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SUBJECT: ALFOODACT 2020-014 – GSK Consumer Healthcare Issues Voluntary Nationwide Recall of Children's Robitussin Honey Cough and Chest Congestion DM and Children's Dimetapp Cold and Cough Due to Dosing Cups Missing Some Graduation Markings

Date Issued: 19 June 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.

BACKGROUND: GSK Consumer Healthcare Issues Voluntary Nationwide Recall of Children's Robitussin® Honey Cough and Chest Congestion DM and Children's Dimetapp® Cold and Cough Due to Dosing Cups Missing Some Graduation Markings, GSK Consumer Healthcare is voluntarily recalling to the retail level two lots (listed below) of Children's Robitussin® Honey Cough and Chest Congestion DM and one lot of Children's Dimetapp® Cold and Cough, due to the inclusion of incorrect dosing cups. During the review of the packaging documents for these products, GSK discovered that the dosing cups for the Children's Robitussin® Honey product are missing the 5 mL and 10 mL graduations, while the dosing cups for the Children's Dimetapp® product are missing the 10 mL graduation. The dosing cups packaged with both products only have the 20 mL graduation.

There is a potential risk of accidental overdose if caregivers dispensing the syrup do not notice the discrepancies between the graduations printed on the dosing cups and the indicated amounts to be administered (as directed in the instructions for use). Children's Robitussin Honey Cough & Chest Congestion DM contains 10 mg dextromethorphan HBr USP and guaifenesin USP 100 mg per 10 mL, and is labeled for children 4 and older, as well as adults. Children's Dimetapp Cold & Cough contains 2 mg brompheniramine maleate USP, 10 mg dextromethorphan HBr USP, and 5 mg phenylephrine HCl USP per 10 mL, and is labeled for children 6 and older, as well as adults.

Symptoms of overdose of either product may include any of the following: impaired coordination; brain stimulation causing increase in energy, elevation in blood pressure, heart rate, and respiration; a lack of energy and enthusiasm; severe dizziness or drowsiness; slow heart rate; fainting; psychotic behavior; restlessness; seizure; decreased respiration; nausea; vomiting; constipation; diarrhea; abdominal pain; visual and hearing hallucinations; urinary retention.

As of the date of the recall announcement, GSK Consumer Healthcare has not received any adverse events related to these products or consumer complaints regarding the incorrect dosing cups supplied with the product.

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These lots were distributed nationwide between February 5, 2020 and June 3, 2020 within the United States. GSK Consumer Healthcare has notified wholesalers, distributors, and retailers to arrange for return of any recalled product.

Wholesalers, distributors, and retailers with an existing inventory of the lots being recalled should stop distribution and quarantine these lots immediately. Wholesalers, distributors, and retailers that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them.

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

2. PRODUCTS AFFECTED: The recall is limited to the three lots listed below:

PRODUCT BRAND / DESCRIPTION	NATIONAL DRUG CODE	LOT CODE	DATE
Children's Robitussin® Honey Cough and Chest Congestion DM (4oz)	NDC 0031-8760-12	02177	Exp. Jan. 2022
		02178	Exp. Jan. 2022
Children's Dimetapp® Cold and Cough (8oz)	NDC 0031-2234-19	CL8292	Exp. Sep. 2021

