Amneal – Recall of ranitidine

- On January 10, 2020, Amneal announced a voluntary, consumer-level recall of prescription ranitidine tablets because of the potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA.
    - This is an update to the recall that was announced by Amneal in November 2019. Amneal has added an additional NDC number and lot numbers to the recall.
- 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.
- Refer to the announcement for a list of recalled NDCs and lot numbers.
- 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 Stericycle (appointed company for Amneal) at **1-866-918-8786** for further information regarding this recall.