020628_s016

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Approval Package

APPLICATION NUMBER:

20-628/S-016

Trade Name: Invirase®

Generic Name: (saquinavir mesylate)

Sponsor: Hoffman-La Roche

Approval Date: July 2, 2002

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-628/S-016

Hoffman-La Roche, Inc
Attention: Barbara S. Taylor, PhD
Program Director
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Taylor:

Please refer to your supplemental new drug application dated February 1, 2001, March 28, 2001, and April 27, 2001, received February 2, 2001, March 29, 2001, and April 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVIRASE® (saquinavir mesylate) Capsules.

This supplemental new drug application (Changes Being Effected) was submitted in response to requests from the Division to address the following labeling issues:

1. Implementation of a risk communication strategy designed to alert patients of the need to find out about potential drug interactions with INVIRASE®. This strategy includes:

   A. Use of the ALERT message on the container (bottle) labeling (INVIRASE® is not distributed with a carton.)

   B. Inclusion of the ALERT message in the professional package insert in the "WARNINGS" section and in the "PRECAUTIONS: Information for Patients" section. (INVIRASE® is not distributed with a Patient Package Insert.)

2. Inclusion of statements regarding the interaction of INVIRASE® with St. John's Wort in the "WARNINGS" section and the "PRECAUTIONS: Information for Patients" section. (INVIRASE® is not distributed with a Patient Package Insert.)

We have completed the review of this supplemental application, as amended, 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, attached 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 enclosed labeling (text for the package insert and immediate container label.)

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *"Providing Regulatory Submissions in Electronic Format - NDA"* (January 1999.) 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. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-628/SLR-016." 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 Professional" 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 Marsha S. Holloman, BS Pharm, JD, Regulatory Health Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Printed Labeling Submitted April 27, 2002 by the sponsor