

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.

Neomycin Sulfate Tablets, USP 500 mg

NDC	Lot #	Exp. Date	Bottle Size
0093-1177-01	3007830	10/2024	100 count
0093-1177-01	3007746	10/2024	100 count
0093-1177-01	3007829	10/2024	100 count

Teva Pharmaceuticals USA Inc. (Teva USA) is initiating a recall of the above drug product lots to the Retail Level. The subject product lots were distributed under label of Teva Pharmaceuticals and were distributed nationwide from 11/24/2021 through 06/28/2022.

This recall is being initiated because foreign matter was found in the Active Pharmaceutical Ingredient (API) used in the manufacture of the three drug product lots in this recall after the product's release to the US market.

The main safety concern is the foreign matter, acrylate adhesives. Even though the amount of the foreign material found within API is most likely clinically insignificant, given that the typical consumption of 12 grams per day or 24 tablets, over a period of five to six days (as indicated for hepatic coma), possible accumulation of the acrylate adhesives and exposure to high amounts, cannot be fully excluded. Exposure to the product of concern could lead to severe health consequences and the likelihood of the harm occurrence is remote. Consequently, the overall risk of harm in patient population is considered to be medium.