

*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.*

Apotex Corp. is recalling one (1) lot of Paroxetine HCl Extended-Release Tablets (lot TY9495) (the “Product”) to the Retail/Pharmacy level.

This recall is being conducted as an extension of the recall initiated on August 13, 2026, for lot TY9494. Subsequent review determined that lot TY9495 was manufactured from the same core batch as lot TY9494. Lot TY9494 failed to meet the specified dissolution acceptance criteria during 24-month stability testing, with the out-of-specification result occurring during the buffer-stage portion of dissolution testing. As the observed dissolution failure may affect the intended release rate of the active ingredient from the extended-release tablet, lot TY9495 is being recalled out of an abundance of caution based on its shared core batch with lot TY9494 and the potential for the same condition to affect lot TY9495.

Based on Apotex’s Health Hazard Assessment and the available data, use of the affected lot is not reasonably expected to cause adverse health consequences, as the observed dissolution increase is not anticipated to impact the safety, efficacy, or risk-benefit profile of the product.

PRODUCT: Paroxetine HCl Extended-Release Tablets 37.5 mg, 30-count bottle

NDC NUMBER: 60505-1318-3

LOT NUMBER: TY9495

EXPIRATION DATE: 05/2027

DISTRIBUTION DATES: 06/13/2024 - 11/11/2024