



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

URGENT PRODUCT RECALL

December 26, 2023

Dear Valued Customer,


American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Benzonatate Capsules, USP, 100 mg, 100 UD; Carton NDC#: 68084-214-01, (Individual Dose NDC: 68084-214-11)**, for the lot listed below:

Product Description		AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Benzonatate Capsules, USP, 100 mg, 100 UD Carton NDC#: 68084-214-01 (Individual Dose NDC: 68084-214-11)		1014208	03/31/2025	09/20/2023 to 11/27/2023
REASON	This recall is being initiated in due to an OOS in the repackaged product for assay at the time zero point. Results were above specification at the time zero point.			
HEALTH HAZARD EVALUATION	Benzonatate capsules are indicated for the symptomatic relief of cough.			
ACTIONS REQUIRED				
<div>1. Distributors/Pharmacies – Immediately examine your inventory, quarantine, and discontinue distribution of this lot.</div> <div>2. Distributors – <u>Complete the enclosed Business Reply Card even if you do not have any product on hand.</u></div> <div>3. Distributors - Please pass this Recall Notice on ONLY to pharmacies that received this product lot.</div> <div>4. Pharmacies – If you have units of the affected products/lot in inventory, please contact Sedgwick at (877)-247-4878 to receive a notification package with the Business Reply Card and return instructions.</div> <div>5. Business Reply Cards can be submitted by any of these methods. Fax: (877) 444-4184 Email: AHP7164@sedgwick.com Mail: 6026 Lakeside Blvd. Indianapolis, IN 46278</div> <div>6. Distributors/Pharmacies – Return recalled product to Sedgwick as instructed in recall/return packet.</div> <div>7. Pharmacies – You do not need to contact any patients.</div>				
OTHER	This Recall extends to the Retail Level only. No other lots, packages, or formulations are being recalled. Please reorder stock immediately. For questions about the recall process, call Sedgwick at (877-)247-4878. 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.			

To receive credit, the reply form and recalled product must be returned to Sedgwick by March 31, 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 (Dec 21, 2023 16:12 EST)

Becky A Mahon
Senior Regulatory Specialist
American Health Packaging