

*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.*

Nephron 503B Outsourcing Facility is initiating a voluntary recall of Albuterol Sulfate Inhalation Solution 0.5%, 25 mg/5 mL (5 mg/mL); NDC: 69374-330-05.

This recall is being initiated due to a labeling defect involving distortion of printed production identifiers (lot number and manufacturing and expiration dates) on the shrink-wrap label that serves as the immediate container label for certain vials from Lot AB6001.

The issue is limited to the printed production identifiers on the vial label. Product name, dosage form, strength, and other identifying information remain accurate and legible, and the carton labeling correctly displays the applicable production identifiers. Based on the evaluation conducted, there is no impact to product quality, sterility, strength, or purity, and no adverse health consequences are expected. Nephron is initiating this recall of Lot AB6001 to address this labeling defect.

PRODUCT: Albuterol Sulfate Inhalation Solution 0.5%, 25 mg/5 mL (5 mg/mL)

NDC NUMBER: 69374-330-05

LOT NUMBER: AB6001