

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 the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: November 14, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-20346 Filed 11-27-72; 8:47 am]

[DESI 5597; Docket No. FDC-D-562;  
NDA No. 8-240]

**PREPARATION CONTAINING ACETAMINOPHEN, SALICYLAMIDE, AMPHETAMINE PHOSPHATE, AND METHYLATROPINE NITRATE**

**Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application**

In a notice (DESI 5597) published in the FEDERAL REGISTER of January 10,