DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021923/S-013

SUPPLEMENT APPROVAL

Bayer Healthcare Pharmaceuticals, Inc.
Attention: Michael Bui, DDS, MPH, JD
PO Box 1000
Montville, NJ 07045-1000

Dear Dr. Bui:

Please refer to your Supplemental New Drug Application (sNDA) dated February 9, 2012, received February 9, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexavar® (sorafenib tosylate) Tablets.

We acknowledge receipt of your amendments dated May 23, July 30 (email), and August 6, 2012.

This "Prior Approval" supplemental new drug application provides for revising the package insert as follows:

- Highlights: addition of Stevens-Johnson syndrome and toxic epidermal necrolysis, and drug induced hepatitis
- Warnings and Precautions: to add information on Stevens-Johnson syndrome and toxic epidermal necrolysis, and, drug-induced hepatitis in sections 5.4 and 5.10.
- Adverse Reactions: to add wording on hypocalcemia in Sections 6.1, 6.2, and 6.3 and to add angioedema, and anaphylaxis, and rhabdomyolysis in Section 6.4
- Adverse reactions: to add information on Stevens-Johnson syndrome and toxic epidermal necrolysis and drug-induced hepatitis, Section 6, 6.4
- Drug Interactions: to add a new section 7.3 "Drugs that Increase Gastric pH"
- Patient Counseling: added information on Stevens-Johnson syndrome and toxic epidermal necrolysis, drug-induced hepatitis, bleeding, hypertension, gastrointestinal perforation, wound healing complications, QT prolongation in Section 17.
- Patient Package insert: to update drug-drug interactions, to add information on skin and mouth reactions, and drug-induced hepatitis

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 text for the patient package insert), 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 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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Amy Tilley, Regulatory Project Manager, at (301) 796-3994.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
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/

AMNA IBRAHIM
08/24/2012