PRODUCT RECALL

Date:	10/18/2019
Manufacturer:	Sanofi
Article Number:	#191353 Zantac150MG 140 CT

Post Until: 4/21/2020

COMPANY ANNOUNCEMENT

Sanofi Provides Update on Precautionary Voluntary Recall of Zantac OTC in U.S.

Summary

Company Announcement Date:

October 22, 2019

FDA Publish Date:

October 23, 2019

Product Type:

Drugs

Reason for Announcement:

May Contain N-Nitrosodimethylamine (NDMA)

Company Name:

Sanofi

Brand Name:

Sanofi

Product Description:

Zantac 150, Zantac 150 Cool Mint, Zantac 75 (OTC Products)

Company Announcement

As a precautionary measure, Sanofi on Friday, October 18, intiated a voluntary recall of all Zantac OTC (over-the-counter) in the United States. This includes Zantac 150®, Zantac 150® Cool Mint, and Zantac 75®. Zantac tablets are an oral, over-the-counter product to prevent and relieve heartburn associated with acid ingestion and sour stomach.

On September 13, 2019, the U.S Food and Drug Administration issued a public statement alerting that some ranitidine medicines, including Zantac OTC, could contain NDMA at low levels and asked manufacturers to conduct testing.

Evaluations are ongoing on both drug substance (active ingredient) and finished drug product. Due to inconsistencies in preliminary test results of the active ingredient used in the U.S. products, Sanofi has made the decision to conduct the voluntary recall as the investigation continues.

Active ingredients used in Sanofi's ranitidine products outside of the U.S. and Canada are sourced from different suppliers. Sanofi has also issued a voluntary recall in Canada. The company is committed to transparency and will continue to communicate results with health authorities from the ongoing testing, and work with them to make informed decisions based on available data and evidence.

Risk Statement: 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.

Sanofi will be notifying its distributors and customers via email and via the Sanofi web site, and will arrange for return of all recalled products. Wholesalers (direct customers) will be asked to immediately stop distribution and return any stock to Sanofi, and contact the retail outlets in their group to do the same. Retailers will be asked to immediately stop dispensing Zantac tablets and return remaining stock to Sanofi by contacting INMAR at 877-275-0993 (option 1) or via fax at 336-499-8145 or email at zantacrecall@inmar.com (mailto:zantacrecall@inmar.com). Consumers are asked to speak to their physician or pharmacist about alternate heartburn relief options.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/node/360543)
- Regular Mail or Fax: Download form (/node/360547) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration

Company Contact Information

Consumers:

INMAR

877-275-0993 (option 1)

zantacrecall@inmar.com (mailto:zantacrecall@inmar.com)

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