BLA 761498/S-001

SUPPLEMENT APPROVAL

CELLTRION, Inc.
c/o Parexel International
Attention: Ally Danta
Regulatory Affairs Consultant
541 Church at North Hills St.
Suite 1000
Raleigh, NC 27609

Dear Ally Danta:

Please refer to your supplemental biologics license application (sBLA) dated and received March 3, 2026, submitted under section 351(k) of the Public Health Service Act for Avtozma (tocilizumab-anoh) injection.

This "Changes Being Effected" supplemental biologics license application provides to correct inadvertently omitted inactive ingredient information in carton labeling.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to carton and container labels submitted on March 3, 2026, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved BLA 761498/S-001.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 application, you are exempt from this requirement.

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 Anita Brown, Senior Regulatory Business Process Manager, at Anita.Brown@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Rapti Madurawe, Ph.D.
Director
Division of Product Quality Assessment XVI
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Carton and Container Labeling

Rapti Madurawe

Digitally signed by Rapti Madurawe
Date: 9/02/2026 04:11:28PM
GUID: 508da72000029fdce2bf6a1514cda660