American Health Packaging – Recall of ranitidine

- On November 8, 2019, American Health Packaging announced a voluntary, consumer-level recall of prescription ranitidine liquid unit dose cups due to the detection of trace amounts of the unexpected impurity, N-nitrosodimethylamine (NDMA), found in the finished drug product.
    - This recall is being initiated in response to the recall by the manufacturer (Lannett), which included affected lots that were repackaged by American Health Packaging.
- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Product Description	NDC#	Lot# (Expiration Date)
Ranitidine oral solution 150 mg/10 mL liquid unit dose cups	Case: 60687-260-23 Individual Dose: 60687-260-42	183723 (10/31/2020); 184278 (10/31/2020); 187652 (05/31/2021)
	Case: 60687-260-69 Individual Dose: 60687-260-42	177874 (1/31/2020); 178413 (2/29/2020); 183449 (10/31/2020); 184445 (12/31/2020); 186563 (3/31/2021)

- Prescription ranitidine 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.
- Patients taking prescription ranitidine who wish to stop should talk to their healthcare provider about other treatment options. Multiple drugs are approved for the same or similar uses as ranitidine.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled ranitidine.
- Anyone with an existing inventory of the recalled product should quarantine the product immediately.
- The FDA continues to evaluate the safety of ranitidine and will provide more information as it becomes available. Updates can be found here.
- Contact Inmar (appointed company for American Health Packaging) at **1-800-967-5952** for further information regarding this recall.