CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761379Orig2s000

OTHER REVIEW(S)

LABEL AND LABELING REVIEW

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)

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Date of This Review:	April 17, 2025
Requesting Office or Division:	Office of Therapeutic Biologics and Biosimilars (OTBB)
Application Type and Number:	BLA 761379/Ori-2 and BLA 761379/S-004
Product Name, Dosage Form, and Strength:	Otulfi (ustekinumab-aauz) injection, Prefilled syringe: 45 mg/0.5 mL and 90 mg/mL Vial: 45 mg/0.5 mL and 130 mg/26 mL (5 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant Name:	Celltrion, Inc.
FDA Received Date:	October 30, 2024 and April 11, 2025
TTT ID #:	2025-13032
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP

1 INTRODUCTION

As part of the approval process for Otulfi (ustekinumab-aauz) injection BLA 761379/Original 2 and BLA 761379/S-004 for interchangeability designation of Otulfi prefilled syringes (45 mg/0.5 mL and 90 mg/mL) and vials (45 mg/0.5 mL and 130 mg/26 mL), the Office of Therapeutic Biologics and Biosimilars (OTBB) requested that we review the proposed Otulfi Prescribing Information (PI), Medication Guide (MG), Instructions for Use (IFU), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND

Otulfi (ustekinumab-aauz) is a proposed 351(k)(4) interchangeable and the US-licensed Reference Product (RP) is Stelara (ustekinumab), BLA 125261 and BLA 761044.

2 CONCLUSION

The Otulfi Prescribing Information (PI), Medication Guide (MG), Instructions for Use (IFU), container labels, and carton labeling remain unchanged from what DMEPA previously found acceptable for BLA 761379/Ori-1 and BLA 761379/S-002.[a,b,c,d] We have no recommendations at this time.

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[a] Patel, M. Label and Labeling Review for Otulfi (BLA 761379). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 APR 12. TTT ID No.: 2023-6565.

[b] Patel, M. Review of Revised Label and Labeling for Otulfi (BLA 761379). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 SEP 25. TTT ID No.: 2023-6565-2.

[c] Patel, M. Label and Labeling Review for Otulfi (BLA 761379). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 FEB 14. TTT ID No.: 2024-12135.

[d] Patel, M. Review of Revised Label and Labeling for Otulfi (BLA 761379). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 MAR 14. TTT ID No.: 2024-12135-1.

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/s/

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