



BLA 761373/S-004

SUPPLEMENTAL BLA APPROVAL

Samsung Bioepis Co., Ltd.
c/o Samsung Bioepis United States Inc.
Attention: Yelena Vayzman
Senior Manager, Regulatory Affairs
400 Frank W Burr Boulevard #125
Teaneck, NJ 07666

Dear Yelena Vayzman:

Please refer to your supplemental biologics license application (sBLA) dated and received August 20, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Pyzchiva (ustekinumab-ttwe) injection.

We acknowledge receipt of your amendment dated January 7, 2025, which constituted a request for approval following our December 20, 2024, provisional determination letter.

This Prior Approval sBLA initially provided for Pyzchiva (ustekinumab-ttwe) injection 45 mg/0.5 mL single-dose vial for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) injection 45 mg/0.5mL single-dose vial for subcutaneous use.

For administrative purposes, we had split S-002 into the following supplements:

- BLA 761373/S-002 – biosimilarity
- BLA 761373/S-004 – interchangeability

The subject of this correspondence is BLA 761373/S-004. A separate correspondence was issued for BLA 761373/S-002 on December 20, 2024.

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, as described at FDA.gov,¹ that is identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

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*.²

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.

At this time, no pediatric assessment will be required under PREA for this sBLA.

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

¹ <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 <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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

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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

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 Chau Nguyen, Regulatory Project Manager at 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

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

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

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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.

/s/

TATIANA OUSSOVA
04/30/2025 12:55:39 PM