

BLA 761338/Original 2

**BLA APPROVAL**

CELLTRION, Inc.  
c/o Parexel International  
Attention: Ally Danta  
Regulatory Affairs Consultant  
2520 Meridian Parkway, Suite 100  
Durham, NC 27713

Dear Ally Danta:

Please refer to your biologics license application (BLA) dated and received June 30, 2023, and your amendments, submitted under section 351(k) of the Public Health Service Act for Steqeyma (ustekinumab-stba) injection.

We acknowledge receipt of your amendment dated January 23, 2025, which constituted a request for approval following our December 17, 2024, provisional determination letter.

BLA 761338 initially provided for:

- Steqeyma (ustekinumab-stba) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use,
- Steqeyma (ustekinumab-stba) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use, and
- Steqeyma (ustekinumab-stba) injection 130 mg/26 mL single-dose vial for intravenous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 130 mg/26 mL single-dose vial for intravenous use.

For administrative purposes, BLA 761338 was split as follows:

- BLA 761338/Original 1 – biosimilarity
- BLA 761338/Original 2 – interchangeability

The subject of this correspondence is BLA 761338/Original 2. A separate correspondence was issued for BLA 761338/Original 1 on December 17, 2024.

## **LICENSING**

We have approved BLA 761338/Original 2 for Steqeyma (ustekinumab-stba) as interchangeable biosimilar products effective this date. You are hereby authorized to

introduce or deliver for introduction into interstate commerce, Steqeyma, under your existing Department of Health and Human Services U.S. License No. 1996.

Steqeyma is indicated for treatment of:

Adult patients with:

- moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)
- moderately to severely active Crohn's disease (CD)
- moderately to severely active Ulcerative colitis (UC)

Pediatric patients 6 years and older with:

- moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)

## **MANUFACTURING LOCATIONS**

Under this license, you are approved to manufacture ustekinumab-stba drug substance at CELLTRION, Inc. (b) (4), Incheon, Republic of Korea (FEI 3005241015). The final formulated product will be manufactured, filled, labeled, and packaged at CELLTRION Pharm, Inc., Cheongju, Republic of Korea (FEI 3012279978) (b) (4). You may label your product with the proprietary name, Steqeyma, and market it in 45 mg/0.5 mL injection, 90 mg/1.0 mL injection and 130 mg/26 mL injection.

## **DATING PERIOD**

The dating period for Steqeyma shall be 36 months from the date of manufacture when stored at  $5\pm 3$  °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 (b) (4) months from the date of manufacture when stored at (b) (4).

## **FDA LOT RELEASE**

You are not currently required to submit samples of future lots of Steqeyma 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 Steqeyma, 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.

**U.S. Food and Drug Administration**  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

## **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.

## **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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, 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)*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

## **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.

We remind you that postmarketing requirement 4765-1 listed in the December 17, 2024 approval letter is still open.

## **POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitments:

4765-2 To repeat the bacterial retention study (b) (4) with CT-P43 drug product (5 mg/mL) to verify that the bacterial retention performance (b) (4) is not impacted by contact with the drug product solution (b) (4)

<sup>1</sup> See <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

The timetable you submitted on December 10, 2024, states that you will conduct this study according to the following schedule:

Final report submission: 03/2025

Submit clinical protocols to your IND 146085 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA. In addition, under 21 CFR 601.70 you should include a status summary of each commitment in your annual progress report of postmarketing studies to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients/subjects entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol**,” “**Postmarketing Commitment Final Report**,” or “**Postmarketing Commitment Correspondence**.”

### **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*.<sup>3</sup>

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.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

### **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

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<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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:

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](http://FDA.gov).

If you have any questions, contact Chau Nguyen, Regulatory Project Manager at [chau.nguyen@fda.hhs.gov](mailto:chau.nguyen@fda.hhs.gov) or (240)-402-0022.

Sincerely,

*{See appended electronic signature page}*

Tatiana Oussova, MD, MPH  
Deputy Director of Safety  
Division of Dermatology and Dentistry  
Office of Immunology and Inflammation  
Office of New Drugs  
Center for Drug Evaluation and Research

**ENCLOSURE(S):**

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

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[www.fda.gov](http://www.fda.gov)

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**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.**  
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/s/  
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TATIANA OUSSOVA  
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