

**URGENT PRODUCT RECALL**

May 12, 2021

Dear Valued Customer,

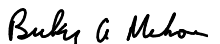
American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Sirolimus Tablets For Oral Use Only, 1 mg, 30UD; Carton NDC#: 68084-915-25, (Individual Dose NDC: 68084-915-95)**, for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
<b>AHP Sirolimus Tablets For Oral Use Only, 1 mg, 30UD</b> <b>Carton NDC#: 68084-915-25</b> <b>(Individual Dose NDC: 68084-915-95)</b>	1000789	10/31/2022	01/25/2021 to 03/15/2021
<b>REASON</b>	This recall is being initiated due to impurities failure at 0-time of the repackaged lot. There was an unknown impurity present.		
<b>HEALTH HAZARD EVALUATION</b>	Sirolimus tablets are indicated for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants.		
<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> - <u>Complete the enclosed Business Reply Card even if you do not have any product on hand.</u></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 877-907-7511 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> 877-907-7510  <b>Email:</b> <a href="mailto:americanhealthpackaging7981@stericycle.com">americanhealthpackaging7981@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 877-907-7511.  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 August 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 (May 11, 2021 15:39 EDT)

Becky A Mahon  
Regulatory Specialist, American Health Packaging