BLA 761371/S-003

SUPPLEMENT APPROVAL

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 January 9, 2026, and your amendment, submitted under section 351(a) of the Public Health Service Act for Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) injection.

This "Changes Being Effected" supplemental biologics license application provides a change to the Ocrevus Zunovo container label by introducing a peel-off label to provide clarifications to ensure proper administration of the product.

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.

CARTON AND CONTAINER LABELS

We acknowledge your January 9, 2026, submission containing final printed container labeling.

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, contact Musse Olani, Pharm.D., Regulatory Business Process Manager, at musse.olani@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
Director, Division of Product Quality Assessment XIII
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Container Labeling

Patrick Lynch

Digitally signed by Patrick Lynch
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