NDA 021923/S-022

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Kaitlyn Orland, Pharm.D., RPh
Manager, Regulatory Affairs
100 Bayer Blvd.
P.O. Box 915
Whippany, NJ 07981-0915

Dear Dr. Orland:

Please refer to your supplemental new drug application (sNDA) dated and received on August 27, 2019, and your amendments dated January 9 and 15, 2020, March 5, 2020, April 10, 2020 and May 27, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexavar (sorafenib) tablets.

This Prior Approval supplemental new drug application provides for the following changes for Nexavar:

- updates to the Warnings and Precautions, subsection 5.7, including retitling this subsection as Risks of Impaired Wound Healing and to specify the recommended duration for withholding Nexavar before elective surgery and after major surgery to reduce the risk of impaired wound healing;
- revisions to section 17 for consistency with updates to subsection 5.7;
- revisions to the patient package insert for consistency with updates to subsection 5.7 and section 17 of the Full Prescribing Information; and
- editorial and grammatical changes throughout the United States Package Insert.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

- Revised the date at the end of the Highlights of Prescribing Information and subsection Recent Major Changes to “6/2020” the most recent revision of the labeling.
- Patient Package Insert revised to include date of last revision as “Revised: 6/2020”.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

PROMOTIONAL MATERIALS

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 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, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

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 you may contact Felicia Diggs, Senior Regulatory Project Manager, at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Meredith K. Chuk, M.D.
Supervisory Associate Director for Safety (acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MEREDITH K CHUK
06/19/2020 02:55:36 PM