NDA 207027/S-013

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Neil Costanza
Regulatory CMC Associate Director - Regulatory Affairs Global Drug Development CMC
One Health Plaza
Bldg. 337/B09.5d
East Hanover, NJ 07936

Dear Mr. Costanza:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 10, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Promacta (eltrombopag) for oral suspension.

This "Changes Being Effected in 30 days" supplemental new drug applications provides for the addition of Lek d.d., Ljubljana, Slovenia (FEI# 3002807460) as an alternate drug product manufacturing, testing and primary packaging site for the 12.5 mg and 25 mg PROMACTA powder for oral suspension, as well as changes in the drug product manufacturing process, in-process controls, process controls and the dimensions of the drug product container associated with the addition of the Lek d.d. site.

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

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on April 10, 2020, 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 207027/S-013.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

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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