



BLA 125104/S-980

SUPPLEMENT APPROVAL

Biogen Inc
Attention: Priya Singhal, M.D.
Sr. Executive Vice President, Head of Development
225 Binney Street
Cambridge, MA 02142

Dear Dr. Singhal:

Please refer to your supplemental biologics license application (sBLA) dated and received April 28, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Tysabri (natalizumab) injection, for intravenous use.

This Prior Approval supplemental biologics license application provides for revisions to the Tysabri US Prescribing Information (USPI) to include changes to the Dosage and Administration section (2.3) regarding the storage time of the refrigerated diluted solution from 8 hours to 48 hours.

APPROVAL & LABELING

We have completed our review of this sBLA, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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, except with the revisions indicated, the enclosed labeling (text for the prescribing information) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *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 Effectuated” (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, 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 Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling



Patrick
Lynch

Digitally signed by Patrick Lynch

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