DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20903

NDA 20-628/S-024
NDA 21-785/S-003

Hoffman-La Roche
Attention: Allison Mueller
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Mueller:

Please refer to your supplemental new drug applications dated May 31, 2006, received June 2, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVIRASE® (saquinavir mesylate) 200 mg capsules and 500 mg film coated tablets.

We acknowledge receipt of your submissions dated October 12, 2006, December 8, 2006, February 20, 2007 and March 20, 2007.

These supplemental new drug applications provide for the revision of the Invirase PI and PPI to reflect the de-listing of Fortovase and to update the drug interactions section of the Invirase PI to provide information on the combination of saquinavir/ritonavir and omeprazole and the combination of saquinavir/ritonavir and tipranavir.

We completed our review of these applications as amended. These applications are 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 enclosed labeling.

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 20-628/S-024 and NDA 21-785/S-003**." Approval of these submissions 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, call Kenny Shade, Regulatory Project Manager, at (301) 796-0807.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant
Director,
Division of Antiviral Products
Center for Drug Evaluation and Research
Food and Drug Administration

Enclosure:

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

/s/

Jeffrey Murray
4/3/2007 08:40:01 AM
for D. Birnkrant