

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.

Zydus Pharmaceuticals (USA) Inc. is extending its previous recall of two lots, Entecavir Tablets, USP 0.5 mg, lot no. E309376 and Entecavir Tablets, USP 1 mg, lot no. E309377 to add two additional lots listed in table 1 below.

The recall is based on an Out of Specification (OOS) result for an individual organic impurity detected in the product during routine eighteen-months stability testing. The potential risk associated with use of the affected product is currently unknown and under active investigation.

The product was shipped to our customers from May 2025 to September 2025.

Product	NDC Number	Lot Number	Expiry Date	Count	Distribution Start Date	Distribution End Date
Entecavir Tablets, USP 0.5 mg	68382-920-06	E409308	12/2026	30's Count Bottle Pack	05/06/2025	05/16/2025
Entecavir Tablets, USP 1 mg	68382-921-06	E409309	12/2026	30's Count Bottle Pack	05/07/2025	09/23/2025