

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 communication is to notify you that Zydus Pharmaceuticals (USA) Inc. ("Zydus"), is recalling Entecavir Tablets, USP.

This recall has been initiated due to 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 February 2024 to March 2025.

Product	NDC Number	Lot Number	Expiry Date	Count	Distribution Start Date	Distribution End Date
Entecavir Tablets, USP 0.5 mg	68382-920-06	E309376	11/2025	30's Count Bottle Pack	02/06/2024	03/06/2025
Entecavir Tablets, USP 1 mg	68382-921-06	E309377	11/2025	30's Count Bottle Pack	02/06/2024	02/14/2025