DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022527/S-021

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Senior Global Program Regulatory Manager
One Health Plaza, BLDG 135, Room 416
East Hanover, NJ 07936-1080

Dear Ms. Stiles:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 25, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gilenya (fingolimod) 0.5 mg capsules.

We also refer to our REMS Modification Notification letter dated September 27, 2016, and acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 14, 2016.

This prior approval supplemental new drug application provides for proposed modification to the approved REMS and proposes to eliminate the requirement for the approved REMS for Gilenya (fingolimod). This supplement was submitted in response to our September 27, 2016, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Gilenya (fingolimod) was originally approved on September 21, 2010, and the most recent REMS modification was approved on May 14, 2015. The approved REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

Your proposed modification consists of elimination of the communication plan and, therefore, release from the requirement for a REMS for Gilenya (fingolimod).

In order to minimize the burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modifications:

- A request to remove the communication plan from the REMS
- A request to release the REMS requirements

Because the communication plan has been completed and the most recent assessment, submitted to the Agency on April 14, 2016, demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Gilenya (fingolimod).

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 Nahleen Lopez, Regulatory Project Manager, at (240) 402-2659.

Sincerely,

{See appended electronic signature page}

Alice Hughes, MD
Deputy Director for Safety
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ALICE HUGHES
11/29/2016