NDA 021923/S-025

SUPPLEMENT APPROVAL

Bayer Healthcare Pharmaceuticals Inc
Attention: Kaitlyn Orland, PharmD
Senior Manager, Regulatory Affairs
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981-0915

Dear Dr. Orland:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 20, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NEXAVAR (sorafenib) tablets, 200 mg.

This "Changes Being Effected" supplemental new drug application provides for changes to the carton and container labels with the salt equivalency statement to be consistent with the package insert.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

We acknowledge your November 20, 2020, submission containing final printed carton and container labeling.

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 Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, B1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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