Subject: **ALFOODACT 032-2013 McNeil Consumer Healthcare Announces Voluntary Recall of Three Lots of Concentrated MOTRIN Infants Drops Original Berry Flavor 1/2 fl oz.**

Date Issued: **September 7, 2013**

1. REFERENCES:

a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.LAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.

b. Allied Communications Publication 121, US SUPP-1 (f).

2. BACKGROUND:

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. ("McNeil") is voluntarily recalling at the retail level three lots, approximately 200,000 bottles, of Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz bottles distributed in the United States (see full product list below). This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA). McNeil is asking retailers to remove the affected lots from store shelves, and is asking consumers to stop using and dispose of any product they may have that is included in this recall.

After releasing these three lots of Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz into the market, tiny plastic particles (approximately 1 mm in size or about the size of a poppy seed) were identified in a different product lot during manufacturing. This lot was not released to the market. It was determined that the particles originated in a shipment from a third party supplier of ibuprofen, the active ingredient in Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz. Out of an abundance of caution, McNeil is voluntarily recalling the three lots released to the market made with the same batch of active ingredient. McNeil has worked with the third party to ensure that corrective measures are currently in place and are effective. The potential for adverse medical events related to the reason for this recall is not likely. Concentrated Infants' MOTRIN® Drops Dye-Free Berry Flavor 1 fl oz is not included in this recall. Children's or Adult MOTRIN® products are not included in this recall.

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

Online: www.fda.gov/medwatch/report.htm1

Regular mail: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm2. Mail to address on the pre-addressed form.

Fax: 1-800-FDA-0178.

3. PRODUCTION DATES/IDENTIFYING CODES:

FULL RECALLED PRODUCT LIST:

Product
Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz bottles
NDC 50580-100-18

Lot #

DCB3T01
DDB4R01
DDB4S01

UPC Code
300450524157

Case UPC Code
30300450524158

4. MANUFACTURER/DISTRIBUTOR:

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (“McNeil”)

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration’s (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

Online: www.fda.gov/medwatch/report.htm1

Regular mail: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm2. Mail to address on the pre-addressed form.

Fax: 1-800-FDA-0178.

5. DISTRIBUTION: All

6. REASON FOR ACTION: Due to the potential to be contaminated with foreign material, “Tiny plastic particles (approximately 1 mm in size or about the size of a poppy seed).”

7. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:

a. Immediately inventory stocks to identify the above items and secure in a "Medical Hold" status to provide assurance of no further issue/sale/use. POSITIVE FINDINGS should be reported to Accountable Officers/Vendor Representatives of that facility. Accountable Officer/Agency representatives/Buyers/Contracting Officers should seek/refund/credit/replacement through the normal distribution channel with which the product was received (i.e. Distribution Centers, Prime Vendors, or Manufacturers).

b. Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. In order to get credit please use a SF 364 and forward to your supporting NAVSUP Fleet Logistics Center (NAVSUP FLC) and copy

furnished to NAVSUP 51. Your supporting NAVSUP FLC should forward to the account manager at DLA Troop Support. The form should include the number of the recall authorizing the survey action. Home-ported ships/galleys will utilize DD form 1149 to transfer w/ reimbursement to the PV. The PV will submit credit invoice to the account manager at DLA Troop Support.

c. DLA Troop Support Subsistence Prime Vendors must report POSITIVE and NEGATIVE RESPONSES directly to the their DLA Troop Support Contracting Officer with a courtesy copy to the Consumer Safety Officer (dscpconssafofc@dla.mil)..

d. DeCA, AAFES, MWR, VA, MCCS, or other non-DLA Troop Support agencies SHOULD NOT respond to the DLA Troop Support Consumer Safety Officer. These agencies should report POSITIVE and NEGATIVE responses in accordance with their agency recall policies.

e. When corresponding with DLA Troop Support concerning this message please include this message's subject in your subject line.

8. The Point of Contact for this ALFOODACT message is CW4 Tony Hemphill, Consumer Safety Officer at DLA-FTW. VOICE, DSN: 444-2922, Commercial (215) 737-2922, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526, email dscpconssafofc@dla.mil.

9. Individuals or groups that would like to receive recall messages electronically can forward their email address to dscpconssafofc@dla.mil, with “add to list” in the subject line. To be removed from the list place “remove from list” in the subject line.

10. Previous recalls and frequently asked questions are available at the following web site: http://www.troopsupport.dla.mil/subs/fso/alfood/alfood.asp. The navigation tool to the left allows you to also view DLA Troop Support Alerts and Archived Vendor Recalls.

Regards,

Mr. Hemphill

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