

DESI 3684; Docket No. FDC-D-406; NDA 3-684 etc.]

CERTAIN SULFONAMIDE-CONTAINING PREPARATIONS FOR TOPICAL, OPHTHALMIC OR OTIC USE

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

In a notice (DESI 3684) published in the FEDERAL REGISTER of September 25, 1970 (35 F.R. 14954) 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 subject drugs, stating that these drugs are regarded as possibly effective, and lacking substantial evidence of effectiveness for the various labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drugs has been submitted within the period provided.

Therefore, notice is given to the holders of the new drug applications listed below, 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 the listed new drug applications and all amendments and supplements thereto on the grounds that new information evaluated together with the evidence available when the applications were approved, shows there is a lack of substantial evidence that the drugs will have all the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

1. NDA 6-187; ACR-Allantomide Ointment containing sulfanilamide, aminacrine hydrochloride and allantoin; National Drug Co., Division of Richardson-Merrell Inc., 4663 Stenton Avenue, Philadelphia, Pa. 19144.

2. NDA 3-684; Allantomide Ointment containing sulfanilamide and allantoin; National Drug Co.

3. NDA 4-494; Sulfathiazole Cream 5 percent; Abbott Laboratories, 14th and Sheridan Road, North Chicago, Ill. 60064.

4. NDA 5-051; Alulotion Sulfathiazole containing sulfathiazole, kaolin and aluminum hydroxide gel; Wyeth Laboratories, Division American Home Products Corp., Post Office Box 8299, Philadelphia, Pa. 19101.

5. NDA 8-781; Gantrisin Ear Solution containing sulfisoxazole diolamine, urea, and chlorobutanol; Roche Laboratories, Division Hoffman-La Roche, Inc., 340 Kingsland Avenue, Nutley, N.J. 07110.

6. NDA 5-623; Otomide Otic Solution containing sulfanilamide, urea, and chlorobutanol; White Laboratories, Inc., Galloping Hill Road, Kenilworth, N.J. 07033.

7. NDA 4-757; Sulfanilamide Powder; Acme Scientific Co., Post Office Box 8826, Richmond, Va. 23225.

8. NDA 6-367; Brandenfels Scalp and Hair Applications and Massage, containing sulfanilamide (Formula A) and lanolin (Formula B); Carl Brandenfels, Scappoose, Oregon 97056.

9. NDA 4-361; Sulfanilamide Powder; Hynson, Westcott and Dunning, Inc., Charles and Chase Streets, Baltimore, Md. 21201.

10. NDA 4-507; Sulfathiazole Cream 5 percent; S. F. Durst and Co., Inc., 5317 North Third Street, Philadelphia, Pa. 19120.

11. NDA 4-604; Triethyl-Diazine Solution containing sulfadiazine; Lederle Laboratories, Division American Cyanamid Co.; Pearl River, N.Y. 10965.

12. NDA 4-122; Sulfadiazine Ointment 5 percent and Sulfadiazine Ophthalmic Ointment 5 percent; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206.

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 applicants, 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 applications 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 applications. 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 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 spe-

cific 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: February 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-2128 Filed 2-11-72; 8:50 am]

[Docket No. FDC-D-412; NDA 8-836, etc.]

GEIGY CHEMICAL CORP. AND ROCHE LABORATORIES; DIVISION OF HOFFMANN-LA ROCHE, INC.

Certain Topical Anti-Infective Drugs; Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Applications

In a notice (DESI 8836) published in the FEDERAL REGISTER of August 26, 1970 (35 F.R. 13604), 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 drugs listed below, stating that the drugs were regarded as possibly effective for the various labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of the drugs has been submitted within the period provided.

Therefore, notice is given to the holders of the new drug applications, 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 the listed new drug applications and all amendments and supplements thereto on the grounds that new information before him with respect to the drugs, evaluated together with the evidence available to him when

the applications were approved, shows there is a lack of substantial evidence that the drugs will have all the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

NDA 8-836, Sterosan Cream and Ointment, containing chlorquinaldol; Geigy Pharmaceuticals, Division of Geigy Chemical Co., Saw Mill River Road, Ardsley, N.Y. 10502.

NDA 11-675, Triburon Ointment; and

NDA 11-925, Triburon Cream, containing triclobisium chloride; Roche Laboratories, Division of Hoffmann-La Roche, Inc., 340 Kingsland Avenue, Nutley, N.J. 07110.

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 applicants, 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 applications would 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 applications. 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 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: February 2, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2130 Filed 2-11-72;8:50 am]

HYNITE CORP.

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409 (b) (5), 72 Stat. 1786; 21 U.S.C. 348 (b) (5)), notice is given that a petition (MF 3488) has been filed by the Hynite Corp., Carrollville Station, Oak Creek, Wis. 53154, proposing that § 121.301 *Hydrolyzed leather meal* (21 CFR 121.301) be amended to provide for the safe use of hydrolyzed leather meal in chick and broiler rations as a source of protein in an amount not to exceed 3.75 percent by weight of the finished feed.

Dated: February 2, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2135 Filed 2-11-72;8:51 am]

[Docket No. FDC-D-423; NDA 12-568]

ORTHO PHARMACEUTICAL CORP.

Chlordantoin and Benzalkonium Chloride Lotion; Notice of Withdrawal of Approval of New Drug Application

In the FEDERAL REGISTER of February 26, 1971 (36 F.R. 3535), the Commissioner of Food and Drugs announced (DESI 12568) his conclusions pursuant to evaluation of a report received from the National Academy of Sciences-Na-

tional Research Council, Drug Efficacy Study Group, concerning the following drug:

NDA 12-568; Sporostacin Lotion containing chlordantoin and benzalkonium chloride; Ortho Pharmaceutical Corp., Route 202, Raritan, N.J. 08869.

The announcement stated that the drug was regarded as possibly effective for the labeled indication. Six months from the date of that publication were allowed for the holder of the application and any person marketing such drug without approval to obtain and submit data providing for substantial evidence of effectiveness of the drug for the possibly effective indication. No such data have been received and the holder of said new drug application has requested withdrawal of approval of its new drug application and thereby has waived opportunity for a hearing.

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 that on the basis of new information before him with respect to said drug, evaluated together with the evidence available to him when the application was approved, 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 new drug application No. 12-568, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (2-12-72).

Dated: February 2, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-2131 Filed 2-11-72;8:50 am]

[Docket No. FDC-D-351; NDA 6-566, etc.]

OXANAMIDE AND CERTAIN OTHER DRUGS DESI 6566

Notice of Withdrawal of Approval of New Drug Applications

A notice was published in the FEDERAL REGISTER of August 3, 1971 (36 F.R. 14277), extending to each holder of a new drug application listed below, and to any interested person who may be adversely affected, 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 each listed application and all amendments and supplements thereto. The basis of the proposed action was the lack of substantial evidence that the drugs are effective for their labeled indications.