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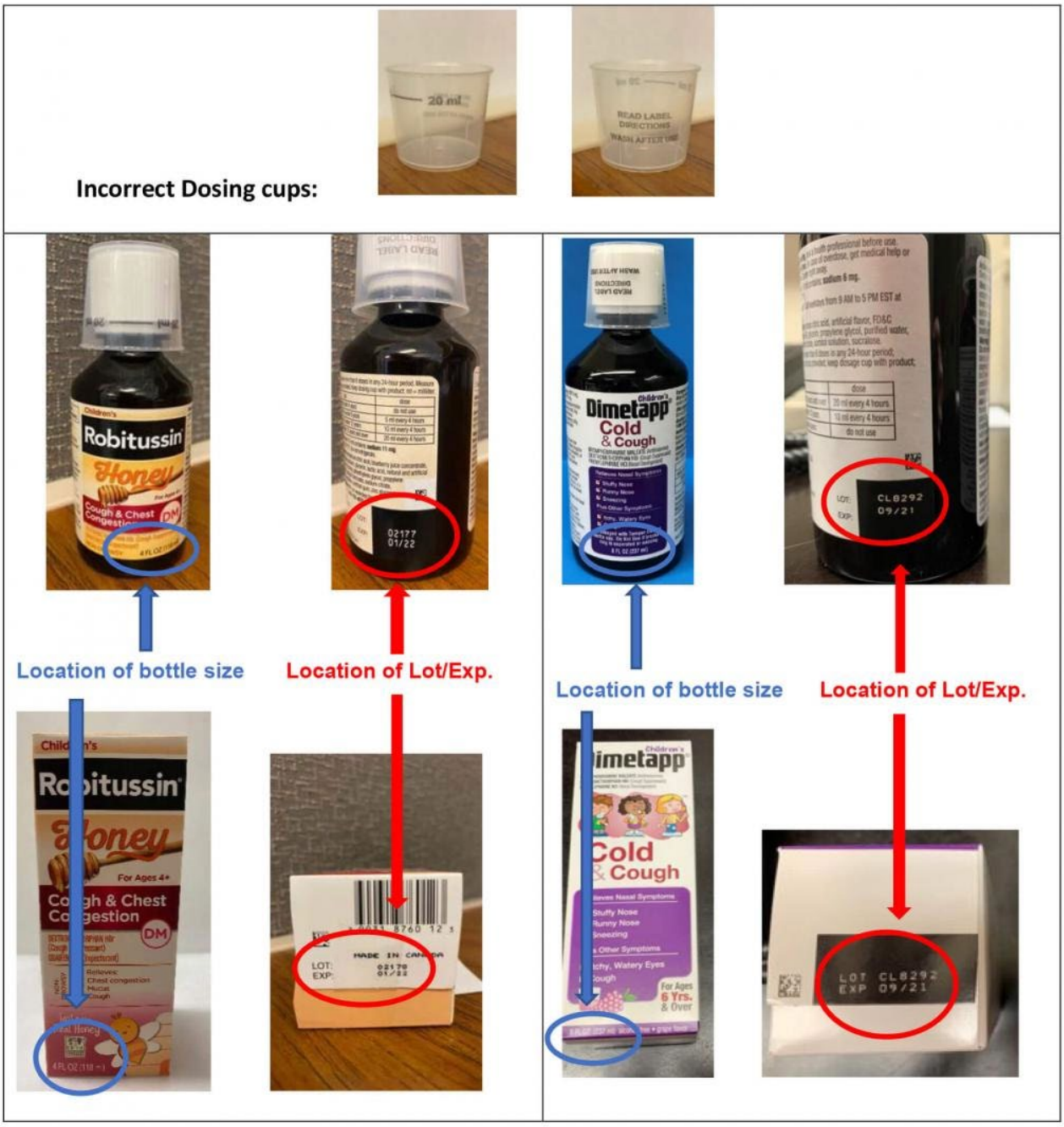
3. PRODUCT LABELS/PICTURES:



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4. CONTACT INFORMATION: Consumers with questions regarding this recall or to report an adverse experience please call 1-800-762-4675, Monday – Friday, 8:00am – 6:00pm EST.

5. POSITIVE AND NEGATIVE FINDINGS:

a. Army Veterinary Services 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. Proceed with the same guidance as above.

c. Defense Logistics Agency (DLA) Contractors: Report positive and negative findings to your Contracting Officer, Contracting Specialist, TVLS and dscpconssafofc@dla.mil 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):

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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. Individuals or groups that would like to BEGIN/STOP receiving recall messages electronically can submit email 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.

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

8. Point of Contact for this ALFOODACT message is the undersigned.

CW4 Marivic J. Brown
Consumer Safety Officer
DLA Troop Support – Subsistence
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