

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. Sun Pharmaceutical Industries, Inc. (Sun Pharma) would like to inform you of a product recall involving Fluocinonide 0.05% Cream, 15g, 30g, 60g, (this is a marketed product under the Taro Pharmaceutical label).

This recall has been initiated in response to Out of Specification (OOS) result, above the specification limit, in viscosity, for Fluocinonide Cream 0.05%, for Batch AD76252 (15g) and Batch AD76251 (30g) during the 6-month and the 12-month, long term stability station, at (25°C, 60%RH), respectively.

Sun Pharma is recalling the lots listed below, which were found impacted based on the investigation. The lots complied with all of the established product specifications at the time the product was released for distribution. The Health Hazard Evaluation concluded *“Although the viscosity results for Fluocinonide 0.05% cream, were above the specification limit, this does not impact the cream’s spreadability and usage and, therefore, is unlikely to pose any risk to the patient due to high viscosity”*.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product between January 28, 2025 and June 25, 2025.

Product Name	Package Description	NDC#	Lot#	Expiration Date	Quantity in Distribution
Fluocinonide 0.05% Cream	15G	51672-1386-1	AD76252	6/30/2026	24,672
Fluocinonide 0.05% Cream	30G	51672-1386-2	AD76251	6/30/2026	41,712
Fluocinonide 0.05% Cream	60G	51672-1386-3	AD76250	6/30/2026	2,640