

SUBJECT: ALFOODACT 040-2007 McNeil Consumer Healthcare Is Voluntarily Withdrawing Infants' Cough and Cold Products

Date Issued: October 12, 2007



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).
- c. http://www.tylenol.com/page.jhtml?id=tylenol/news/subpressrelease_101007.inc
<http://www.pediacare.com/page2.html>

2. BACKGROUND:

McNeil Consumer Healthcare, a division of McNeil-PPC, Inc., announced today that the company is voluntarily withdrawing certain infants' cough and cold products from the market. When used as directed, these medicines are generally recognized as safe and effective. While most parents use these medicines appropriately and follow dosing directions, an assessment of available data on the use of pediatric cough and cold medicines has identified rare instances of misuse leading to overdose, particularly in infants under 2 years of age.

3. PRODUCTION DATES/IDENTIFYING CODES:

Over-the-counter (OTC) infants' cough and cold medicines included in the recall:

- Concentrated Tylenol® Infants' Drops Plus Cold
- Concentrated Tylenol® Infants' Drops Plus Cold & Cough
- PediaCare® Infant Dropper Decongestant
- PediaCare® Infant Dropper Long-Acting Cough
- PediaCare® Infant Drops Decongestant (containing pseudo ephedrine)
- PediaCare® Infant Dropper Decongestant & Cough
- PediaCare® Infant Drops Decongestant & Cough (containing pseudo ephedrine)

This voluntary removal does NOT include:

- Children's Tylenol cough and cold medicines for children over age two
- PediaCare children's cough and cold medicines for children over age two
- Infants' and Children's Tylenol pain relievers and fever reducers
- Infants' and Children's Motrin pain relievers and fever reducers

4. Manufacturer/Establishment Number:

McNeil Consumer Healthcare
 7050 Camp Hill Road
 Fort Washington, PA 19034

5. DISTRIBUTION: Worldwide

6. REASON FOR RECALL: Labeling (Potential misuse by consumer)

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 of the item. POSITIVE FINDINGS should be reported to Accountable Officers/Vendor Representatives of that facility. Accountable Officer/Agency Representatives should seek refund/credit/replacement through the normal distribution channel with which the product was received (i.e. Distribution Centers, Prime Vendors, 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/gallies 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. Unless otherwise specified above, POSITIVE and NEGATIVE RESPONSES directly to DSCP Consumer Safety Officer (CSO) are NOT required.

d. 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 CW4 Ramona Hemphill, Consumer Safety Officer, at DSCP-FTW. VOICE, DSN: 444-2905, Commercial (215) 737-2905, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526

Any individual or office that would like to receive recall messages electronically can forward their email address to Ramona.Hemphill@dla.mil.

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 view DSCP Alerts and Archived Vendor Recalls also.

Very Respectfully,

Mrs. Ramona Hemphill

CW4 Ramona Hemphill

Consumer Safety Officer, DSCP

Food Safety Office

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