Mylan – Recall of nizatidine

- On January 8, 2020, Mylan announced a voluntary, consumer-level recall of nizatidine capsules due to detected trace amounts of N-nitrosodimethylamine (NDMA) contained in the active pharmaceutical ingredient (API), manufactured by Solara Active Pharma Sciences Limited.

- 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 300 mg capsules	0378-5300-93	3082876 (1/2020); 3082877 (1/2020)
Nizatidine 150 mg capsules	0378-5150-91	3086746 (5/2020)

- Nizatidine is indicated for the short-term treatment (up to 8 weeks) of active duodenal ulcers and active benign gastric ulcers, as maintenance therapy for duodenal ulcer patients for up to one year, and for up to 12 weeks for the treatment of endoscopically diagnosed esophagitis and associated heartburn due to gastroesophageal reflux disease (GERD).

- Patients should 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.

- The FDA continues to evaluate the safety of ranitidine, including other common heartburn medications such as nizatidine and will provide more information as it becomes available. Updates can be found here.

- For more information regarding this recall, contact Stericycle (appointed company for Mylan) at **1-888-628-0727**.