

*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.*

Graviti Pharmaceuticals Private Limited (Graviti) is initiating a voluntary recall to the Retail Level on Bupropion Hydrochloride Extended-Release Tablets USP (XL) 300 mg (ANDA# 211020) batch # BPB124341A manufactured by Graviti and marketed by Rising Pharma Holdings, Inc., USA.

This voluntary recall to the Retail Level is being initiated based on a product complaint received from a pharmacy, which reported finding a single oversized tablet of Bupropion Hydrochloride Extended-Release Tablets USP, 300 mg in a 30-count HDPE bottle of Bupropion Hydrochloride Extended-Release Tablets USP, 300 mg for Batch # BPB124341A.

Graviti has conducted a thorough health hazard assessment and interim investigation. The assessment concluded that one defective tablet identified is unlikely to cause any health hazard even if accidentally ingested by the patient. This product was shipped between the dates of 02/28/25 – 04/14/25.

PRODUCT: Bupropion Hydrochloride Extended-Release Tablets USP (XL) 300 mg

NDC NUMBER: 16571-863-03

BATCH NUMBER: BPB124341A

EXPIRATION DATE: 10/2026

DISTRIBUTION DATES: 02/28/25 – 04/14/25