

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.

Endo USA, Inc. is recalling Adrenalin® Chloride Solution (EPINEPHrine Nasal Solution, USP) 30mg/30ml (1mg/ml)

NDC#: 42023-103-01

Package Size: Unit Carton

The scope of the recall impacts the below lots:

Lot#	Date of Expiry
82809	03/2026
79637	11/2025
77776	07/2025
74716	05/2025
71835	01/2025
72916	01/2025

This product, which pre-dates the 1938 Federal Food, Drug & Cosmetic Act, was never submitted for approval by the FDA, and as such, is an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. In addition, FDA has determined the product to be misbranded with a misleading label similar in appearance to the FDA-approved drug product Adrenalin® (epinephrine injection, USP) (1mg/ml) 30ml vial, also produced by Endo USA, Inc.

The similarity in labeling makes it difficult to distinguish between the non-sterile topical and sterile injectable product which can lead to potential administration errors.

This recall does not include the approved Adrenalin® (epinephrine injection, USP) (1mg/ml) 30ml vial.

The product lots were distributed nationwide to wholesale distributors from October 10, 2023 through December 11, 2024.