BLA 761364/S-005

SUPPLEMENT APPROVAL

Accord BioPharma, Inc.
Attention: Sabita Nair
VP Regulatory Affairs
8041 Acro Corporate Drive
Suite 200
Raleigh, NC 27617

Dear Sabita Nair:

Please refer to your supplemental biologics license application (sBLA) received August 7, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Imuldosa (ustekinumab-srlf).

This Prior Approval supplemental biologics license application provides for:

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

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)

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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.

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).

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. You have provided a pediatric assessment for Crohn's disease in pediatric patients 2 years of age and older, and nothing further is required at this time.

We remind you of the postmarketing requirement 4700-1 listed in the October 10, 2024, Approval letter that is still open.

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]

[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.

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).

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.

If you have any questions, contact Sascha Randolph, Regulatory Project Manager, at Sascha.Randolph@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gary Chiang, MD, MPH
Acting Associate Director for Therapeutic Review
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

- Content of Labeling
  - Prescribing Information
  - MG
  - IFU

[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/

GARY T CHIANG
06/05/2026 12:38:38 PM