CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761498Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	August 7, 2025
Application Type and Number:	BLA 761498
Product Name, Dosage Form, and Strength:	Avtozma (tocilizumab-anoh) injection, 162 mg/0.9 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc.
PNR ID #:	2025-1044726577
DMEPA 1 Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to assess the proposed proprietary name, Avtozma, which was found acceptable under BLA 761420 on April 24, 2024.[a] Celltrion submitted the proposed proprietary name, Avtozma, under BLA 761498 for review on July 3, 2025.[b]

2 REGULATORY HISTORY

We note that Avtozma (tocilizumab-anoh) was originally approved on January 24, 2025, under BLA 761240 in single-dose vial for intravenous use and in prefilled syringe and autoinjector for subcutaneous use. BLA 761498 was submitted to separate the subcutaneous use formulations (prefilled syringe and autoinjector) from the intravenous use formulation (single-dose vial) for commercial purposes. The two BLAs share the same prescribing information that was approved under BLA 761240.

3 DISCUSSION

3.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Avtozma would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Avtozma. The Division of Rheumatology and Transplant Medicine (DRTM) did not comment on the findings of OPDP's assessment for Avtozma.

3.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Avtozma, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The July 8, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name, Avtozma.

3.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On August 7, 2025, DMEPA 1 communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

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[a] Vee, S. Proprietary Name Review for Avtozma (BLA 761420). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 APR 24. PNR ID No. 2024-1044725610.

[b] Request for Proprietary Name Review for Avtozma (BLA 761498). Lake Zurich (IL): Celltrion, Inc.; 2025 JUL 03. Available from: \\CDSESUB1\EVSPROD\bla761498\0004\m1\us\proprietary-name.pdf.

4 CONCLUSION

Our assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Avtozma, is conditionally acceptable.

4.1 COMMENTS TO CELLTRION, INC

We have completed our review of the proposed proprietary name, Avtozma, and have concluded that this proprietary name is conditionally acceptable.

If any of the proposed product characteristics as stated in your submission, received on July 3, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

5 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

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/

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08/07/2025 08:02:12 AM

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Signed on behalf of Idalia Rychlik