American Health Packaging®
An AmerisourceBergen Company

Phone: (614) 492-8177
Toll Free Phone: (800) 707-4621

URGENT PRODUCT RECALL

November 20, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **CONSUMER LEVEL** for **AHP Ranitidine Tablets, USP, 150 mg 100 count Unit Dose Blisters, Carton NDC#: 60687-322-01, (Individual Dose NDC: 60687-322-11),** for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Ranitidine Tablets, USP, 150 mg 100 count Unit Dose Blisters **Case NDC#: 60687-322-01** **(Individual Dose NDC: 60687-322-11)**	179516	12/31/2019	07/30/2018 to 09/04/2018
	179745	12/31/2019	09/04/2018 to 10/15/2018
	180712	02/29/2020	10/11/2018 to 11/12/2018
	180819	04/30/2020	11/12/2018 to 12/11/2018
	181403	05/31/2020	12/11/2018 to 01/31/2019
	182544	05/31/2020	01/31/2019 to 05/31/2019
	183155	05/31/2020	02/26/2019 to 04/11/2019
	183236	05/31/2020	04/11/2019 to 05/13/2019
	185739	12/31/2020	05/09/2019 to 08/02/2019
	186600	12/31/2020	08/02/2019 to 09/12/2019
	186702	12/31/2020	09/12/2019 to 10/02/2019

REASON	This recall is being initiated in support of the recall by the manufacturer (Amneal Pharmaceuticals, LLC) dated November 13, 2019, which included lots that were repackaged by American Health Packaging. Amneal stated that " This recall has been initiated due to the potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA. 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. Ranitidine is a histamine-2 blocker, which decreases the amount of acid created by the stomach. Prescription ranitidine is approved for multiple indications, including 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. **Patients** - If you have units of the affected products/lots in inventory, please contact Inmar Pharmaceuticals Services at 1-800-967 -5952(Option 1) to receive a Business Recall Response form or acquire it from clsnetlink.com.
2. **Patients** - Return recalled product to Inmar Pharmaceuticals Services as instructed in recall/return packet.
3. **Patients** - Reimbursement will be provided by American Health Packaging for the amount of affected product returned. Only the affected lot will be reimbursed. Include copies of original pharmacy receipts detailing out of pocket expense.
4. 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
5. Reimbursement will be sent from American Health Packaging following receipt of the returned product at Inmar Pharmaceuticals Services, please allow 3 to 4 weeks for processing.

OTHER	This Recall extends to the Consumer Level only. No other lots, packages, or formulations are being recalled. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. For questions about the recall process, call Inmar Pharmaceuticals Services at 1-800-967 -5952(Option 1). 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.

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,
American Health Packaging