

Docket No. 76N-0014; DESI 7819P

DIAMTHAZOLE DIHYDROCHLORIDE

Withdrawal of Approval of New Drug Applications for Topical Preparations Containing

AGENCY: Food and Drug Administration (FDA)

ACTION: Notice

SUMMARY: This notice withdraws approval of the new drug applications for

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topical diamthazole dihydrochloride. The products have been used for the prophylaxis and treatment of athlete's foot.

DATES: Effective date: July 19, 1977.

ADDRESSES: Request for opinion concerning applicability of notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Ronald L. Wilson, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3630.

SUPPLEMENTARY INFORMATION: In a notice (DESI 7819, Docket No. 76N-0014) published in the Federal Register of October 29, 1976 (41 FR 47578), the Director of the Bureau of Drugs offered an opportunity for a hearing on a proposal to issue an order withdrawing approval of the new drug applications for the drug products described below. The basis of the proposed action was that the drugs are not shown to be safe for use.

1. Asterol Powder (NDA 7-321),
 2. Asterol Ointment (NDA 7-319),
- and;
3. Asterol Tincture (NDA 7-320), all containing diamthazole dihydrochloride; formerly marketed by Roche Laboratories, Division of Hoffmann-La Roche, Inc., 340 Kingsland Ave., Nutley, NJ 07110.

All drug products that are identical, related or similar to a drug product named above, not the subject of an approved new drug application, are covered by the new drug applications reviewed and are subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Neither the holder of the applications nor any other person filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to him (21 CFR 5.31), finds that new evidence, not contained in the applications or not available until after the applications were approved, evaluated together with the evidence available when the applications were approved, reveals that the drug is not shown to be safe for use under the conditions of use upon the basis of which the applications were approved. Therefore, pursuant to the foregoing finding, approval of new drug applications numbers 7-319, 7-320, 7-321, and all amendments and supplements applying thereto, is withdrawn effective July 19, 1977.

Shipment in interstate commerce of the above listed products or of any identical, related, or similar product not the subject of an approved new drug application, is now unlawful.

Dated: June 27, 1977.

J. RICHARD CROUT,
Director, Bureau of Drugs.

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