NDA 021923/S-24

CBE SUPPLEMENT –
ACKNOWLEDGEMENT/
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 dated and received June 18, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nexavar (sorafenib) tablets.

We also refer to our approval letter dated July 9, 2020, which contained the following error:

> Contents of labeling did not include revisions from the most recent approval on June 19, 2020, which provides for revisions to include the risk of impaired wound healing to the U.S. package insert.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain July 9, 2020, the date of the original approval letter.

We have received your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA NUMBER: 021923

SUPPLEMENT NUMBER: 24

PRODUCT NAME: Nexavar (sorafenib) tablets

DATE OF SUBMISSION: June 18, 2020

DATE OF RECEIPT: June 18, 2020

This supplemental application, submitted as a "Changes Being Effected supplement, proposes the following changes:

Updates to the Adverse Reactions subsection 6.2 to include "Vascular: Arterial (including aortic) aneurysms, dissections, and rupture" to the U.S. prescribing information.

APPROVAL & LABELING

We have completed our review of this application. 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.

- Updated the date at the end of the Highlights of Prescribing Information to "Revised: 7/2020".
- Revised the system organ class preceding arterial (including aortic) aneurysms, dissections, and rupture to "Vascular".

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, 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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 new drug application (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

[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.

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).

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, Safety Regulatory Project Manager, at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.
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Sincerely,

{See appended electronic signature page}

Shaily Arora, PharmD.
Associate Director for Safety (acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

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/

SHAILY ARORA
07/09/2020 12:00:00 AM