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.

This is to inform you of a product recall by Cipla USA, Inc. for 1 lot (Lot# 4IA0505) of Budesonide Inhalation Suspension 0.5mg/2ml. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers #69097-319-86 (Pouch), 69097-319-87 (Carton).

This recall has been initiated due to market complaint received for leakage and empty respule. The patient safety risk with leaked respules are potentially contamination and dose insufficiency. The use of any leaked respule is remote, as the leakage is readily visible and will not be used by the patient and complaint is registered. If there are intact respules there are no expected risk, assuming container integrity is maintained.

This recall should be carried out to the Retail level.

PRODUCT: Budesonide Inhalation Suspension 0.5mg/2ml

NDC NUMBERS: 69097-319-86 (Pouch), 69097-319-87 (Carton)

LOT NUMBER: 4IA0505

DISTRIBUTION DATES: 12/12/2024 to 01/24/2025