

chlorpheniramine maleate, and theophylline; Cole Pharmacal Co., Inc., 3721 Laclede Avenue, St. Louis, MO 63108. Asminyl H-F Tablets, although listed in the announcement of July 26, 1972, as being a part of NDA 3-523, was never specifically included in, or supplemented to, this NDA. It is thus not an appropriate subject of this notice but will be affected by this notice as it is a related drug.

The announcement stated that there is a lack of substantial evidence that these combination drugs, as presently formulated, will have the effects that they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, or 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 for the drugs.

Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcement. No data providing substantial evidence of effectiveness have been 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) or pertinent parts thereof 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person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing.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) or pertinent parts thereof.

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. 72-20250 Filed 11-24-72; 8:46 am]

[DESI 2411; Docket No. FDC-D-510;  
NDA 2-411]

ELI LILLY

### Potassium Thiocyanate; Notice of Withdrawal of Approval of New Drug Application

A notice was published in the FEDERAL REGISTER of August 30, 1972 (37 F.R. 17574) extending to the holder of the new drug application listed below, and to any interested person an opportunity for hearing on the proposal of the Commissioner of Food and Drugs to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act, withdrawing approval of the listed application and all amendments and supplements thereto. The basis of the proposed action was the lack of substantial evidence that the effectiveness of this product is sufficient to justify its use in view of known serious hazards associated with its use.

NDA 2-411; Potassium Thiocyanate Enseals (enteric coated tablets); Eli Lilly & Co., Post Office Box 618, Indianapolis, IN 46206.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application reviewed and are subject to this notice. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). 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.

Neither Eli Lilly & Co., nor any other interested person has filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes an election by such persons not to avail themselves of an opportunity for hearing.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended; 21 U.S.C. 355), and the Administrative Procedure

Act (5 U.S.C. 554), and under authority delegated to him (21 CFR 2.120), finds that on the basis of new information <sup>made</sup> before him with respect to the 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 findings, approval of the above-listed new drug application and all amendments and supplements thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER. Shipment in interstate commerce of the above drug product or of any identical, related, or similar product, not the subject of an approved new drug application, is henceforth unlawful.

Dated: November 16, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-20251 Filed 11-24-72;8:47 am]

National Institutes of Health  
CHEMICAL/BIOLOGICAL INFORMATION-HANDLING REVIEW COMMITTEE

Notice of Meeting

<sup>nuse</sup> Pursuant to Executive Order 11671, notice is hereby given of the meeting of the Chemical/Biological Information-Handling Review Committee, Tuesday, December 19, 1972, at 9 a.m., University of Pittsburgh, Pittsburgh, Pa. This meeting will take place in two different locations at the University, as follows:

Part 1: 401 Bruce Hall, 9 a.m.-9:30 a.m. Closed executive session for briefing evaluators. 9:30 a.m.-12 Noon. Open seminar on the contract activities of the University of Pittsburgh in the Development of Techniques for Computer Based Inferential Information Retrieval in Pharmacology.

Part 2: 618 Scaife Hall, 1 p.m.-3 p.m. Open presentation of application of the PROPHET System by the University of Pittsburgh.

Attendance by the public will be limited to space available.

The Information Officer who will furnish summaries of the meeting and rosters of committee members is Mr. James Augustine, Division of Research Resources, Building 31, Room 4B03, Bethesda, Md. 20014, telephone 301-496-5545.

The Executive Secretary from whom substantive program information may be obtained is Dr. William Raub, Chief, Biotechnology Resources Branch, Division of Research Resources, Building 31,

Room 5B19, Bethesda, Md. 20014, telephone 301-496-5411.

JOHN F. SHERMAN,  
Deputy Director,  
National Institutes of Health.

NOVEMBER 17, 1972.

[FR Doc.72-20298 Filed 11-24-72;8:51 am]

ATOMIC ENERGY COMMISSION

[Docket No. 50-346]

CLEVELAND ELECTRIC ILLUMINATING CO. AND TOLEDO EDISON CO.

Notice of Availability of Draft Environmental Statement and Applicant's Environmental Report and Supplemental Environmental Reports

Pursuant to the National Environmental Policy Act of 1969 and the Atomic Energy Commission's regulations in Appendix D to 10 CFR Part 50, notice is hereby given that a document entitled "Draft Environmental Statement," related to the construction and operation of the Davis-Besse Nuclear Power Station, located on the southwest shore of Lake Erie in Ottawa County, Ohio, by the Toledo Edison Co., and the Cleveland Electric Illuminating Co., has been prepared by the Commission's Directorate of Licensing. The statement is available for inspection by the public in the Commission's Public Document Room at 1717 H Street NW., Washington, DC, and in the Ida Rupp Public Library, Port Clinton, Ohio 43452. The statement is also being made available at the Office of the Governor, State Clearinghouse, 62 East Broad Street, Second Floor, Columbus, OH 43215. Copies of the Commission's draft environmental statement may be obtained upon request addressed to the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing.

Documents entitled "Applicants' Environmental Report Construction Permit Stage" and supplements thereto, submitted by The Toledo Edison Co. and The Cleveland Electric Illuminating Co. are also available for public inspection at the above-designated locations. Notice of the availability of "Applicants' Supplemental Environmental Report Construction Permit Stage" was published in the FEDERAL REGISTER on December 24, 1971 (36 F.R. 24946).

Pursuant to Appendix D to 10 CFR Part 50, interested persons may, within forty-five (45) days from date of publication of this notice in the FEDERAL REGISTER, submit comments on the proposed continuation, modification, or termination of Construction Permit No. CFP-80, "Applicants' Environmental Report" and supplements thereto, and the Draft Environmental Statement for

the Commission's consideration. Federal and State agencies are being provided with copies of these reports and the Draft Environmental Statement (local agencies may obtain these documents upon request) and, when any comments thereon by Federal, State, and local officials are received, they will be made available for public inspection at the above-designated locations. Comments from interested members of the public should be addressed to the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing.

Dated at Bethesda, Md., this 17th day of November 1972.

For the Atomic Energy Commission.

DANIEL R. MULLER,  
Assistant Director for Environmental Projects, Directorate of Licensing.

[FR Doc.72-20168 Filed 11-24-72;8:45 am]

[Docket No. 50-263]

NORTHERN STATES POWER CO.

Notice of Availability of Final Environmental Statement for the Monticello Nuclear Generating Plant, Unit 1

Pursuant to the National Environmental Policy Act of 1969 and the Atomic Energy Commission's regulations in appendix D to 10 CFR Part 50, notice is hereby given that the "Final Environmental Statement Related to the Monticello Nuclear Generating Plant, Unit 1, Docket No. 50-263," prepared by the Directorate of Licensing, U.S. Atomic Energy Commission, is being placed in the following locations where it will be available for inspection by members of the public: The Commission's Public Document Room at 1717 H Street NW., Washington, DC 20545, and at the Environmental Resources Center, Minneapolis Public Library, 1222 Southeast Fourth Street, Minneapolis, MN 55414. The report is also being made available at the Minnesota State Planning Agency, Suite 802, 550 Cedar Street, St. Paul, MN 55101.

The notice of availability of applicant's Environmental Report and AEC's Draft Environmental Statement for the Monticello Nuclear Generating Plant and requests for comments from interested persons was published in the FEDERAL REGISTER on June 2, 1972 (37 F.R. 11080). The comments received from Federal, State, and local officials and interested members of the public have been included as appendices to the Final Environmental Statement.

Single copies of the Final Environmental Statement may be obtained by writing the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: