**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-438/S006

Hoffmann-LaRoche, Inc.
Attention: Lynn DeVenezia-Tobias
Program Manager
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application S006 dated May 15, 2007 and received May 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VESANOID® (tretinoin) 10 milligram capsules.

This prior approval labeling supplemental new drug application provides for new, updated information in the OVERDOSAGE section of the package insert regarding experience with acute overdosage in humans. The changes to the package insert are as follows:

In the overdosage section, the following text was deleted:

> There has been no experience with acute overdosage in humans.

In the overdosage section, the following new text was added:

> In case of overdose with VESANOID, reversible signs of hypervitaminosis A (headache, nausea, vomiting, mucocutaneous symptoms) can appear.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling and/or submitted labeling (package insert) submitted May 15, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-438/S006**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Carl Huntley, Regulatory Project Manager, at (301) 796-2330.

Sincerely,

*{See appended electronic signature page}*

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

---

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

---

/s/

---

Robert Justice
7/1/2008 05:43:58 PM