

Subject: ALFOODACT 025-2010 Expansion of ALFOODACT 004-2010 McNeil Consumer Healthcare Recall of OTC Products

Date Issued: June 18, 2010

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

2. BACKGROUND:

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling five product lots as an addition to the list of products included in ALFOODACT 004-2010 McNeil Consumer Healthcare Recall of OTC Products. The additional lots involved are four product lots of BENADRYL® ALLERGY ULTRATAB™ TABLETS, 100 count, sold in the U.S.; and one product lot of EXTRA STRENGTH TYLENOL® Rapid Release Gels, 50 count sold in the U.S., Trinidad and Tobago, Bermuda, and Puerto Rico. This recall is a follow-up to the product recall that McNeil Consumer Healthcare announced on January 15th, 2010 and is being taken because the products were inadvertently omitted from the initial recall action. McNeil Consumer Healthcare identified the omission and informed the U.S. Food and Drug Administration (FDA) of its decision to add these product lots to the recall list. All these products were produced before the January 15th, 2010 recall. Since January, McNeil Consumer Healthcare has continued to analyze and evaluate 2,4,6-tribromoanisole (TBA) and has shared that information with the FDA. This further analysis confirms that the risk of serious adverse medical events is remote.

3. PRODUCTION DATES/IDENTIFYING CODES:

Product Name// Product Form// Lot Number// NDC Number// UPC Code.

BENADRYL Allergy ULTRATAB Tablets 100 count// Ultratab Tablet// AJA008, ADA194, ABA022, ABA264// 50580-226-10// 312547170338.

EXTRA STRENGTH Tylenol Rapid Release Gels 50 count// Rapid Release Gelcap// ASA202// 50580-488-50// 300450488503.

The product lot numbers for the recalled products can be found on the side of the bottle label.

4. MANUFACTURER/DISTRIBUTOR:

McNeil Consumer Healthcare
Division of McNEIL-PPC, Inc

5. DISTRIBUTION: U.S. Nationwide; the Americas, the United Arab Emirates, and Fiji.

6. REASON FOR ACTION: Presence of trace amounts of a chemical called 2,4,6-tribromoanisole.

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 FISC and copy furnished to NAVSUP 51. Your supporting FISC should forward to the account manager at DSCP. 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 DSCP.
- c. DSCP Subsistence Prime Vendors must report POSITIVE and NEGATIVE RESPONSES directly to the their DSCP Contracting Officer with a courtesy copy to the Consumer Safety Officer (dscpconssafofc@dla.mil).
- d. DeCA, AAFES, MWR, VA, MCCS, or other non-DSCP agencies SHOULD NOT respond to DSCP Consumer Safety Officer. These agencies should report POSITIVE and NEGATIVE responses in accordance with their agency recall policies.
- e. When corresponding with DSCP concerning this message please include this message's subject in your subject line.

8. The Point of Contact for this ALFOODACT message is COL John C. Smith, DSCP Veterinary Advisor at DSCP-FTW. VOICE, DSN: 444-8461, Commercial (215) 737-8461, 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: <https://www.dscp.dla.mil/subs/fso/alfood/alfood.asp>. The navigation tool to the left allows you to also view DSCP Alerts and Archived Vendor Recalls.

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