Ranitidine – Sandoz, Inc.

On September 23, 2019 the U.S. Food and Drug Administration (FDA) announced that Sandoz Inc. is voluntarily recalling all quantities and lots within expiry of Ranitidine Hcl capsules because of confirmed contamination with N-Nitrosodimethylamine (NDMA) above levels established by the FDA. To date, Sandoz has not received any reports of adverse events related to use of the product as part of this recall.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Ranitidine Hydrochloride Capsules is an oral product, indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable.

Patients are asked to continue taking their medication and should consult with their healthcare provider or pharmacy to determine if they have the affected product lots.

Consumers with questions regarding this recall can contact Sandoz at 1-800-525-8747 between 8:30am – 5:00pm Monday – Friday EST or www.us.sandoz.com (http://www.us.sandoz.com/) (http://www.fda.gov/about-fda/websitepolicies/website-disclaimer) for more information. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.