CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

761498Orig1s000

Trade Name:	AVTOZMA
Generic or Proper Name:	Tocilizumab-anoh
Sponsor:	Celltrion, Inc.
Approval Date:	January 21, 2026
Indication:	For the treatment of: • Rheumatoid arthritis (RA) in adults • Giant cell arteritis (GCA) in adults • Polyarticular juvenile idiopathic arthritis (PJIA), pediatric patients 2 years and older • Systemic juvenile idiopathic arthritis (SJIA), pediatric patients 2 years and older

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APPROVAL LETTER

BLA 761498

BLA 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 biologics license application (BLA) received May 19, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Avtozma (tocilizumab-anoh) injection.

This BLA seeks licensure of:

- Avtozma (tocilizumab-anoh) injection, 162 mg/0.9 mL (180 mg/mL) single-dose prefilled syringe for subcutaneous use as interchangeable with US-Actemra (tocilizumab) injection 162 mg/0.9 mL (180 mg/mL) single dose prefilled syringe for subcutaneous use; and
- Avtozma (tocilizumab-anoh) injection, 162 mg/0.9 mL (180 mg/mL) single-dose prefilled autoinjector for subcutaneous use as biosimilar to US-Actemra (tocilizumab) injection 162 mg/0.9 mL (180 mg/mL) single dose pre-filled autoinjector for subcutaneous use.

This BLA also provides for unbranded biological product labeling.

LICENSING

We have approved your BLA for Avtozma (tocilizumab-anoh) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Avtozma under your existing Department of Health and Human Services U.S. License No. 1996. Avtozma is indicated for the treatment of:

- Rheumatoid arthritis (RA) in adults
- Giant cell arteritis (GCA) in adults
- Polyarticular juvenile idiopathic arthritis (PJIA), pediatric patients 2 years and older
- Systemic juvenile idiopathic arthritis (SJIA), pediatric patients 2 years and older

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture tocilizumab-anoh drug substance at [redacted] (b) (4) The final formulated drug products in single dose prefilled syringe and single dose autoinjector will be manufactured, filled, labeled, and packaged at Celltrion Pharm, Inc., Cheongju, Republic of Korea. You may label your product with the proprietary name, Avtozma, and market it in 162 mg/0.9 mL single dose prefilled syringe and single dose prefilled autoinjector, injection.

DATING PERIOD

The dating period for Avtozma single dose prefilled syringe and autoinjector shall be 36 months from the date of manufacture when stored at 5 ± 3 °C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be [redacted] (b) (4) months from the date of manufacture when stored at [redacted] (b) (4) °C.

We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Avtozma to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Avtozma, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

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, with minor editorial revisions listed below and reflected in the enclosed labeling.

Unbranded Biological Product Prescribing Information

- HIGHLIGHTS, DOSAGE AND ADMINISTRATION, Administration of Intravenous Formulation, second bullet: comma after “SJIA”
- FULL PRESCRIBING INFORMATION, DOSAGE AND ADMINISTRATION, SECTION 2.8, 8 mg/kg row: comma and space after “SJIA”

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.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide). 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 (October 2009)*.[2]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted on May 19, 2025, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved BLA 761498**.” 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 (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.

Rheumatoid arthritis, Giant Cell Arteritis, Polyarticular Juvenile Idiopathic Arthritis, and

[1] See 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 at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Systemic Juvenile Idiopathic Arthritis:

At this time, we have determined that no pediatric studies will be required under PREA for your BLA.

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]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 21 CFR 600.80.

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements at 21 CFR 600.81.

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

[3] For the most recent version of a guidance, check the FDA guidance web page at 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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have questions, contact Anh-Thy Ly, Project Manager, at 240-402-1001 or Anh-Thy.Ly@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Raj Nair, MD
Division Director
Division of Rheumatology and Transplant
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):
Branded Product Labeling
- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

Unbranded Biological Product Labeling
- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

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/

RAJ NAIR
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