URGENT VOLUNTARY RECALL: Hospital Level, June 10, 2026

IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL (5 mg/mL)

Accord BioPharma, Inc. ("Accord BioPharma") is voluntarily recalling one lot of IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL (5 mg/mL), at the Hospital Level.

This action follows recent FDA inspections in July 2025 and April 2026 of the contracted manufacturing facility of Catalent Indiana, LLC at 1300 S Patterson Drive, Bloomington, Indiana (IN) 47403, United States (USA) during which observations were documented and subsequently communicated to the facility. FDA issued a Warning Letter to the facility on November 20, 2025. During the April 2026 inspection, FDA determined that the responses provided by the facility do not adequately resolve the concerns raised.

Accord BioPharma has released one lot of Imuldosa® vial (Lot no. 004L24A) on August 05, 2025, that was manufactured at the Catalent facility. Comprehensive investigations were conducted into the out-of-trend result for major A defects observed during manual visual inspection of this lot. A tightened Level II AQL inspection (200-unit sample) was performed in accordance with validated procedures and met all acceptance criteria, with only two major A defects observed (within the allowable limit of ≤3). This provides strong, statistically valid evidence that the batch is under control and meets quality requirements. The totality of evidence available for this lot confirms that the batch is of acceptable quality.

Based on the data currently available, this lot is not anticipated to present a risk to patients. However, due to the recent FDA inspectional observations and FDA's additional concerns regarding Catalent's responses to the FDA Warning Letter, the possibility of quality issues cannot be completely ruled out. Therefore, out of an abundance of caution, Accord has decided to voluntarily recall the identified lot from the market to mitigate any potential risk to patient safety. To date, no adverse events associated with this matter have been reported.

Please examine your inventory of IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL for the below listed lot number.

The product label for the recalled product should have the following details. Please also refer to the enclosed product label included with this recall letter.

IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL				
Strength	**Vial Pack size**	**Product NDC**	**Lot No.**	**Expiry Date**
130 mg/26 mL	**Pack of One Single-Dose Vial**	**69448-019-26**	**004L24A**	**02/19/2027**

Hospitals/Wholesalers/Speciality Pharmacy - Please perform the following activities:

- Examine your inventory immediately for the listed lot number of IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL.
- Immediately discontinue distribution of the recalled Lot number of IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL.
- Promptly complete the attached Product Recall Response Form and reply even if you do NOT have product to return.
- If you have product to return, complete the attached Product Recall Response Form, quarantine the stock, and follow the instructions given on the Product Recall Response Form.
- If you have further distributed this lot number to other hospitals/retailers, please immediately contact them and advise them of the recall and have them return their outstanding recalled stock to you. Return this stock as per the instructions on the attached Product Recall Response Form.

Your assistance is appreciated and necessary to prevent any potential health risk to the consumer.

Accord BioPharma is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Please complete and return the enclosed "PRODUCT RECALL RESPONSE FORM" as soon as possible, but no later than five business days from receipt of this letter.

Completed Product Recall Response Form should be emailed, or sent via FAX to INMAR,
Attn: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050.
INMAR Email: rxrecalls@inmar.com. FAX: 1-817-868-5362.

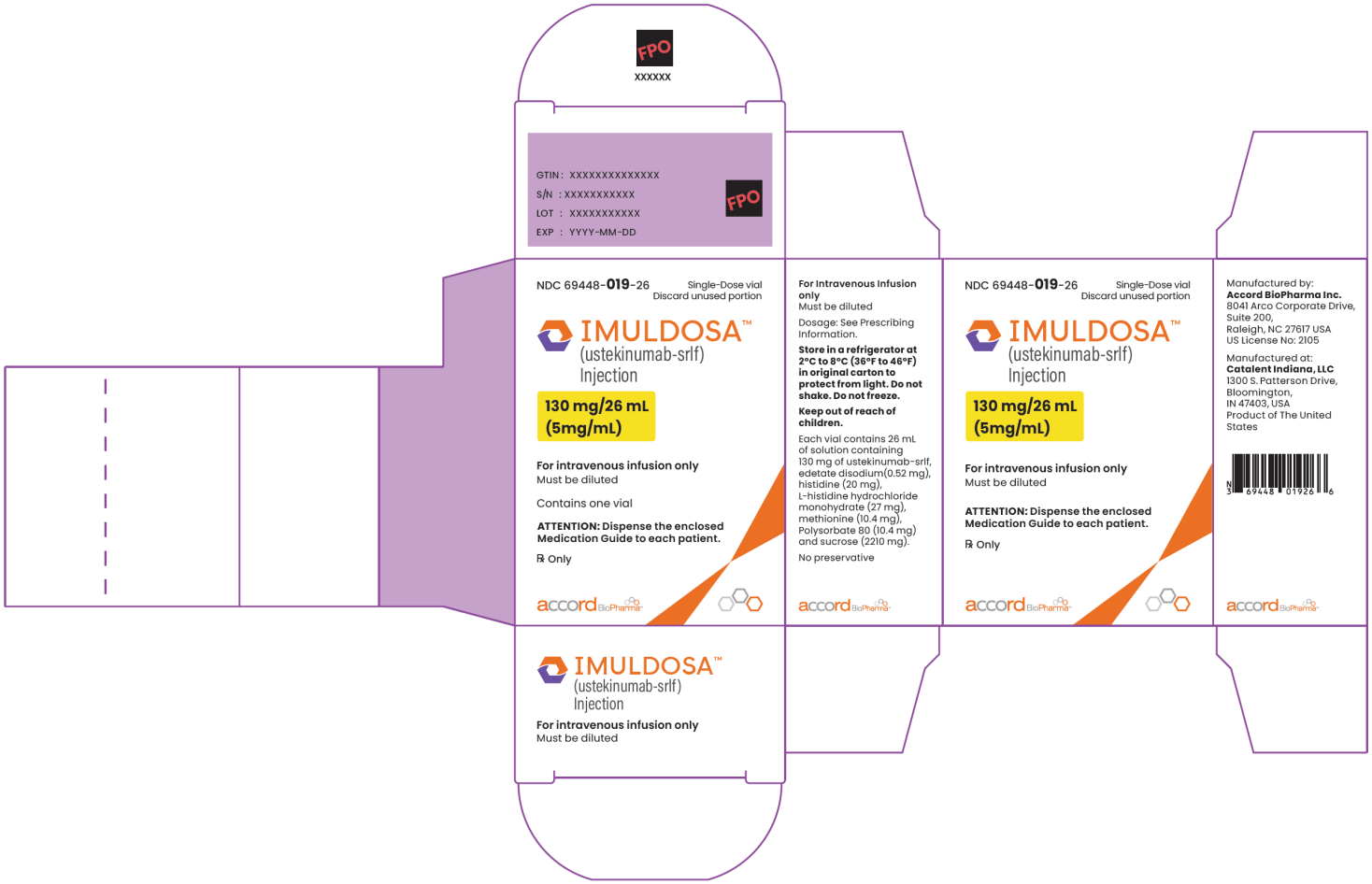
If you have any questions about the logistics for returning the affected lot or other issues, please call Recall Services at 1-855-937-2860, Monday – Friday (excluding holidays), 9am to 5 pm EST.

