



BLA 761420/S-006

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 4, 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 for correction of carton labeling for Avtozma for IV use (80 mg, 200 mg and 400 mg vials) to delete misprinted information indicating the presence of sucrose.

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 labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to 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 Labeling for approved BLA 761420/ S-006.**” Approval of this submission by FDA is not required before the labeling is used.

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 Kristine Leahy, Sr. Regulatory Business Process Manager, at (240) 402 - 5834 or Kristine.Leahy@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

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