



NDA 22527/S-26

**SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation  
Attention: Sumana Biswas, Ph.D.  
Sr. Global Program Regulatory Manager  
One Health Plaza BLDG 310, Room 2130B  
East Hanover, NJ 07936-1080

Dear Dr. Biswas:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 13, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gilenya (fingolimod) capsules, 0.25 mg and 0.5 mg.

Prior Approval supplemental new drug application provides for revisions to the Prescribing Information (PI) to include the following changes:

- Under Contraindications: “concomitant treatment with Class Ia or Class III anti-arrhythmic drugs” was revised to “cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs”
- Under Warnings and Precautions: the existing “Cutaneous Malignancies” subsection title was revised to “Malignancies” with both a “Cutaneous Malignancies” and a “Lymphoma” heading. Information regarding cases of lymphoma, including both T-cell and B-cell types and CNS lymphomas, was relocated from the Adverse Reactions/Clinical Trials Experience subsection. Language pertaining to reported cases of cutaneous T-cell lymphoma was also added.
- Under Adverse Reactions: a new Postmarketing Experience subsection was included with new adverse reactions of arthralgia, myalgia, and status epilepticus added

In addition, minor revisions to the Medication Guide were included to correspond to the new PI language.

**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 text.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):

Content of Labeling

Prescribing Information

Patient Package Insert and Medication Guide

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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