The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.
Accord BioPharma, Inc. ("Accord BioPharma") is 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 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.

PRODUCT: IMULDOSA (Ustekinumab-srlf) Injection 130 mg/26 mL, Pack of One Single-Dose Vial

NDC NUMBER: 69448-019-26

LOT NUMBER: 004L24A

EXPIRY DATE: 02/19/2027