DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020628/S-037
NDA 021785/S-014

**SUPPLEMENT APPROVAL**
**RELEASE REMS REQUIREMENT**

Hoffmann-La Roche, Incorporated
Attention: Maria Ferrara
Program Manager – Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Ferrara:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 17, 2011, received May 18, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INVIRASE® (saquinavir mesylate), 200 mg capsules and 500 mg film-coated tablets.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 26, 2011.

These supplemental new drug applications propose to eliminate the requirement for the approved INVIRASE ® (saquinavir mesylate) capsules and film-coated tablets REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

## RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for INVIRASE® (saquinavir mesylate), capsules and film-coated tablets was originally approved on October 6, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for INVIRASE® (saquinavir mesylate), capsules and film-coated tablets.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of INVIRASE® (saquinavir mesylate), capsules and film-coated tablets outweigh their risks.

Therefore, we agree with your proposal, and a REMS for INVIRASE ® (saquinavir mesylate) capsules and film-coated tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

**REPORTING REQUIREMENTS**

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 Myung-Joo Patricia Hong, Regulatory Project Manager, at (301) 796-0807.

Sincerely,

*{See appended electronic signature page}*

/Kendall Marcus M.D./
for Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

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KENDALL A MARCUS
05/26/2011