

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 2 lots (Lot # IA30390 and IA30517) of Ipratropium Bromide and Albuterol Sulfate Inhalation Solution USP 0.5 mg & 3mg/3ml. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers 69097- 173-48 (Pouch), NDC-69097-173-53 (Carton).

This recall has been initiated due to market complaint sample evaluation of the 2 lots (IA30390 and IA30517) showing less fill volume in vial (respule) and few drops of liquid observed after opening the intact pouch.

Based on the health hazard evaluation, the observed nonconformance may impact patient safety if leaked respules are used for therapy. There will be no impact expected on the patient safety if intact respules without leak is used as other respules apart from leaked one were found intact inside the pouch.

Sr. No.	Product Name	Batch No.	Exp Date	Dates distributed
1.	Ipratropium Bromide and Albuterol Sulfate Inhalation Solution USP 0.5 mg & 3mg/3ml	IA30390	April 2025	08/25/2023 to 08/31/2023
2.	Ipratropium Bromide and Albuterol Sulfate Inhalation Solution USP 0.5 mg & 3mg/3ml	IA30517	June 2025	10/26/2023 to 11/03/2023