

URGENT PRODUCT RECALL

September 13, 2021

Dear Valued Customer,

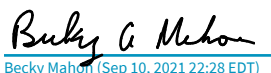
American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **Valproic Acid Oral Solution, USP, 500 mg/10 mL, 100UD; Case NDC#: 60687-262-56, (Individual Dose NDC: 60687-262-42)**, for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Valproic Acid Oral Solution, USP, 500 mg/10 mL, 100UD Case NDC#: 60687-262-56 (Individual Dose NDC: 60687-262-42)	1000082	06/30/2022	10/22/2020 to 01/21/2021
REASON	This recall is being initiated in support of the recall notification by the manufacturer (Wockhardt products manufactured at Morton Grove Pharmaceuticals, Inc.) dated September 2, 2021, which included lots that were repackaged by American Health Packaging. Wockhardt stated that "This recall has been initiated due to a potential concern with products manufactured using liquid sugar batches contaminated with microbial Organisms."		
HEALTH HAZARD EVALUATION	Valproic acid is indicated as monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures. Valproic acid is indicated for use as sole and adjunctive therapy in the treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types which include absence seizures.		
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 Stericycle at 866-204-6110 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: 866-629-6190 Email: americanhealthpackaging4312@sedgwick.com Mail: 6026 Lakeside Blvd. Indianapolis, IN 46278 Distributors/Pharmacies - Return recalled product to Stericycle as instructed in recall/return packet. Pharmacies - You do not need to contact any patients. 			
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 Stericycle at 866-204-6110. 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 Stericycle by December 31, 2021.

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 (Sep 10, 2021 22:28 EDT)

Becky A Mahon
Regulatory Specialist, American Health Packaging