Amneal – Recall of nizatidine

- On April 15, 2020, Amneal announced a voluntary, consumer-level recall of three lots of nizatidine oral solution because of the potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA.

- 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)
Nizatidine oral solution, 15 mg/mL (75 mg/5 mL), 480 mL bottle	60846-301-15	06598004A (4/2020); 06599001A (12/2020); 06599002A (12/2020)

- Nizatidine oral solution is a prescription product used for the short-term treatment and maintenance therapy of ulcers and for the treatment of esophagitis and associated heartburn due to gastroesophageal reflux disease.

- Patients who have the recalled nizatidine should stop use and contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled nizatidine.

- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.

- Contact Amneal by phone at **1-877-835-5472** or by email at **DrugSafety@amneal.com** for further information regarding this recall.