

**URGENT PRODUCT RECALL**

September 17, 2021

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Glipizide Extended-Release Tablets, 2.5 mg, 30 UD; Carton NDC#: 68084-295-21, (Individual Dose NDC: 68084-295-11)**, for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
<b>AHP Glipizide Extended-Release Tablets, 2.5 mg, 30 UD</b> <b>Carton NDC#: 68084-295-21</b> <b>(Individual Dose NDC: 68084-295-11)</b>	194141	3/31/2022	09/19/2020 to 10/23/2020
<b>REASON</b>	This recall is being initiated due to dissolution failure at 0-time of the repackaged lot. Drug release results were above specification at the 0-time.		
<b>HEALTH HAZARD EVALUATION</b>	Glipizide extended-release tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.		
<b>ACTIONS REQUIRED</b>			
<ol style="list-style-type: none"> <li><b>Distributors/Pharmacies</b> - Immediately examine your inventory, quarantine and discontinue distribution of this lot.</li> <li><b>Distributors</b> - Complete the enclosed Business Reply Card even if you do not have any product on hand.</li> <li><b>Distributors</b> - Please pass this Recall Notice on <b>ONLY</b> to pharmacies that received this product lot.</li> <li><b>Pharmacies</b> - If you have units of the affected products/lot in inventory, please contact Stericycle at 888-345-0256 to receive a notification package with the Business Reply Card and return instructions.</li> <li>Business Reply Cards can be submitted by any of these methods.  <b>Fax:</b> 888-216-7326  <b>Email:</b> <a href="mailto:americanhealthpackaging8340@stericycle.com">americanhealthpackaging8340@stericycle.com</a>  <b>Mail:</b> 6026 Lakeside Blvd. Indianapolis, IN 46278</li> <li><b>Distributors/Pharmacies</b> - Return recalled product to Stericycle as instructed in recall/return packet.</li> <li><b>Pharmacies</b> - You do not need to contact any patients.</li> </ol>			
<b>OTHER</b>	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 888-345-0256.  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 16, 2021 12:14 EDT)

Becky A Mahon  
Regulatory Specialist, American Health Packaging