DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-628/S-027
NDA 21-785/S-006

SUPPLEMENT APPROVAL

Hoffmann-La Roche Inc.
Attention: Barbara S. Taylor, Ph.D.
Director, Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110

Dear Dr. Taylor:

Please refer to your supplemental new drug applications dated August 8, 2008, received August 11, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVIRASE® (saquinavir mesylate) 200 mg capsules and 500 mg tablets.

We acknowledge receipt of your submissions dated August 8, 2008, February 16, 2009, March 12, 2009, April 6, 2009, June 12, 2009, November 2, 2009, November 25, 2009 and December 17, 2009.

These Prior Approval supplemental new drug applications provide revisions to the INVIRASE® (saquinavir mesylate) US package insert (Microbiology, Clinical Pharmacology, Contraindications, Warnings, Precautions, Adverse Reactions, Overdosage and How Supplied Sections) and patient information leaflet to update information on the saquinavir/ritonavir combination.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). For administrative purposes, please designate this submission, "**SPL for approved NDA 20-628/S-027 and NDA 21-785/S-006**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Stacey Min, Pharm.D., Regulatory Project Manager, at (301) 796-4253.

Sincerely,

{See appended electronic signature page}

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

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21785	SUPPL-6	HOFFMANN LA ROCHE INC	INVIRASE (SAQUINAVIR MESYLATE) 500 MG
NDA-20628	SUPPL-27	HOFFMANN LA ROCHE INC	INVIRASE(SAQUINAVIR MESYLATE) 200MG CAPS

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

/s/

KENDALL A MARCUS
01/20/2010