DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021923/S-008 and S-009

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceutical, Inc.
Attention: Deepika Jalota, Pharm.D.
Global Regulatory Strategist
Global Regulatory Affairs, Specialized Medicines
P.O. Box 1000
Montville, NJ 07045

Dear Dr. Jalota:

Please refer to your Supplemental New Drug Applications (sNDA) dated October 1, 2008, and August 10, 2009, received October 2, 2008 and August 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexavar (sorafenib tosylate) Tablets, 200 mg.

We acknowledge receipt of your amendments dated August 24, 2009; November 10, 2009; December 4, 2009; May 13, 2010; June 10, 2010 and July 8, 2010.

S-008 (Changes Being Effected) provides for the addition of cholecystitis and cholangitis as uncommon adverse reactions and the addition of renal failure as a common adverse reaction to Section 6.3 (ADVERSE REACTIONS, Additional Data from Multiple Clinical Trials) of the Package Insert.

S-009 (Changes Being Effected) provides for the addition of the following information to the Package Insert:

- WARNINGS AND PRECAUTIONS
  - Addition of information on neomycin co-administration with sorafenib as section 5.13
  - Addition of information on the use of carboplatin and paclitaxel in combination with sorafenib in Non-Small Cell Lung Cancer based on Study 11961 (ESCAPE Trial) as section 5.8
- ADVERSE REACTIONS in section 6.3 Additional Data from Multiple Clinical Trials
  - Reclassification of congestive heart failure as a common adverse reaction
  - Addition of Stevens-Johnson Syndrome, hyperthyroidism, and interstitial lung disease-like events as uncommon adverse reactions
- DRUG INTERACTIONS
  - Addition of information on neomycin co-administration with sorafenib in Section 7.12
- Editorial Changes

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), 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, text for the patient package insert, Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 pending "Changes Being Effected" (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.

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
Division of Drug Marketing, Advertising, and Communications
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.(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 Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Diane Hanner, Regulatory Project Manager, at (301) 796-4058.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

ROBERT L JUSTICE
10/26/2010