



BLA 125290/S-66

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 Biologics License Application (sBLA), dated and received June 5, 2018, submitted under section 351(a) of the Public Health Service Act for Extavia (interferon beta-1b).

This Prior Approval supplemental biologics application provides for revisions to the Extavia prescribing information (PI), including revisions to comply with the Pregnancy and Lactation Labeling Rule (PLLR). In addition, it provides for the addition of the dosage form to Sections 11 and 16 (according to CFR 201.57(c)(12)(i)(B) and 201.57(c)(17), respectively), addition of the identifying characteristics of the dosage form to Sections 3 and 16 (according to CFR 201.57(c)(4)(ii) and 201.57(c)(17)(iii), respectively), and revisions to the appropriate package term in Highlights and Sections 3 and 16 consistent with the Guidance for Industry, "Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use."

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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and

Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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 BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call LCDR Nahleen Lopez, Regulatory Project Manager, at (240) 402-2659.

Sincerely,

{See appended electronic signature page}

Alice Hughes, MD
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
- Medication Guide
- Instructions for Use

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.

/s/

ALICE HUGHES
12/11/2018