NDA 209884/S-005

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Ryan Conway, PharmD
Global Program Regulatory Manager
One Health Plaza
Building 310 / Room 2130d
East Hanover, NJ 07936-1080

Dear Dr. Conway:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 15, 2021, and your amendment submitted on April 8, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mayzent (siponimod) Tablets.

This "Changes Being Effected" supplemental new drug application provides for updates to the carton and container labels to change the text for country of origin from "Product of Switzerland" to "Product of Slovenia".

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 carton and container labels submitted on March 15, 2021, 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 209884/S-005.**" Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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