



Phone: (614) 492-8177
Toll Free Phone: (800) 707-4621

URGENT PRODUCT RECALL

June 24, 2024

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Bupropion Hydrochloride Extended-Release Tablets USP (XL), 150 mg, 100 UD; Carton NDC#: 60687-782-01, (Individual Dose NDC: 60687-782-11)**, for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Bupropion Hydrochloride Extended-Release Tablets USP (XL), 150 mg, 100 UD Carton NDC#: 60687-782-01 (Individual Dose NDC: 60687-782-11)	1017343	12/31/2025	03/15/2024 to 05/31/2024
REASON	This recall is being initiated due to an out of specifications for dissolution at the initial stability time point. The product is dissolving faster than specified limits which could lead to a change in therapeutic efficacy.		
HEALTH HAZARD EVALUATION	Bupropion hydrochloride extended-release tablets (XL) are indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM). Bupropion hydrochloride extended-release tablets (XL) are indicated for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD).		
ACTIONS REQUIRED			
<ol style="list-style-type: none"> Distributors/Pharmacies – Immediately examine your inventory, quarantine and discontinue distribution of this lot. Distributors – <u>Complete the enclosed Business Reply Card even if you do not have any product on hand.</u> Distributors – Please pass this Recall Notice on ONLY to pharmacies that received this product lot. Pharmacies – If you have units of the affected products/lot in inventory, please contact Sedgwick at (888)-965-5797 to receive a notification package with the Business Reply Card and return instructions. Business Reply Cards can be submitted by any of these methods. Fax: (888)-965-6139 Email: ahp4743@sedgwick.com Mail: 2670 Executive Dr., Ste. A, Indianapolis, IN 46241 Distributors/Pharmacies – Return recalled product to Sedgwick as instructed in recall/return packet. Pharmacies - You do not need to contact any patients. 			
OTHER	<p>This Recall extends to the Retail Level only. No other lots, packages, or formulations are being recalled. Please reorder stock immediately.</p> <p>For questions about the recall process, call Sedgwick at (888)-965-5797.</p> <p>This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.</p>		

To receive credit, the reply form and recalled product must be returned to Sedgwick by September 30, 2024.

Thank you for your support in complying with the requests in this letter. We apologize for the inconvenience that this incident may cause you or your customers.

Sincerely,

Becky Mahon (Jun 20, 2024 15:37 EDT)

Becky A Mahon
Sr. Regulatory Specialist
American Health Packaging