DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-628/S-025
NDA 21-785/S-004

Hoffman-La Roche
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Taylor:

Please refer to your supplemental new drug applications dated December 20, 2006, received December 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVIRASE® (saquinavir mesylate) 200 mg capsules and INVIRASE® (saquinavir mesylate) 500 mg tablets.

We acknowledge receipt of your submissions dated June 14, 2007 and June 25, 2007.

These supplemental new drug applications provides revisions to the INVIRASE® (saquinavir mesylate) US package insert (Drug Interaction and Warnings sections) and patient information leaflet to provide updated drug interaction information on the combination of saquinavir/ritonavir with methadone, saquinavir/ritonavir with digoxin, and saquinavir/ritonavir with midazolam.

We completed our review of this supplemental new drug application as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html,that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDA 20-628/S-025 and NDA 21-785/S-004.

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
7/11/2007 04:58:07 PM