



NDA 022291/S-040

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Neil Costanza
RA CMC Director
One Health Plaza
East Hanover, NJ 07936

Dear Mr. Costanza:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 27, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PROMACTA (eltrombopag) tablets.

This Prior Approval supplemental new drug application provides for the addition of Novartis d.o.o. Kolodvorska cesta 27 1234 Menges, Slovenia, FEI # 3002807470 as an alternative eltrombopag drug substance manufacturing and testing site and associated changes.

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 022291/S-040.**” 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, contact Mikee Aguirre, Regulatory Business Process Manager, at mikee.aguirre@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
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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