NDA 203985/S-027

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Neil Costanza
RA CMC Director
One Health Plaza, Building 337
East Hanover, NJ 07936-1080

Dear Neil Costanza:

Please refer to your supplemental New Drug Application (sNDA) dated and received September 15, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AFINITOR DISPERZ® (everolimus tablets for oral suspension).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4) as an alternate site for the manufacture, quality control and packaging (primary and secondary) of Afinitor Disperz® (everolimus tablet for oral suspension) 2 mg, 3 mg and 5 mg. The change is associated with the change in batch size and minor changes to the primary packaging.

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, 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 203985/S-027.**" 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, please contact Janell Artis, PharmD., Regulatory Business Process Manager at email: Janell.Artis@fda.hhs.gov, or (301) 796 – 6309.

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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