

NDA 16-399, Triazura Tablets containing azaribine; formerly marketed by Parke, Davis & Co., Joseph Campau at the River, Detroit, MI 48232.

The basis of the proposed action was that very serious thromboembolic events associated with the use of azaribine in the treatment of psoriasis outweigh the benefit that can be derived from its use.

Neither the holder of the new drug application nor any other person filed a written appearance of election as provided by the 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 5.82) (recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)), finds that new evidence of clinical experience, not contained in the application or not available until after the application was approved, evaluated together with the evidence available when the application was approved, reveals that the drug is not shown to be safe for use under the conditions of use on the basis of which the application was approved.

Therefore, pursuant to the foregoing finding, approval of new drug application number 16-399 and all amendments and supplements applying thereto, is withdrawn effective June 10, 1977.

Dated: May 25, 1977.

J. RICHARD CROUT,  
Director, Bureau of Drugs.

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Food and Drug Administration

[Docket No. 76N-0471; NDA 16-399]

AZARIBINE TABLETS

Withdrawal of Approval of New Drug Application

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is withdrawing approval of the new drug application for azaribine tablets, a drug that was formerly used in the treatment of psoriasis but which is no longer marketed.

DATES: Effective date: June 10, 1977.

FOR FURTHER INFORMATION CONTACT:

Robert H. Hahn, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857 (301-443-3650).

SUPPLEMENTARY INFORMATION: A notice was published in the FEDERAL REGISTER of January 11, 1977 (42 FR 2356), in which the Director of the Bureau of Drugs offered an opportunity for hearing on his proposal to withdraw approval of the new drug application for the following product: