NDA 203085/S-012

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: James B. Davis
Deputy Director, Regulatory Affairs
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981

Dear Mr. Davis:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 4, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Stivarga (regorafenib) Tablets, 40 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change to the Stivarga outer carton box to include a product website URL and Quick Response Code.

APPROVAL & LABELING

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.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 203085/S-012.**" Approval of this submission by FDA is not required before the labeling is used.

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 Yajun Jason Tu, Regulatory Business Process Manager, at (240) 402 - 4202.

Sincerely,

{See appended electronic signature page}

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

Enclosure:

Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
Date: 9/24/2020 10:09:56PM
GUID: 502d0913000029f375128b0de8c50020