DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202429/S-006

SUPPLEMENT APPROVAL

Hoffmann-La Roche, Incorporated
Attention: Irene Figari
Regulatory Program Management
1 DNA Way, MS 241b
South San Francisco, CA 94080

Dear Ms. Figari:

Please refer to your Supplemental New Drug Application (sNDA) dated April 30, 2014, received April 30, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zelboraf (vemurafenib), tablet; 240 mg.

We acknowledge receipt of your amendments dated October 30, 2014, November 17, 2014, November 21, 2014, November 24, 2014, and November 25, 2014.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the label:

- Addition of information regarding observed cases of liver injury in WARNINGS AND PRECAUTIONS, (Section 5.6 Hepatotoxicity), PATIENT COUNSELING INFORMATION (SECTION 17), and the Medication Guide
- Addition of panniculitis and neutropenia in ADVERSE REACTIONS, (Section 6.1 Clinical Trials Experience and Section 6.2 Postmarketing Experience)

APPROVAL & LABELING

We have completed our review of this supplemental 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, 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 the 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.

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.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

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 Norma Griffin, Senior Regulatory Health Project Manager, at (301) 796-4255.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology 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/

JEFFERY L SUMMERS
11/25/2014