



BLA 761379/S-006

## SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC  
Attention: Navayath Shobana, PhD  
Senior Director, Regulatory Affairs Lead  
Three Corporate Drive  
Lake Zurich, IL 60047

Dear Dr. Shobana:

Please refer to your supplemental biologics license application (sBLA) dated and received May 13, 2025, and your amendment, submitted under section 351(k) of the Public Health Service Act for Otulfi (ustekinumab-aauz) injection.

This “Changes Being Effected” supplemental biologics license application provides for 1) Change regarding the 45 mg/0.5 mL and 90 mg/mL prefilled syringe needle gauge from 27 to 29 gauge. 2) Removal of [REDACTED] (b) (4) from the carton label of the 45 mg/0.5 mL vial.

### **APPROVAL & LABELING**

We have completed our review of this sBLA, 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](http://www.fda.gov)<sup>1</sup>, that is identical to the enclosed labeling (text for the prescribing information) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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 MS Word format that includes the changes approved in this supplemental application.

### **CARTON LABELS**

Submit final printed carton labels that are identical to enclosed carton labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 “**Product Correspondence – Final Printed Carton Labels for approved BLA 761379/S-006.**” Approval of this submission by FDA is not required before the labeling is used.

### **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 Kristi De Lisle, MS, BSN, RN, Regulatory Business Process Manager, at [kristi.delisle@fda.hhs.gov](mailto:kristi.delisle@fda.hhs.gov) or (301) 796 - 8013.

Sincerely,

*{See appended electronic signature page}*

Patrick Lynch, Ph.D.  
Director  
Division of Product Quality Assessment XIII  
Office of Product Quality Assessment III  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

### ENCLOSURE

- Content of Labeling
  - Prescribing Information
- Carton Labeling



Patrick  
Lynch

Digitally signed by Patrick Lynch

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