

include the status of beginning and ending inventories of finished watch movements and component parts, scheduled entry dates and number of watch movement parts and components ordered, number of watch movements assembled, number of watch movements entered into the customs territory of the United States, and a list of confirmed orders for shipment of finished watch movements into the customs territory of the United States prior to December 31, 1973. Each producer to which a quota is granted will also report on Form OIPF-844 any change in ownership and control which has occurred subsequent to the filing of an application for a watch quota on Form OIPF-764 (see section 8, below).

Sec. 3. Application forms will be mailed to recipients of initial quota allocations as soon as practicable and must be filed with the Departments on or before January 31, 1973. All data required must be supplied as a condition for annual allocations and are subject to verification by the Departments. In order to accomplish this verification it will be necessary for representatives of the Departments to meet with appropriate officials of quota recipients in the insular possessions in order to have access to company records. Representatives of the Departments plan to perform this verification beginning on or about February 15, 1973 in Guam and American Samoa and beginning on or about March 1, 1973 in the Virgin Islands, and will contact each producer locally regarding the verification of its data.

Sec. 4. (Virgin Islands only) The annual quotas for calendar year 1973 for the Virgin Islands will be allocated as soon as practicable after April 1, 1973, on the basis of (1) the number of units assembled by each producer in the territory and entered by it duty-free into the customs territory of the United States during calendar year 1972, (2) the total dollar amount of wages subject to FICA taxes paid by such producer in the territory during calendar year 1972 to persons whose pay was attributable to its Headnote 3(a) watch assembly operation, and (3) the total net dollar amount of income taxes applicable to its calendar year 1972 Headnote 3(a) watch assembly operation, irrespective of whether such taxes are partially or fully exempt by the territorial government. In making allocations under this formula, an equal weight of 40 percent will be assigned to production and shipment history and to wages subject to FICA taxes, and a weight of 20 percent will be assigned to the total net dollar amount of income taxes applicable to calendar year 1972 Headnote 3(a) watch assembly operations.

Sec. 5. (Guam only) The annual quotas for calendar year 1973 for Guam will be allocated as soon as practicable after April 1, 1973 on the basis of the number of units assembled by each producer in the territory and entered by it duty-free into the customs territory of the United States during calendar year 1972, and the total dollar amount

of wages subject to FICA taxes paid by such producer in the territory during calendar year 1972 to persons whose pay was attributable to its Headnote 3(a) watch assembly operation. In making allocations under this formula, equal weight will be assigned to production and shipment history and to wages subject to FICA taxes.

Sec. 6. (Virgin Islands and Guam) For purposes of allocating watch quotas for calendar year 1973 under sections 4 and 5 above, any watches or watch movements shipped from the Virgin Islands or Guam during calendar year 1972 for duty-free entry into the customs territory of the United States against a producer's 1972 watch quota, and which were lost prior to entry into the customs territory of the United States, shall nevertheless be considered as having been entered into the customs territory for purposes of quota fulfillment: *Provided*, That the Departments have been satisfied that shipment was in fact made but lost prior to entry into the customs territory.

Sec. 7. (Virgin Islands only) With respect to the Virgin Islands quota, in the event that the quantity of any unused calendar year 1972 quota plus any increase (or minus any decrease) in the amount of quota available for calendar year 1973 in comparison with that for 1972, equals or exceeds 200,000 units, the Departments may set aside 200,000 units of the calendar year 1973 Virgin Islands quota for new firms and invite quota applications from new firms on Form OIPF-764. The Departments may also require new firms to provide information regarding the applicant's experience in watch movement assembly and distribution; anticipated employment of local workers and proposed wage rates; watch movement assembly operations to be performed in the Virgin Islands and estimated direct labor costs; anticipated capital investment in the Virgin Islands and proposed source of financing. (By "new firm" is meant an entity which has not heretofore been allocated a quota under Public Law 89-805 and which is completely separate and unassociated with any present or previous producer in terms of ownership and control.) Based on the Departments' evaluation of the information submitted by applicants, the Departments may allocate the set-aside portion of the calendar year 1973 Virgin Islands quota among those applicants whose proposals, in the judgment of the Departments, offer the likelihood of the greatest contribution to the economy of the Virgin Islands, and in such a manner as, in the judgment of the Departments, will best serve the interests of the territory.

Sec. 8. The rules restricting transfers of duty-free quotas issued on January 29, 1968, and published in the FEDERAL REGISTER on January 31, 1968 (33 F.R. 2399), are hereby incorporated by reference as applicable to transfers of quotas issued during calendar year 1973 except that detailed reporting of ownership and control will be reported on an

annual basis on Form OIPF-764 at the time the producer applies for an annual duty-free watch quota for calendar year 1973. Subsequent change in ownership and control will be reported on April 15, July 15, and October 15, 1973, on Form OIPF-844 required in section 2 above.

Any interested party has the right to petition for the amendment or repeal of the foregoing rules and may seek relief from the application of any of their provisions upon a showing of good cause under the procedures relating to reviews by the Secretaries of Commerce and the Interior which were published in the FEDERAL REGISTER on November 17, 1967 (32 F.R. 15818).

Dated: November 20, 1972.

STANLEY NEHMER,
*Deputy Assistant Secretary, and
Director, Bureau of Resources
and Trade Assistance, De-
partment of Commerce.*

HARRISON LOESCH,
*Assistant Secretary for Public
Land Management, Depart-
ment of the Interior.*

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
[DESI 3523; Docket No. FDC-D-531; NDA
6-257 etc.]

CERTAIN COMBINATION DRUGS CONTAINING XANTHINE DERIVA- TIVES

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

In an announcement (DESI 3523) published in the FEDERAL REGISTER of July 26, 1972 (37 F.R. 14899), 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:

1. Deltasmyl tablets containing theophylline, ephedrine hydrochloride, prednisone, and phenobarbital; Roussel Corp., 155 East 44th Street, New York, NY 10017 (NDA 11-314).
2. That part of NDA 6-257 pertaining to Hydryllin tablets and elixir containing diphenhydramine and aminophylline; G. D. Searle & Co., Post Office Box 5110, Chicago, IL 60680.
3. Nethaprin Capsules and Syrup (2 reports) containing etafedrine hydrochloride, ambuphylline, and doxylamine succinate; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, OH 45215 (NDA 6-821).
4. Asminyl H-F Tablets containing sodium phenobarbital, ephedrine sulfate,

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