DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 203341/S-013

SUPPLEMENT APPROVAL

Pf Prism C.V.
c/o Pfizer Inc.
Attention: Bhanu Purohit, M.S
Global Regulatory Lead, Worldwide Safety and Regulatory
445 Eastern Point Road, MS 8260-1118
Groton, CT 06340

Dear Ms. Purohit:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 3, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bosulif® (bosutinib) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of professional sample container label for bosutinib 400 mg tablets.

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 text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 203341/S-013.**" 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 Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

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
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