



NDA 20-438 / S-004

Hoffman-La Roche Inc
340 Kingsland Street
Nutley, NJ 07110-1199

Attention: Lynn DeVenezia-Tobias
Program Manager, Regulatory Affairs

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated July 28, 2004, received July 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vesanoïd (tretinoin) Capsules.

This supplemental new drug application provides for revised labeling for the package insert following a review of Roche's worldwide safety information database.

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

The final printed labeling (FPL) must be identical to the agreed upon enclosed labeling (text for the package insert dated July 19, 2004).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-438 / S-004." 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.

Director

Division of Oncology Drug Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

Enclosure: Labeling

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

/s/

Richard Pazdur
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