

NDA 16-399; Triamra Tablets containing
azaribine; formerly marketed by Parke, Da-
vis & Co., Joseph Campau at the River, De-
troit, 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 ap-
plication nor any other person filed a
written appearance of election as pro-
vided 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 Cos-
metic Act (sec. 505, 52 Stat. 1052-1053,
as amended (21 U.S.C. 355)), and un-
der 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, re-
veals 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 applica-
tion 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withdrawn effective June 10, 1977.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.

[FR Doc. 77-15230 Filed 5-9-77; 8:45 am.]

Food and Drug Administration

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

AZARIBINE TABLETS

**Withdrawal of Approval of New Drug
Application**

AGENCY: Food and Drug Administra-
tion.

ACTION: Notice.

SUMMARY: The Food and Drug Ad-
ministration 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 CON-
TACT:**

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(HFD-32), Food and Drug Adminis-
tration, Department of Health, Edu-
cation, 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 Bu-
reau of Drugs offered an opportunity for
hearing on his proposal to withdraw ap-
proval of the new drug application for
the following product: