

**Subject: ALFOODACT 127-2009 FDA Warns Consumers to Stop Using Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Nasal Swabs, and Zicam Cold Remedy Swabs, Kids Size**

**Date Issued: June 20, 2009**

## **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. FDA posting: <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm166059.htm>
- d. Product website: <http://www.matrixxinc.com/releasedetail.cfm?ReleaseID=390200>

## **2. BACKGROUND:**

FDA is alerting consumers that Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Nasal Swabs, and Zicam Cold Remedy Swabs, Kids Size, a discontinued product that consumers may still have in their homes, have all been associated with long lasting or permanent loss of smell (referred to as anosmia). These products, marketed by Matrixx Initiatives, are zinc-containing, nasal cold remedies used to reduce the duration and severity of cold symptoms. However, these products have not been shown to be effective in the reduction of the duration and severity of cold symptoms. This advisory does not concern oral zinc tablets and lozenges taken by mouth. FDA recommends that consumers stop using these products and throw them away. See the FDA website for How to Dispose of Unused Medicines.

Since the introduction of Zicam Cold Remedy Nasal Gel to the market in 1999, FDA has received more than 130 reports of anosmia associated with the use of Zicam zinc-containing intranasal products. The reports vary. Many people state that the loss of sense of smell occurred with the first dose of the Zicam product, although some people report it happened after later doses. The loss of sense of smell may be long-lasting or even permanent in some people.

Loss of the sense of smell may cause serious problems, such as failing to smell smoke, a gas leak, or spoiled food. Also, loss of the sense of smell is often linked with a loss of the sense of taste. People who cannot taste could unintentionally eat spoiled food and not appreciate flavors, and lose much of the pleasure of eating.

## **3. PRODUCTION DATES/IDENTIFYING CODES:**

The products (listed with their size and product numbers) are:  
Zicam Cold Remedy Nasal Gel (15mL, NDC 62750-003-10)  
Zicam Cold Remedy Swabs (20 swabs, NDC 67250-003-20)  
Zicam Cold Remedy Swabs, Kids Size (20 swabs, NDC 67250-003-21)

#### **4. MANUFACTURER/DISTRIBUTOR:**

Matrixx Initiatives Inc.  
8515 E. Anderson Drive  
Scottsdale, AZ 85255  
United States

**5. DISTRIBUTION:** Nationwide. This product is reportedly found in the Commissary system.

**6. REASON FOR ACTION:** Loss of smell

#### **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, 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. Except for Prime Vendors, POSITIVE and NEGATIVE RESPONSES directly to DSCP Consumer Safety Officer (CSO) are NOT required. Prime Vendors should report finding to their assigned Contracting Officer and courtesy copy the Consumer Safety Officer ([dscpconssafofc@dla.mil](mailto:dscpconssafofc@dla.mil)). Other agencies such as DeCA, AAFES, MWR, VA, MCCS, etc. should report POSITIVE and NEGATIVE responses to their agencies recall coordinator.

d. DSCP will not issue further updates or product expansion information. Further information and any future update or product expansion on Nutro Products recalls related to this incident may be found at references c and d.

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 MAJ Dwayne Overby, Command Liaison Officer at DSCP-FTW. VOICE, DSN: 444-2934, Commercial (215) 737-2934, 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 [dscpconssafofc@dla.mil](mailto:dscpconssafofc@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.

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