RECALL LETTER

Bupropion Hydrochloride Extended-Release Tablets USP (XL) 300 mg, 30's count Bottle pack, Batch # BPB124341A, Exp date: 10/2026

Date: 09/23/2025

Marketing and Distribution Firm:	**Manufacturing & Recalling Firm:**
Rising Pharma Holdings. Inc, DBA Rising Pharmaceuticals 2 Tower Center Blvd, #1401 East Brunswick, NJ 08816	Graviti Pharmaceuticals Private Limited, Survey No. 621/E & 621/EE, Isnapur Village, Patancheru Mandal, Sangareddy, Telangana – 502307, India,

Product Name	NDC(s)	Lot(s) / Exp. date	Distribution dates
Bupropion Hydrochloride Extended-Release Tablets USP (XL) 300 mg	16571-863-03	Batch # BPB124341A, Exp date: 10/2026	February 28, 2025 to April 14,2025

Dear Valued Wholesaler/Retailer,

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.

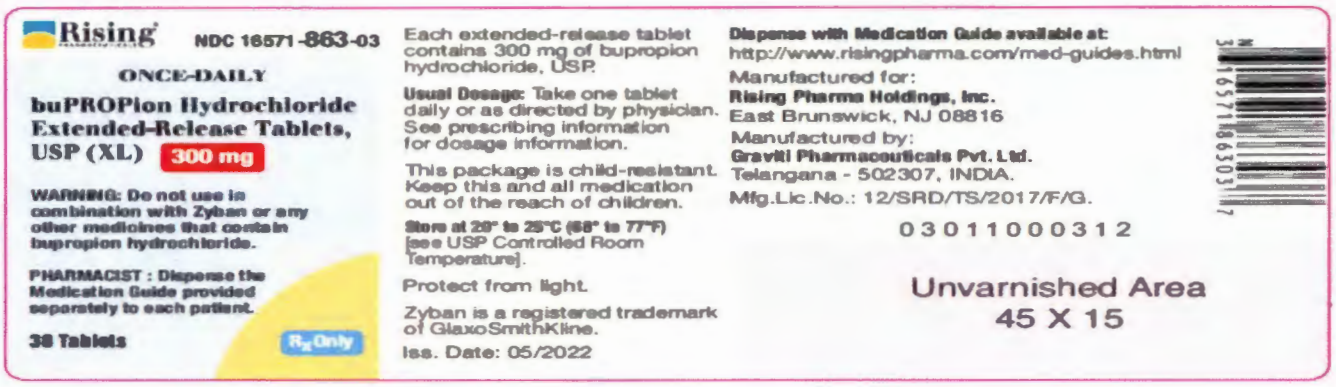
This product was shipped between the dates of 02/28/25 – 04/14/25, and our records indicate that you purchased this product during the dates it was marketed.

As per the product information leaflet, the description of the product is as below, and the product label is also included along with this letter for your ease of identification:

Description: Bupropion hydrochloride extended-release tablets, USP (XL) 300 mg are pink, round biconvex coated tablet imprinted with '189' in black ink on one side and plain on the other side.

64980-00477-01183116
INDEPENDENT PHARMACY DIST.
1107 W MARKET CENTER DR
HIGH POINT, NC 27260

Product Label:



This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Action to be taken by the Wholesaler/Retailer:

1. Immediately examine your inventory, stop distribution and dispensing this lot, and quarantine the product.
2. Please carry out a physical count and record this data on the enclosed response form.
3. Even if you don't have the recalled product, please email the completed response form to Email: recall@qualanex.com or Fax: 847-737-3719
4. Once the business response form is received by Qualanex, a return goods authorization will be sent to you. Please return your product along with the return authorization using the postage-paid shipping label included in your recall return packet.

If you have further distributed this recalled product to other wholesalers/distributors, please notify them that they must further notify their retailers (hospitals, pharmacy, clinics, etc.) accordingly. If they have any questions regarding the return of this recall product, please have them contact: recall@qualanex.com or phone # 800-505-9291.

This action applies only to Bupropion Hydrochloride Extended-Release Tablets 300 mg, Batch # BPB124341A, 30 tablets, NDC 16571-863-03. Only the product from this batch will be accepted under the terms of this recall. **No other batches of Bupropion Hydrochloride Extended-Release Tablets 300 mg are affected by this recall.**

1. If you have any medical questions regarding this recall, please contact Rising's drug safety group at 1-844-874-7464 (8:30 am - 5:00 pm EST).
2. If you have any general questions regarding the return of this product, please contact Qualanex, LLC, at Email: recall@qualanex.com or phone # 800-505-9291.

We regret any inconvenience and appreciate your immediate cooperation.

Signature: Sivaprasad Bachina Digitally signed by Sivaprasad Bachina Date: 2025.09.23 15:17:47 -04'00'

Title: Manager - QA

Date:09/23/2025

64980-00477-01183116
INDEPENDENT PHARMACY DIST.
1107 W MARKET CENTER DR
HIGH POINT, NC 27260

Rising® PHARMACEUTICALS

[Bupropion Hydrochloride Extended-Release Tablets USP (XL) 300 mg, 30's count, Lot / Batch No. BPB124341A]

[Class II- Retail or Pharmacy Level Recall]

[September 23, 2025]
[Notice # 477]

VOLUNTARY RECALL RESPONSE FORM

Date Form Completed _____

Please fill out this form completely, by doing so this will acknowledge that you have read and understand the recall notice and have taken the appropriate action. Once complete please return your response form by any one of these means to Qualanex, Attn: Recall Team: EMAIL: recall@Qualanex.com FAX: 1-847-737-3719

This Response Form is for (Check One)	☐ **Direct Customer (Purchased Directly from MANUFACTURER)** ☐ **Non-Direct Customer**
Customer/Store Name:	
*DEA #: ***DEA # is required in order to process your form***	Debit Memo # (If Applicable)
Address:	City/State/Zip
Contact Name (please print):	Email Address: Telephone #: Fax #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(Complete Below Table)** **OR** ☐ I ***do not*** have stock of the recalled item(s).

Direct Customers

Does your response include **all** your DC locations? ☐ YES ☐ NO

Have you notified your customers of this recall down to the appropriate level? ☐ YES ☐ NO

Non-Direct Customers

Name of Wholesaler/Distributor and address the product(s) in this recall were purchased from (Please include DEA):

☐ ***I have quarantined and listed in the table below the quantity of recall units I will be returning to Qualanex.***

If additional space is needed please make copies of this form

NDC	Lot #	Exp. Date	Qty. Case to be returned	Qty. Sealed Bottles to be returned	Qty. Partial Bottles to be returned
16571-863-03	BPB124341A	10/2026			

Any Adverse Events Associated with this recalled product? ☐ No ☐ Yes (if yes please attach additional sheet and explain)

Please indicate the number of (additional) shipping labels that you need to return the recalled product(s): _____

64980-00477-01183116
INDEPENDENT PHARMACY DIST.
1107 W MARKET CENTER DR
HIGH POINT, NC 27260