DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 761053/S-12

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Arlene Bartolome, Pharm.D.
Regulatory Program Director
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Bartolome:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received April 25, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for Ocrevus (ocrelizumab).

This Prior Approval supplemental biologics application provides for updating the Ocrevus labeling with information from a Phase 3b randomized, open-label study to assess the impact of drug administration on vaccination response. Labeling revisions include recommendations regarding immunizations for patients prior to treatment with Ocrevus and for infants born to mothers treated with Ocrevus during pregnancy. The following labeling and sections were revised:

- Prescribing Information
  - Dosage and Administration (2.1)
  - Warnings and Precautions (5.2)
  - Drug Interactions (7.2)
  - Use in Specific Populations (8.1)
  - Patient Counseling Information (17)
- Medication Guide

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) 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}

Eric Bastings, MD
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Prescribing Information

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/

ERIC P BASTINGS
11/12/2018