

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.

Glenmark Pharmaceuticals Inc. is initiating a recall for Fluocinolone Acetonide Oil 0.01% (Ear Drops). The recall of these batches have been initiated due to an out-of-specification (OOS) result observed for the content of Isopropyl Alcohol in the Fluocinolone Acetonide Oil 0.01% (Ear Drops), Batch #05212513 (23 months stability expiry testing time point at the 25°C/60%RH storage condition) as manufactured for the USA market. The Isopropyl Alcohol content result was reported to be 78.6 % against the specification limit of Not Less Than (NLT) 80.0% and not more than 120.0% of the labeled amount of Isopropyl Alcohol. The tested OOS batch# 05212513 expired in November 2023; therefore, this batch is not included in product Recall.

S. No.	NDC	Batch #	Expiry
1.	68462-185-56	05220346	January 2024
2.	68462-185-56	05220369	January 2024
3.	68462-185-56	05220582	February 2024
4.	68462-185-56	05220861	March 2024