



NDA 22527/S-019

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Thomas Watson
Global Therapeutic Area Leader
Drug Regulatory Affairs; Neuroscience
One Health Plaza
Building 135, Room 474
East Hanover, NJ 07936-1080

Dear Mr. Watson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on July 15, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gilenya (fingolimod) 0.5 mg capsules.

This supplemental application provides for addition of a new subsection to the Warnings and Precautions section of the prescribing information; the new subsection describes the cases of progressive multifocal leukoencephalopathy (PML) and probable PML that have occurred in Gilenya-treated patients. Corresponding changes have been made to the Patient Counseling Information section and the Medication Guide with respect to PML.

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 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 package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effectuated" (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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

POSTMARKETING SURVEILLANCE

We request that you provide expedited reporting of events of PML. Annual reporting should include a cumulative analysis of these events.

If you have any questions, call Nahleen Lopez, PharmD, 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

ENCLOSURE:
Content of Labeling

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
08/04/2015