American Health Packaging has voluntarily recalled eleven (11) lots of Ranitidine Tablets, USP 150 mg, 100 count Unit Dose Blisters to the consumer level due to the potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA. This recall was initiated in response to the recall by the manufacturer (Amneal Pharmaceuticals, LLC), which included affected lots that were repackaged by American Health Packaging.

Risk Statement: 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. No reports of injury or adverse events to date.

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.

American Health Packaging has not received any reports of adverse events that have been confirmed to be directly related to this recall.

Product was distributed Nationwide to Wholesalers for use in hospital settings.

Product Description	AHP Lot No.	Expiration Date
AHP Ranitidine Tablets, USP 150 mg, 100 count Unit Dose Blisters Carton NDC#: 60687-322-01 (Individual Dose NDC: 60687-322-11)	179516	12/31/2019
	179745	12/31/2019
	180712	02/29/2020
	180819	04/30/2020
	181403	05/31/2020
	182544	05/31/2020
	183155	05/31/2020
	183236	05/31/2020
	185739	12/31/2020
	186600	12/31/2020
	186702	12/31/2020

American Health Packaging has notified its distributors by recall letter, sent November 20th, 2019, to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. American Health Packaging has arranged for return of all recalled products to lnmar Pharmaceuticals Services. Anyone with an existing inventory of the product should

quarantine the recalled lots immediately. Instructions for returning recalled products are given in the recall letter. Pharmacies that have received the affected lot should contact (877) 475-5864 to receive a return packet. Hours of operation are 9:00 am - 5:00 pm, Eastern Standard Time (EST) Monday thru Friday.

Any general questions regarding the return of this product please contact Inmar Pharmaceuticals Services at 800-967-5952 (option 1). Hours of operation are 9:00 am - 5:00 pm, EST Monday through Friday.

Consumers who have Ranitidine Tablets, USP which are being recalled should stop using the product or with questions regarding this recall can contact Inmar Pharmaceuticals Services by 800-967-5952 (option 1). Hours of operation are 9:00 am - 5:00 pm, EST Monday through Friday.

Consumers who would like to report adverse reactions or quality problems experienced with the use of this product can contact Amneal Drug Safety by phone at 1-877-835-5472, Monday thru Friday, 8:00 am – 6:00 pm, EST, or e-mail at DrugSafety@amneal.com.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.