on the date of publication of this document.

Dated: March 20, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-483/ Filed 3-29-72;8:50 am]

[DESI 8881; Docket No. FDC-D-437; NDA 9-459]

RICHLYN LABORATORIES, INC.

Hexamethonium Chloride for Oral Use; Notice of Withdrawal of Approval of New-Drug Application

In an announcement (DESI 8881) published in the FEDERAL REGISTER of May 22, 1971 (36 F.R. 9342) 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 Hexamethonium Chloride Tablets. The announcement stated that there is a lack of substantial evidence that oral forms of hexamethonium chloride will have the antihypertensive effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug applications providing for this drug. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. No such data have been received. Richlyn Laboratories, Inc., Castor and Kensington Avenues, Philadelphia, Pa. 19124, holder of NDA 9-459 Hexamethonium Chloride Tablets, one of the two drugs included in the announcement, has voluntarily requested withdrawal of approval of their application, thereby waiving their opportunity for a hearing, stating that the drug is no longer marketed.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of the above new-drug application, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (3-30-72).

Dated: March 23, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-4821 Filed 3-29-72;8:49 am]

[Docket No. FDC-D-432; NDA 1-593]

SCHERING CORP.

Ethisterone for Oral Use; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New-Drug Application

In a notice (DESI 1593) published in the FEDERAL REGISTER of October 24, 1970 (35 F.R. 16607), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the drug described below, stating that the drug is regarded as possibly effective and lacking substantial evidence of effectiveness for the labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drug has been submitted within the period provided.

NDA 1-593; Pranone Tablets containing ethisterone; Schering Corp., 1011 Morris Ave., Union, N.J. 07003.

Progesterol (ethisterone) Tablets (NDA 1-704) was also included in the announcement of October 24, 1970. Organon, Inc., holder of NDA 1-704, having discontinued marketing of the drug, requested withdrawal of approval of the application. Withdrawal of approval of that application was published in the FEDERAL REGISTER October 27, 1971 (36 F.R. 20619).

Therefore, notice is given to Schering Corporation and to any interested person who may be adversely affected, 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 new drug application No. 1-593 and all amendments and supplements thereto on the grounds that new information before him with respect to the drug, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug will have all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its 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 applicant, 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 application should not be withdrawn. Any related drug for human use, not the subject of an approved new-drug application, may be affected by this action.

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 6-88, 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 application. 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 an 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, Oct. 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 authority delegated to the Commissioner (21 CFR 2.120).

Dated: March 20, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-4838 Filed 3-29-72;8:51 am]