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SUBJECT: ALFOODACT 2019-056 – Sanofi Voluntarily Recalls Zantac OTC Products Due to Possible Contamination with a Nitrosamine Impurity called N-nitrosodimethylamine (NDMA)

Date Issued: 24 October 2019

1. REFERENCES:

a. DHA-MSR 6025.01/AR 40-660/ DLAR 6025.01/NAVSUPINST 10110.8D/AFI 48-161_IP/MCO 10110.38D, DOD Hazardous Food & Nonprescription Drug Recall System, 6 September 2018.

2. BACKGROUND: As a precautionary measure, Sanofi initiated a voluntary recall of all Zantac OTC (over-the-counter) in the United States. This recall is being taken due to possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA). The U.S Food and Drug Administration issued a public statement, on September 13, 2019, 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. 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 website, 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. Consumers are asked to speak to their physician or pharmacist about alternate heartburn relief options.

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

3. PRODUCT AFFECTED: Regular Strength Zantac® 75, Maximum Strength Zantac® 150, Maximum Strength Zantac® 150 Cool Mint Tablets (all product within expiration date)

Zantac tablets are an oral, over-the-counter product to prevent and relieve heartburn associated with acid ingestion and sour stomach.

4. CONTACT INFORMATION: Sanofi Retailer POC: INMAR at 877-275-0993 (option 1) or via fax at 336-499-8145 or email at zantacrecall@inmar.com.

5. POSITIVE AND NEGATIVE FINDINGS:

a. Army and Air Force Public Health personnel, report your negative and positive findings in the Veterinary Service Information Management System (VSIMS) Subsistence Recalls application. If you are not in one of these two groups, please use the instructions below (paragraphs b-d).

b. Navy:
SHIPS AT SEA: Must report positive and negative findings to supporting Veterinary Service unit. Are authorized to destroy or dispose of recalled products utilizing the procedures and reporting requirements outlined in NAVSUP P-486 Paragraph 5302 and 6000(4), to include completion of a DD Form 200 and Standard Form 364. Procedures for completing the DD Form 200 are found in NAVSUP P-486 Paragraph 6001. Procedures for completing Standard Form 364 are found in NAVSUP P-486 Paragraph 5300(2)(c).

SHIPS IN PORT/HOMEPORTED/ASHORE GALLEYS: Supporting Veterinary Service unit will conduct inspection and report positive and negative findings in VSIMS Subsistence Recalls application. Contact the appropriate DLA Account Manager via Regional NAVSUP Fleet Logistics Center (NAVSUP FLC) to arrange pickup of recall items. Contact your supporting (NAVSUP FLC) for any issues regarding PV Pickup.

c. Defense Logistics Agency (DLA) Contractors, report positive and negative findings to your Contracting Officer, Contracting Specialist, TVLS and dscpconssafofc@dla.mill within 72 hours:

Positive Response Information required: (Vendor must provide all the following information):
1) ALFOODACT 201X-XXX
2) DLA Contract Number:
3) Unit of Measure:
4) Quantity Currently in Stock:
5) List of customers that received product AND (a-h) for each customer
    a. Customer name and location:
    b. DLA Purchase Order Number:
    c. Vendor Invoice Number:
    d. Item Stock number (LSN, NSN):
    e. Quantity Shipped:
    f. Date Shipped:
    g. Value of Affected Product:
    h. Amount of credit due:

d. AAFES, MWR, NEX, MCCS, DeCA, DLA, dining facilities, and all other agencies, report your findings in accordance with the procedures outlined by your agency.

6. The Point of Contact for this ALFOODACT message is the undersigned.

7. Individuals or groups that would like to BEGIN/STOP receiving recall messages electronically can submit requests to usarmy.jbsa.medcom.mbx.medcom-vsims@mail.mil. Copy and paste email address into your email platform and ensure you title the subject accordingly.

8. Previous recalls are available at the following web site: https://www.dla.mil/TroopSupport/Subsistence/FoodSafety/fso/ALFOODACT/.

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