19-019 QA PRODUCT RECALL – ZANTAC PRODUCTS BY SANOFI DUE TO POSSIBLE CONTAMINATION WITH NDMA

Date: 23 October 2019 **Recall:** 19-019

Scope: WORLDWIDE RETAIL FACILITIES

Description: A voluntary recall for Zantac products has been issued due to possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA).

The following product is affected.

UPC	ITEM DESCRIPTION
681421032025	Maxiumum Strength Zantac 150 Cool Mint Tablets
681421031035	Maxiumum Strength Zantac 150 (24 count)
681421031042	Maxiumum Strength Zantac 150 (50 count)
681421030069	Regular Strength Zantac 75 (60 count)

Hazard: Inconsistencies in preliminary test results reveal concerns about possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA). NDMA is considered a possible carcinogen by the US Environmental Protection Agency.

Remedy: Customers who purchased the product should discontinue use and reach out to their doctors or pharmacists with questions about treatment going forward. Product may be returned to the store where it was purchased for a full refund.

Incidents/Injuries: To date, no adverse events have been reported.

Sold at: Exchange facilities, ecommerce and other retailers.

Consumer Contact: Customers who have additional questions or concerns should contact Sanofi Medical Information Services in the US at 1-800-633-1610.

Manufacturer(s): Sanofi