

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.

Based on the FDA’s recommendation, Zydus Pharmaceuticals (USA) Inc. (“Zydus”), is reclassifying this voluntarily recall from the **WHOLESALE** to the **RETAIL LEVEL** for the drug product mentioned in the table below.

Zydus has decided to initiate a recall of Venlafaxine Hydrochloride Extended-Release Capsules, USP, 37.5mg based on an out-of-specification (OOS) result observed by a repackager during routine stability testing.

Based on the investigation done by the repackager, the failure to meet dissolution specification in the repackaged batch is attributed to the repackaging process, during which extensive down time was observed. Despite this issue not originating from Zydus’ manufacturing site, we are recalling the above listed lots out of an abundance of caution and with our continuous focus on patient safety.

Product	NDC Number	Lot Number	Expiry Date	Count	Distribution Start Date	Distribution End Date
Venlafaxine Hydrochloride Extended-Release Capsules, USP, 37.5mg	68382-034-16	M213175	09/2024	90s Count HDPE Bottle 1000s	12/28/2022	01/06/2023
Venlafaxine Hydrochloride Extended-Release Capsules, USP, 37.5mg	68382-034-10	M213176	09/2024	Count HDPE Bottle	05/24/2023	10/03/2023