NDA 050625/S-060

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Nancy Del Viscio
Regulatory CMC Director - Regulatory Affairs GDD CMC
One Health Plaza
Bldg. 337 - B08.3B
East Hanover, NJ 07936

Dear Ms. Del Viscio:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 28, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sandimmune (cyclosporine, USP) Soft Gelatin Capsules, 25 mg and 100 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for:

- A redesign of the blister pack for the 100 mg strength capsules to improve (b) (4) (b) (4) effectiveness and updates to various primary packaging components used in the container closure system for both the 25 mg and 100 mg strength capsules.

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 050625/S-060.**" 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 Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
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

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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