



NDA 020628/S-043  
NDA 021785/S-019

## SUPPLEMENT APPROVAL

Hoffmann-La Roche, Inc.  
Attention: Elizabeth Wishart  
Regulatory Agent on behalf of Roche, OptumInsight  
c/o Genentech, Inc.  
1 DNA way  
South San Francisco, CA 94080

Dear Ms. Wishart

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 18, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INVIRASE<sup>®</sup> (saquinavir mesylate) capsules, 200mg (NDA 20628) and INVIRASE<sup>®</sup> (saquinavir mesylate) tablets, 500 mg (NDA 21785).

These “Prior Approval” supplemental new drug applications provide for updates to the INVIRASE Prescribing Information (PI) for drugs that are contraindicated or interact with INVIRASE/ritonavir. A warning is added to reflect that cobicistat is not recommended for concomitant use with INVIRASE. The Medication Guide is updated to reflect the changes made to the USPI and reformatted according to current labeling best practices.

### **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are 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, 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 that includes labeling changes for this NDA, 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).

If you have any questions, call Suzanne Strayhorn, Regulatory Project Manager, at (240) 402-4247.

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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POONAM MISHRA  
12/16/2015