



BLA 761373/S-003  
BLA 761425/S-003

## SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.  
c/o ICON Clinical Research LLC  
Attention: Wendy DeSpain, BSc, MBA, RAC  
Senior Director, US Regulatory Affairs  
4130 Parklake Avenue, Suite 400  
Raleigh, NC 27612

Dear Wendy DeSpain:

Please refer to your supplemental biologics license applications (sBLAs), dated and received August 21, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Pyzchiva (ustekinumab-ttwe) injection.

These Prior Approval supplemental biologics applications provide for unbranded biological product labeling for Ustekinumab-ttwe 45 mg/0.5 mL and 90 mg/mL, in prefilled syringe (PFS), and 130 mg/26 mL vial and updated storage conditions for Pyzchiva (Ustekinumab-ttwe) PFS injection with associated labeling updates.

### **APPROVAL & LABELING**

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed 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,<sup>1</sup> 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.

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

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*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, 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 *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved BLA 761373/S-003 and BLA 761425/S-003.**” 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.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

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<sup>2</sup> 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>.

## **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).

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 (240)-402-0022 or [chau.nguyen@fda.hhs.gov](mailto:chau.nguyen@fda.hhs.gov).

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):

#### Branded and Unbranded Product Labeling

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

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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  
03/13/2025 11:02:01 AM