BLA 761053/S-038

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Genentech, Inc.
Attention: Katherine Valentine
Senior Regulatory Program Director
1 DNA Way
South San Francisco, CA 94080

Dear Katherine Valentine:

Please refer to your supplemental biologics license application (sBLA) dated and received November 10, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Ocrevus (ocrelizumab) injection.

This Prior Approval sBLA provides for the use of Ocrevus for the treatment of relapsing-remitting multiple sclerosis in pediatric patients 10 years of age and older who weigh 25 kilograms or more.

APPROVAL & LABELING

We have completed our review of this application, 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 FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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).

BEST PHARMACEUTICALS FOR CHILDREN ACT

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), also known as the Best Pharmaceuticals for Children Act (BPCA), allows the FDA to request pediatric studies for new drugs before approval.

This supplemental application provides for pediatric labeling pursuant to BPCA. This supplemental application is approving use in pediatric patients ages 10 years and older who weigh 25 kilograms or more, for the treatment of relapsing-remitting multiple sclerosis. This approval is in response to a Written Request.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplement application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submissions dated November 10, 2025, and November 11, 2025, containing the final report for the following postmarketing requirement listed in the September 15, 2023, postapproval postmarketing requirement letter for BLA 761053.

3194-14 Conduct a two-part study of ocrelizumab in pediatric patients with relapsing multiple sclerosis (RMS) at least 10 years and less than 17 years of age. Part A is an open-label study of the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of ocrelizumab in pediatric patients weighing 40 kg or less. The objective of Part A is to determine a dose of ocrelizumab that will result in PK and PD effects that are comparable to those of a 600 mg dose (300 mg given twice 14 days

apart) in adult patients with RMS. Safety assessments will continue for at least 2 years after the last dose of ocrelizumab. Part B is a randomized, double-blind, parallel-group study to evaluate the efficacy and safety of ocrelizumab compared to an appropriate comparator.

We have reviewed your submissions and conclude that the above requirement has been fulfilled.

We remind you that there are postmarketing requirements listed in the March 28, 2017, approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]
You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 601.12(f)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(f)(4).

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).

[3] https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Elaine Gettelman, Regulatory Project Manager, by phone at (240) 402-6425 or by email at elaine.gettelman@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laura Jawidzik, MD
Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

LAURA A JAWIDZIK
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