Subject: ALFOODACT 070-2012 Matrixx Initiatives Issues Nationwide Voluntary Recall of One Lot of Zicam Extreme Congestion Relief Due to Contamination With Burkholderia Cepacia

Date Issued: December 19, 2012

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:

Matrixx Initiatives is voluntarily recalling 1 lot of Zicam® Extreme Congestion Relief nasal gel. The company is taking this step after finding a small amount of Burkholderia cepacia in a single sample of the product taken from the affected lot. The problem was detected during a routine review at the manufacturing facility. Tests on additional samples from the same lot have shown no evidence of the organism.

Burkholderia cepacia poses little medical risk to healthy individuals. However, Burkholderia cepacia in a nasal spray could cause upper airway colonization and secondarily lead to respiratory infections in individuals with a compromised immune system or those with chronic lung conditions, such as cystic fibrosis. The organism is resistant to many antibiotics and may be difficult to eradicate in this sensitive population if an infection occurs. Matrixx has not received any reports of illness.

Matrixx is notifying its distributors and retail customers by FEDEX letter and by phone and is arranging for return of all recalled products. Consumers that have the affected lot of Zicam® Extreme Congestion Relief nasal gel should stop using the product and contact Matrixx for a full refund at 1-877-942-2626 from 8am-8pm Central Time Mondays-Fridays and 9am-1pm Central Time on Saturdays.

Consumers with questions regarding this recall can contact Matrixx at 1-877-942-2626 at the times stated above or via the internet at www.zicam.com .

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

3. PRODUCTION DATES/IDENTIFYING CODES:

Zicam® Extreme Congestion Relief nasal gel

The product is a non-drip liquid nasal gel used as a nasal decongestant and is packaged in a 0.5 oz. spray bottle contained in an outer carton, bearing NDC number 62750-005-10. The affected Zicam® Extreme Congestion Relief lot is 2J23, Expiration 09/15. The product was distributed to retailers nationwide throughout the United States.

4. MANUFACTURER/DISTRIBUTOR:

Matrixx Initiatives

1-877-942-2626

602-385-8861

5. DISTRIBUTION: All

6. REASON FOR ACTION: Due to the potential to be contaminated with Burkholderia cepacia

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

CW4 Tony D. Hemphill
Consumer Safety Officer
DLA Troop Support
700 Robbins Ave.
Philadelphia, PA. 19111
Ph. (215) 737-2922
DSN 444-2922
Cell. (215) 298-2808
Fax 215-737-7526
Tony.Hemphill@dla.mil
Tony.Hemphill@us.army.mil
TonyHemphill@ln.amedd.army.mil