

# DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 5743; Docket No. FDC-D-529; NDA 5-743]

## AYERST LABORATORIES

### Sodium Fluoride, Ascorbic Acid, and Ergocalciferol Lozenge; Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application

In an announcement (DESI 5743) 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 a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on Enziflur Lozenges containing sodium fluoride, ascorbic acid, and ergocalciferol; previously marketed by Ayerst Laboratories, 685 Third Avenue, New York, NY 10017 (NDA 5-743).

The announcement stated that there is a lack of substantial evidence that this drug will have the effects 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 intended to initiate proceedings to withdraw approval of the new drug application. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. No data have been received, and Ayerst has informed the Administration that marketing of the drug was discontinued in 1971.

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/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 7, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-19566 Filed 11-14-72; 8:46 am]

[DESI 6261; Docket No. FDC-D-524;  
NDA 6-257]

## G. D. SEARLE AND CO.

### Combination Containing Diphenhydramine, Aminophylline, and Racedephedrine Hydrochloride for Oral Use; Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application

In an announcement (DESI 6261) published in the FEDERAL REGISTER of July 27, 1972 (37 F.R. 15031), 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 that part of NDA 6-257 pertaining to Hvdrvllin with Racedephedrine Tablets containing diphenhydramine, aminophylline, and racedephedrine hydrochloride; G. D. Searle and Co., Post Office Box 5110, Chicago, Ill. 60680.

The announcement stated that there is a lack of substantial evidence that this fixed combination drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling and that each component of such drug contributes to the total effects claimed and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of that part of the new drug application providing for that drug. Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcement. No