CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 20-438/S-001

Approval Letter

Div File

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-438/S-001

FEB 14 2000

Roche, Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Attention: Lynn DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated August 18, 1999, received August 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VESANOID (tretinoin) Capsules, 10 mg.

This supplemental new drug application provides for a "Geriatric Use" subsection under the PRECAUTIONS section of the package insert in accordance with 21 CFR 201.57 (f)10. Additionally, as recommended in our March 8, 1999 letter, it contains minor terminology changes to the PHARMACOKINETICS section for cytochrome P450 enzymes.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the August 18, 1999 draft labeling.

Please submit 20 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-001." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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,

/S/ 2/14/00

Robert L. Justice, M.D.
Deputy Director
Division of Oncologic Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CC:
Archival NDA 20-438/SLR-001
HFD-150/Div. Files
HFD-150/M.Pelosi
HFD-150/ Rahman/2-7-00
Hirschfeld/2-7-00
Johnson/2-11-00
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-101/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT (with labeling)
HFD-810/DNDC Division Director
DISTRICT OFFICE

Drafted by: map/February 4, 2000
Initialed by:Pease
final:Pelosi/ 2-11-00
filename: NDA/20438/ SLR001/Geriatric_AP

S

2-14-00

APPROVAL (AP)

Div File

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-438/S-001

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

JUN 29 2000

Attention: Lynn De Venezia-Tobias
Program Manager, Regulatory Affairs

Dear Ms. De Venezia-Tobias:

We acknowledge the receipt of your June 8, 2000 submission containing final printed labeling in response to our February 14, 2000 letter approving your supplemental new drug application for Vesanoid (tretinoin) Capsules.

We have reviewed the labeling that you submitted in accordance with our February 14, 2000 letter, and we find it acceptable. However, that in the section CLINICAL PHARMACOLOGY, Pharmacokinetics, Drug-Drug Interactions, the comma after "*CYP*" should be removed at the next printing. The sentence should read as follows:

> "The precise cytochrome P450 enzymes involved in these interactions have not been specified; *CYP* 3A4, 2C8 and 2E have been implicated in various preliminary reports."

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

Sincerely,

S 6-29-00

Richard Pazdur, M.D.
Director
Division of Oncologic Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Archival NDA 20-438
HFD-150/Div. Files
HFD-150/M.Pelosi
HFD-150/ John Johnson
S. Hirschfeld
A. Rahman
J. Duan

HF-2/Medwatch (with labeling)
HFD-101/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/OPDRA (with labeling)
DISTRICT OFFICE

Drafted by: mp/June 27, 2000
Initialed by Pease: June 27, 2000
Final by Pelosi:June 28, 2000

filename: NDA/20438/SLR001/FA_slr001_AR

ACKNOWLEDGE AND RETAIN (AR)