Inmar will send you a Return Goods Authorization and shipping label. Appropriate credit for the returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

We appreciate your assistance in this matter.

Sincerely,

Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
Accord BioPharma, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617, USA


FPO
XXXXXX
GTIN : XXXXXXXXXXXXX
S/N : XXXXXXXXXX
LOT : XXXXXXXXXX
EXP : YYYY-MM-DD
FPO
NDC 69448-019-26
Single-Dose vial
Discard unused portion
IMULDOSA™
(ustekinumab-srlf)
Injection
130 mg/26 mL
(5mg/mL)
For intravenous infusion only
Must be diluted
Contains one vial
ATTENTION: Dispense the enclosed Medication Guide to each patient.
℞ Only
accord BioPharma
For Intravenous Infusion only
Must be diluted
Dosage: See Prescribing Information.
Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not shake. Do not freeze.
Keep out of reach of children.
Each vial contains 26 mL of solution containing 130 mg of ustekinumab-srlf, edetate disodium(0.52 mg), histidine (20 mg), L-histidine hydrochloride monohydrate (27 mg), methionine (10.4 mg), Polysorbate 80 (10.4 mg) and sucrose (2210 mg).
No preservative
accord BioPharma
NDC 69448-019-26
Single-Dose vial
Discard unused portion
IMULDOSA™
(ustekinumab-srlf)
Injection
130 mg/26 mL
(5mg/mL)
For intravenous infusion only
Must be diluted
ATTENTION: Dispense the enclosed Medication Guide to each patient.
℞ Only
accord BioPharma
Manufactured by:
Accord BioPharma Inc.
8041 Arco Corporate Drive,
Suite 200,
Raleigh, NC 27617 USA
US License No: 2105
Manufactured at:
Catalent Indiana, LLC
1300 S. Patterson Drive,
Bloomington,
IN 47403, USA
Product of The United States
accord BioPharma
IMULDOSA™
(ustekinumab-srlf)
Injection
For intravenous infusion only
Must be diluted

PRODUCT RECALL RESPONSE FORM

Product Recall Date: June 10, 2026 **Voluntary Recall: Hospital Level**

IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL				
Strength	**Vial Pack size**	**Product NDC**	**Lot No.**	**Expiry Date**
130 mg/26 mL	Pack of One Single-Dose Vial	69448-019-26	004L24A	02/19/2027

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____ DEA #_____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address_____

City_____ State_____

Zip_____

Contact Name (please print)_____ Telephone # _____

Contact Signature _____ Date_____

If you did not purchase the product directly from the Manufacturer, please complete the following section.

Purchased from: Name _____ DEA #_____

Address _____

City_____ State_____

Zip_____

Please check all appropriate boxes:

☐ I have read and understand the recall instructions provided in the letter.
☐ I have checked my stock and have quarantined inventory consisting of_____ vials/units.

Any adverse events associated with recalled product?

☐Yes ☐ NO If yes, please explain: _____

Please describe your business: _____

I have checked my stock and:

_____Do not have any stock of recalled **items**.

OR

_____Have quarantined and listed in the box above the quantity of vials/units of **IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL,** and will be returning them to Inmar, as soon as possible.

Upon receipt of this Response Form, Inmar will issue return authorization label(s).

Please indicate the number of box labels needed:_____

Completed Product Recall Response Form should be emailed, or sent via FAX to INMAR,
Attn: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050.
INMAR Email: rxrecalls@inmar.com. FAX: 1-817-868-5362.

Even if you do not possess any inventory of the lot being recalled, we would appreciate it if you could still fill out and return the "PRODUCT RECALL RESPONSE FORM".

If you have any questions about the logistics for returning affected lot or other issues, please call Recall Services at 1-855-937-2860, Monday – Friday (excluding holidays), 9am to 5 pm EST.