NDA 050791/S-032

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Albina Taigounov, Regulatory CMC Associate Director
One Health Plaza
Bldg. 337 - B08.4C
East Hanover, NJ 07936

Dear Ms. Taigounov:

Please refer to your Supplemental New Drug Application (sNDA) dated July 3, 2020, received July 6, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Myfortic (mycophenolate acid) Delayed-release Tablets, 180 mg and 360 mg.

This Prior Approval supplemental new drug application provides for the addition of (b) (4) as an alternate manufacturer of mycophenolate sodium along with the following changes associated with the (b) (4) process:

- Registration of a different manufacturing process from that at the currently approved site
- Addition of (b) (4) as an analytical facility for mycophenolate sodium
- Changed drug impurity specifications
- Replacement of the current methods for identification, assay, and impurities with different methods specific to (b) (4)
- Addition of alternate methods to determine levels of sodium and (b) (4)
- Addition of an alternate packaging material for mycophenolate sodium
- Deregistration of the current drug substance manufacturing facility, Novartis Schweizerhalle

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 050791/S-032.**" 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 Phillip Williams, Regulatory Business Process Manager, at (240) 402 - 3974.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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