DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0157]

Determination That VESANOID (Tretinoin) Capsules, 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that VESANOID (tretinoin) Capsules, 10 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will neither begin procedures to withdraw approval of the abbreviated new drug application (ANDA) that refers to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6237, Silver Spring, MD 20993–0002, 301–796–3543.

Product to the
vesanoid capsules, 10 mg, were being
Roche notified FDA that VESANOID
VESANOID labeling).

anthracycline chemotherapy, or for
to, or who have relapsed from,
variant), characterized by the presence
acute promyelocytic leukemia (APL),
in the Orange Book and, following the
discontinuation of VESANOID, was
designated as the reference listed drug
to which new ANDAs should refer.

Rakoczy Molino Mazzechi Siwik LLP
submitted a citizen petition dated
March 17, 2010 (Docket No. FDA–2010–
P–0157), under 21 CFR 10.30,
requesting that the agency determine
whether VESANOID (tretinoin)
Capsules, 10 mg, were withdrawn from
sale for reasons of safety or
effectiveness.

After considering the citizen petition
and reviewing agency records, FDA has
determined under § 314.161 that
VESANOID (tretinoin) Capsules, 10 mg,
were not withdrawn for reasons of
safety or effectiveness. The petitioner
has identified no data or other
information suggesting that VESANOID
(tretinoin) Capsules, 10 mg, were
withdrawn for reasons of safety or
effectiveness. We have carefully
reviewed our files for records
concerning the withdrawal of
VESANOID (tretinoin) Capsules, 10 mg,
since, at the time of the petition,
we had also independently
evaluated relevant literature and data
for possible postmarketing adverse
events and have found no information
that would indicate that this product
was withdrawn from sale for reasons of
safety or effectiveness.

Accordingly, the agency will continue
to list VESANOID (tretinoin) Capsules,
10 mg, in the “Discontinued Drug
Product List” section of the Orange
Book. There is one approved ANDA for
tretinoin capsules, 10 mg (ANDA No.
77–684); this drug product is listed in
the Orange Book and, following the
discontinuation of VESANOID, was
designated as the reference listed drug
to which new ANDAs should refer.

In a letter dated December 2, 2009,
Roche notified FDA that VESANOID
(tretinoin) capsules, 10 mg, were being
discontinued, and FDA moved the drug
product to the “Discontinued Drug

The 1984 amendments include what
is now section 505(j)(7) of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C.
355(j)(7)), which requires FDA to
publish a list of all approved drugs.
FDA publishes this list as part of the
“Approved Drug Products With
Therapeutic Equivalence Evaluations,”
which is known generally as the
“Orange Book.” Under FDA regulations,
drugs are removed from the list if the
agency withdraws or suspends approval
of the drug’s NDA or ANDA for reasons
of safety or effectiveness or if FDA
determines that the listed drug was
withdrawn from sale for reasons of
safety or effectiveness (21 CFR 314.162).
Under § 314.161(a)(1) (21 CFR
314.161(a)(1)), the agency must
determine whether a listed drug was
withdrawn from sale for reasons of
safety or effectiveness before an ANDA
that refers to that listed drug may be
approved. FDA may not approve an
ANDA that does not refer to a listed
drug.

VESANOID (tretinoin) Capsules, 10
mg, are the subject of NDA 20–438, held
by Hoffman-La Roche Inc. (Roche), and
initially approved on November 22,
1995. VESANOID is indicated for the
induction of remission in patients with
acute promyelocytic leukemia (APL),
French-American-British (FAB)
classification M3 (including the M3
variant), characterized by the presence
of the t(15;17) translocation and/or the
presence of the PML/RARα
[promyelocytic leukemia/retinoic acid
receptor alpha] gene who are refractory
to, or who have relapsed from,
anthraclycline chemotherapy, or for
whom anthraclycline-based
chemotherapy is contraindicated”
(VESANOID labeling).

In a letter dated December 2, 2009,
Roche notified FDA that VESANOID
(tretinoin) capsules, 10 mg, were being
discontinued, and FDA moved the drug
product to the “Discontinued Drug

Draft Guidance for Industry on Chronic
Hepatitis C Virus Infection: Developing
Direct-Acting Antiviral Agents for
Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing the
availability of a draft guidance for
industry entitled “Chronic Hepatitis C
Virus Infection: Developing Direct-
Acting Antiviral Agents for Treatment.”
The purpose of this guidance is to assist
sponsors in all phases of development
of direct-acting antiviral agents (DAAs),
defined as agents that interfere with
specific steps in the hepatitis C virus
(HCV) replication cycle. The guidance
outlines the types of nonclinical studies
and clinical trials recommended
to support approval of treatments for
chronic hepatitis C (CHC), including in
patients with compensated and
decompensated cirrhosis and those co-
infected with human immunodeficiency
virus (HIV).

The guidance also addresses pre-
approval access in the form of treatment
investigational new drug applications
(INDs) and intermediate-sized safety
protocols.

DATES: Although you can comment on
guidance at any time (see 21 CFR
10.115(g)(5)), to ensure that the agency
considers your comment on this draft
guidance before it begins work on the
final version of the guide, submit
either electronic or written comments
on the draft guidance by November 15,
2010.

ADDRESSES: Submit written requests for
single copies of the draft guidance to the
Division of Drug Information, Center for
Drug Evaluation and Research, Food
and Drug Administration, 5630
Hampshire Ave., Bldg. 51, rm. 2201,
Silver Spring, MD 20993–0002. Send
one self-addressed adhesive label to
assist that office in processing your
requests. See the SUPPLEMENTARY
INFORMATION section for electronic
access to the draft guidance document.
Submit electronic comments on the
draft guidance to http://www.regulations.gov.
Submit written comments to the Division of
Dockets Management (HFA–305), Food and Drug
Administration, 5630 Fishers Lane, rm.
1061, Rockville, MD 20852.