AMERICAN HEALTH PACKAGING®
An AmerisourceBergen Company

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URGENT PRODUCT RECALL

November 1, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Ranitidine Syrup (Ranitidine Oral Solution USP) 150 mg/10 mL Liquid Unit Dose Cups, Case NDC#: 60687-260-23, (Individual Dose NDC: 60687-260-42) and Case NDC#: 60687-260-69, (Individual Dose NDC: 60687-260-42),** for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Ranitidine Syrup (Ranitidine Oral Solution USP) 150 mg/10 mL Liquid Unit Dose Cups **Case NDC#: 60687-260-23** **(Individual Dose NDC: 60687-260-42)**	183723	10/31/2020	03/28/2019 to 07/08/2019
	184278	10/31/2020	07/08/2019 to 10/03/2019
	187652	05/31/2021	10/03/2019 to 10/03/2019
AHP Ranitidine Syrup (Ranitidine Oral Solution USP) 150 mg/10 mL Liquid Unit Dose Cups **Case NDC#: 60687-260-69** **(Individual Dose NDC: 60687-260-42)**	177874	01/31/2020	10/16/2018 to 12/13/2018
	178413	02/29/2020	12/13/2018 to 02/07/2019
	183449	10/31/2020	03/18/2019 to 04/04/2019
	184445	12/31/2020	04/04/2019 to 07/30/2019
	186563	03/31/2021	07/30/2019 to 10/03/2019

REASON	This recall is being initiated in support of the recall by the manufacturer (Lannett Company, Inc.) dated October 24, 2019, which included lots that were repackaged by American Health Packaging. Lannett stated that " This recall has been initiated due to the presence of N-nitrosodimethylamine (NDMA) in Ranitidine syrup. This recall is for all lots within expiration."
HEALTH HAZARD EVALUATION	NDMA is classified as a probable human carcinogen, a substance that can cause cancer, based on laboratory testing. NDMA is also a known environmental contaminant found in water and foods, including meats, dairy and vegetables. The product is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of GERD and treatment of endoscopically diagnosed erosive esophagitis.

ACTIONS REQUIRED

1. **Distributors/Pharmacies** - Immediately examine your inventory, quarantine and discontinue distribution of these lots.
2. **Distributors** - Complete the enclosed Business Reply Form even if you do not have any product on hand.
3. **Distributors** - Please pass this Recall Notice on **ONLY** to pharmacies that received these product lots.
4. **Pharmacies** - If you have units of the affected products/lots in inventory, please contact In mar Pharmaceuticals Services at 800-967-5952 (option 1) to receive a Business Recall Response form or acquire it from clsnetlink.com.
5. Business Recall Response Form can be submitted by any of these methods.
   Fax: 817-868-5362
   Email: rxrecalls@inmar.com
   Address: Inmar, Attn: Recall Coordinator - 635 Vine St, Winston Salem, NC 27101
6. **Distributors/Pharmacies** - Return recalled product to Inmar Pharmaceuticals Services as instructed in recall/return packet.
7. **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 Inmar Pharmaceuticals Services at 800-967-5952. 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 Inmar by February 1st, 2020.

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

Becky A Mahon
Regulatory Specialist, American Health Packaging