

Administration announced its conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, concerning the subject drugs. Among the drugs included in that announcement were the following:

1. Delvex Tablets containing dithiazanine iodide; Eli Lilly & Co., Post Office Box 618, Indianapolis, IN 42606 (NDA 11-440).

2. Lucanthone Hydrochloride Tablets; Burroughs Wellcome and Co., Inc., 3030 Cornwallis Road, Research Triangle Park, NC 27709 (NDA 12-344).

For these two drugs, the announcement required, among other things, submission of abbreviated new drug applications, abbreviated supplements, and data to assure bioavailability.

Because of the potential toxicity of these two drugs, the Commissioner concludes that the requirement for bioavailability testing is not appropriate, and that, for the same reason, abbreviated applications and supplements are not acceptable. Therefore, with respect to these two drugs, only, marketing 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. 12273), 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 and a supplement for updating information as described in paragraphs (a)(1)(i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new drug application, the submission of a full new drug application as described in paragraph (a)(3)(iii) of that notice. The Office of Scientific Evaluation (BD-100), Bureau of Drugs should be contacted concerning the clinical studies required.

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 authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: November 6, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-19403 Filed 11-10-72;8:47 am]

[Docket No. FDC-D-533; NADA No. 11-353V]

WHITMOYER LABORATORIES, INC. Thera-Tergent; Notice of Opportunity for Hearing

In an announcement published in the FEDERAL REGISTER of September 5, 1970 (35 F.R. 14168, DESI 901V), the Commissioner of Food and Drugs announced the conclusions of the Food and Drug Administration following evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on

Thera-Tergent NADA (new animal drug application) No. 11-353V; marketed by Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., 19 North Railroad Street, Myerstown, PA 17067 (formerly marketed by Warren-Teed Pharmaceuticals, Inc.). The announcement invited the holder of said new animal drug application and any other interested persons to submit pertinent data on the drug's effectiveness.

A satisfactory supplemental new animal drug application has not been submitted in response to said announcement and available information fails to provide substantial evidence that this drug will have the effect it purports to have when administered in accordance with the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, notice is given to Whitmoyer Laboratories, Inc., and to any other interested person who may be adversely affected that the Commissioner proposes to issue an order under the provisions of section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) withdrawing approval of NADA No. 11-353V, including all amendments and supplements thereto.

In accordance with the provisions of section 512 of the Act (21 U.S.C. 360b), the Commissioner hereby gives the applicant and any interested persons who would be adversely affected by an order withdrawing such approval an opportunity for a hearing at which time such persons may produce evidence and arguments to show why approval of NADA No. 11-353V should not be withdrawn. Promulgation of the order will cause any drug similar in composition to the above-cited drug product and recommended for similar conditions of use to be a new animal drug for which an approved new animal drug application is not in effect. Any such drug then on the market would be subject to appropriate regulatory 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, Office of the General Counsel, 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 animal 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 the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing concerning a method or process that the Commissioner finds is 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 a written appearance requesting the hearing and giving the reasons why approval of the new animal 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 to the grounds for this notice. A request for a hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine and substantial issue of fact requiring 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 stating his findings and conclusions of such data. If a hearing is requested, and is justified by the response to this notice, the issues will be defined, an administrative law judge will be named, and he shall issue a written notice of a time and place at which the hearing will commence.

Responses to this notice will be available for public inspection in the Office of the Hearing Clerk (address given above), during regular business hours, Monday through Friday.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b) and under the authority delegated to the Commissioner (21 CFR 2.120).

Dated: November 6, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-19401 Filed 11-10-72;8:47 am]

Health Services and Mental Health Administration

NATIONAL ADVISORY HEALTH SERVICES COUNCIL AND FEDERAL HOSPITAL COUNCIL

Notice of Meetings During November

Pursuant to Executive Order 11671, the Administrator, Health Services and Mental Health Administration, announces the reissuance of meeting dates and other required information for the following National Advisory bodies scheduled to assemble during the month of November 1972, in accordance with provisions set forth in section 13(a) (1) and (2) of that Executive Order:

Committee name, date, time, place, type of meeting and/or contact person

Joint Meeting of the National Advisory Health Services Council and the Federal Hospital Council, November 15, 9 a.m., Conference Room G-H, Parklawn Building, 5600 Fishers Lane, Rockville, Md., Open, Contact Russell Z. Seidel, Room 15-85, Parklawn Building, 5600 Fishers Lane, Rockville, Md. Code 301-443-2940.

Purpose: The Councils are charged with advising on policies and regulations under title III and title VI of the Public Health Service Act.

Agenda: The Councils will be receiving reports from the Director and Staff members of