## American Health Packaging – Recall of ranitidine

- On November 20, 2019, American Health Packaging announced a voluntary, consumer-level recall of prescription ranitidine tablets due to potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA.
    - This recall is being initiated in response to the recall by Amneal 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 150 mg tablets | Carton: 60687-322-01<br>Individual Dose: 60687-322-11 | 186702 (12/31/20);<br>186600 (12/31/20);<br>185739 (12/31/20);<br>183236 (05/31/20);<br>183155 (05/31/20);<br>182544 (05/31/20);<br>181403 (05/31/20);<br>180819 (04/30/20);<br>180712 (02/29/20);<br>179745 (12/31/19);<br>179516 (12/31/19) |

- 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 gastroesophageal reflux disease, 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 stop distribution and 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.