Precision Dose – Recall of ranitidine

- On November 14, 2019, Precision Dose announced a voluntary, consumer-level recall of prescription ranitidine oral solution 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 Precision Dose.
- 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 unit dose product	68094-204-59; 68094-204-61; 68094-204-62	501290 (11/30/2019); 501326 (11/30/2019); 501501 (11/30/2019); 501592 (4/30/2020); 501679 (4/30/2020)

- 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 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 Precision Dose at **1-815-624-8523** for further information regarding this recall.