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 Paxil CR® (Paroxetine Extended-Release Tablets) (lot TY9494) (the "Product") to the Retail/Pharmacy level. No retrieval of Product already dispensed to patients is requested under this recall communication. Patients should not stop taking prescription medication without consulting their healthcare professional. Adverse events or quality problems associated with use of this Product may be reported to Apotex at drug.safety@apotex.com and to FDA's MedWatch Adverse Event Reporting program.

For purposes of this notice, "Recipient" means a Wholesaler or Distributor that received the affected lot directly from Apotex.

This recall is being initiated because the affected lot did not meet the specified dissolution acceptance criteria during 24-month stability testing. The out-of-specification result occurred during the buffer-stage portion of dissolution testing, which evaluates drug release under specified test conditions. A dissolution failure may affect the rate at which the active ingredient is released from an extended-release tablet.

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: Paxil CR® (Paroxetine Extended- Release Tablets) 37.5 mg, 30-count bottle

NDC NUMBER: 60505-4379-3

LOT NUMBER: TY9494

EXPIRY DATE: 05/2027

DISTRIBUTION DATES: 06/14/2024 - 01/02/2026