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 notice is to inform you of a product recall involving **Fluocinolone Acetonide Solution USP, 0.01% in 60 mL bottle** by Sun Pharmaceutical Industries, Inc.

This recall has been initiated in response to Out of Specification (OOS) results observed in a known impurity D test for Fluocinolone 0.01% Solution Batch AD81290, during analysis at the 6-month long term stability station, at (25°C, 60%RH). The additional three (3) listed batches, manufactured as part of the same campaign are impacted and, therefore, subject to this recall. Based on the Health Hazard Evaluation, *"Overall, it can be concluded that the OOS results of impurity D (21-Aldehyde analog) at the current level of 1.3 % at 6M stability testing at CRT (25°C/ 60%RH) is unlikely to pose any serious safety concern in patients".*

All lots complied with all of the established product specifications at the time the products were released for distribution. Sun Pharmaceutical Industries, Inc. initiated shipment of this product between May 15, 2025 and November 3, 2025.

Product Name	**Package Description**	**NDC#**	**Lot#**	**Expiration Date**
Fluocinolone Acetonide Solution USP, 0.01%	60 ml bottle	51672-1365-4	AD81290	1/31/2027
Fluocinolone Acetonide Solution USP, 0.01%	60 ml bottle	51672-1365-4	AD81291	1/31/2027
Fluocinolone Acetonide Solution USP, 0.01%	60 ml bottle	51672-1365-4	AD81292	1/31/2027

Fluocinolone Acetonide Solution USP, 0.01%	60 ml bottle	51672-1365-4	AD81293	1/31/2027