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SUBJECT: ALFOODACT 2019-057 – Perrigo Company plc Issues Voluntary Worldwide Recall of OTC Ranitidine Due to Possible Presence of NDMA Impurity

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, Perrigo Company plc announced that it has initiated a voluntary worldwide product recall. The recall is being taken due to possible presence of a nitrosamine impurity called N-nitrosodimethylamine (NDMA).

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 is an over-the-counter (OTC) and prescription product indicated for the relief of heartburn associated with acid indigestion and sour stomach and prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages.

After regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results.

Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall and is doing so with the knowledge of the U.S. Food and Drug Administration.

3. PRODUCT AFFECTED: Retail customer-level OTC Ranitidine, all-pack sizes.

Perrigo Company plc has not publicly made available the National Drug Code (NDC), or brand names associated with this recall. Therefore, retail agencies shall place ***all brand names*** *under the Perrigo Company on medical hold, then advised to immediately contact customer support to determine final disposition of products.*

4. CONTACT INFORMATION: Perrigo Company plc, Customer support: 888-817-2180

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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