DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-785/S-001 NDA 21-785/S-002
NDA 20-828/S-019 NDA 20-828/S-020
NDA 20-628/S-022 NDA 20-628/S-023

Hoffman-La Roche
Attention: Karen H. Noh, Pharm.D.
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Noh:

Please refer to your supplemental new drug applications dated March 7, 2005, received March 9, 2005 (NDA 21-785/S-001, NDA 20-828/S-019, and NDA 20-628/S-022) and your supplemental new drug applications dated March 11, 2005, received March 14, 2005 (NDA 21-785/S-002, NDA 20-828/S-020, and NDA 20-628/S-023) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Invirase® (saquinavir mesylate) capsules and Invirase® (saquinavir mesylate) film coated tablets.

We acknowledge receipt of your submissions dated August 31, 2005, and September 1, 2005.

These supplemental new drug applications provide for revisions to the Invirase labeling to reflect drug interaction information with rifampin and drug interaction information between saquinavir/ritonavir and tenofovir, fosamprenavir, lopinavir, and atazanavir.

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 (text for the package insert).

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 supplements NDA 21-785/S-001, 20-828/S-019, 20-628/S-022 and NDA 21-785/S-002, 20-828/S-020 and 20-628/S-023**." 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, 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 Kenny Shade, Regulatory Project Manager, at (301) 796-0807.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Center for Drug Evaluation and Research

Enclosure: approved draft labeling

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
9/8/2005 11:17:38 AM