DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-821/S-010

Debra Iorio
Program Manager, Drug Regulatory Affairs
Hoffmann-La Roche
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Iorio:

Please refer to your supplemental new drug application dated September 23, 2003, September 24, 2003, submitted , under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Soriatane (acitretin) Capsules, 10 mg and 25 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a sample package containing seven Soriatane® (acitretin) Capsules, 25 mg, packaged in the identical packaging material and configuration as that currently approved for the marketed product presentation of thirty capsules. The container label is unchanged except for the information about the amount of capsules in the bottle (seven vs. thirty).

We have completed our review of this supplemental new drug application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling. These revisions are terms of the approval of this application.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-821/S-010." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Ms. Kalyani Bhatt, Regulatory Project Manager, at (301) 2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the Division of
Dermatological and Dental Drug Products

Enclosure

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

/s/

Wilson H. DeCamp
3/22/04 02:56:34 PM
approved