

URGENT PRODUCT RECALL

March 4, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Aspirin and Extended-release Dipyridamole Capsules, 25 mg/200 mg, 20 count Unit Dose Blisters, Carton NDC#: 60687-305-32, (Individual Dose NDC: 60687-305-33)**, for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
Aspirin and Extended-release Dipyridamole Capsules, 25 mg/200 mg, 20 count Unit Dose Blisters Carton NDC#: 60687-305-32 (Individual Dose NDC: 60687-305-33)	174262	3/31/2019	11/17/2017 to 1/16/2018
	176469	6/30/2019	2/08/2018 to 2/16/2018
	177897	8/31/2019	3/20/2018 to 3/30/2018
	178318	9/30/2019	4/11/2018 to 4/11/2018
	178436	9/30/2019	4/25/2018 to 5/23/2018
	179547	11/30/2019	6/14/2018 to 1/24/2019
REASON	This recall is being initiated in response to an out of specification result for an unknown impurity in stability samples.		
HEALTH HAZARD EVALUATION	Aspirin and extended-release dipyridamole capsules are indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis		
ACTIONS REQUIRED			
<ol style="list-style-type: none"> Distributors/Pharmacies - Immediately examine your inventory, quarantine and discontinue distribution of these lots. Distributors - Complete the enclosed Business Reply Card even if you do not have any product on hand. Distributors - Please pass this Recall Notice on ONLY to pharmacies that received these product lots. Pharmacies - If you have units of the affected products/lots in inventory, please contact GENCO Pharmaceutical Services at 855-633-1429 to receive a recall return packet. If you have not received this product you do not need to request a return packet. Distributors/Pharmacies - Return recalled product to GENCO as instructed in recall/return packet. Pharmacies - You do not need to contact any patients. Carry out a physical count and record this data on the Business Reply Card and the Packing slip, which are included with this letter. Return the recalled product and the Packing Slip using the prepaid FedEx shipping labels to: GENCO Pharmaceutical Services a subsidiary of FedEx Supply Chain 6101 North 64th Street Milwaukee, WI 53218 			
OTHER	<p>This Recall extends to the Retail Level only. No other lots, packages, or formulations are being recalled. For questions about the recall process, call GENCO Pharmaceutical Services at (855) 633-1429.</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 GENCO by June 4th, 2019.

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 A Mahon
Regulatory Specialist
American Health Packaging