DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20628/S-034
NDA 21785/S-011

SUPPLEMENT APPROVAL

Hoffmann La-Roche, Incorporated
c/o Genentech, Inc.
Attention: Diane deBruin
Regulatory Agent on behalf of Roche
1 DNA Way MS., #241B
South San Francisco, CA 94080-4990

Dear Ms. deBruin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated July 29, 2010 and received July 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Product Name
NDA 20628	S-034	Invirase® (saquinavir mesylate), 200 mg Capsules
NDA 21785	S-011	Invirase® (saquinavir mesylate), 500 mg Tablets

We acknowledge receipt of your amendments dated August 27, 2010, September 17, 2010, September 24, 2010, October 11, 2010, October 19, 2010, October 20, 2010, November 3, 2010, November 5, 2010, December 15, 2010, December 16, 2010, January 4, 2011, January 14, 2011, January 28, 2011, February 3, 2011, February 4, 2011, February 16, 2011, September 29, 2011, January 24, 2012, April 6, 2012, May 30, 2012, November 19, 2012, November 28, 2012 and November 29, 2012

The May 30, 2012, submissions constituted a complete response to our January 28, 2011, action letter.

These "Prior Approval" supplemental new drug applications update the labeling with information from pediatric studies HIVNAT 017 and NV20911. Based on our review of these studies, pediatric dose recommendations that are both reliably effective and below thresholds of concern with respect to QT and PR prolongation could not be determined for subjects less than 16 years of age. Although no dosing recommendations are provided for pediatric patients, updated labeling provides description of these pediatric trials and their results as required by the Best Pharmaceutical for Children Act.

We have completed our review of these supplemental applications as amended. The supplements are approved, effective on the date of this letter. The labeling may now be used 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement from birth to less than 4 months of age because you have demonstrated that reasonable attempts to produce a pediatric formulation necessary for this age group have failed.

We note that you have fulfilled the pediatric study requirement for 4 months to less than 18 years of age for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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}

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

ENCLOSURE(S):
Content of 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 S MURRAY
11/30/2012