UNCLAS

SUBJECT: ALFOODACT 2020-007 – Pfizer Consumer Healthcare Recalls Advil Allergy Congestion Relief Tablet 10 and 20 CT and Advil Liqui-Gels 200MG minis 160CT Due to the Missing FDA Mandated Warning

Date Issued: 03 April 2020

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: Due to the missing FDA mandated warning from the affected product label, a consumer who uses the product and experiences a cardiovascular or cerebrovascular event may fail to recognize the event or the severity of the event.

The missing information includes the risk of heart failure and the symptoms of heart problems or stroke (i.e., chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling). Although the present label on the affected product does include the risk of heart attack and stroke, it lacks the detailed warnings required by the FDA. As a result, the potential incremental risk to an individual consumer exposed to this incident is considered high and may impact the benefit/risk of the product affected. In addition, no complaints have been reported related to this issue.

This recall is being carried out to the retail level.

3. PRODUCT AFFECTED:

Material Description	Item Number	Manufacturer NDC/UPC	LOT # - Expiration Date
ADVIL ALLERGY CONGEST RELIEF TABLET 10CT	10104790	305730196109	0017DA - 07/31/2021 0045DB - 07/31/2021 9324HA - 07/31/2021 9327HA - 07/31/2021 9327VB - 07/31/2021 9353WA - 07/31/2021 R73995 - 07/31/2021
ADVIL ALLERGY CONGEST RELIEF TABLET 20CT	10150325	305730196208	R53915 - 05/31/2020
ADVIL LIQUI-GELS 200MG MINIS 160CT	10174644	305731769890	9093EB - 10/31/2020 R53074 - 10/31/2020 R53075 - 10/31/2020 R53076 - 11/30/2020 R53077 - 11/30/2020 R53081 - 11/30/2020 R53901 - 02/28/2021 R53902 - 03/31/2021 R62780 - 06/30/2021

4. CONTACT INFORMATION: If you have any questions or need additional information, please contact Inmar at 855-611-6113.

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/.

CW2 Arthur E. Cameron
USA, VC
DLA Troop Support, Philadelphia
Quality Assurance Auditor
RDT White Team - Class I LNO
Office: 215-737-7659
DSN: 444-7659
DLA Cell: 215-280-4871
DLA: Arthur.cameron@dla.mil
NIPR: arthur.e.cameron4.mil@mail.mil