

Matrixx Initiatives Issues Nationwide Voluntary Recall of One Lot of Zicam® Extreme Congestion Relief Due to Contamination With *Burkholderia Cepacia*

Matrixx Initiatives Contact:
Tim Clarot
Phone Number (602) 385 8861

Media Contact:
Elinor Polack, Edelman
Phone Number: (212) 704-4528

FOR IMMEDIATE RELEASE – December 18, 2012 – Scottsdale, AZ - 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.



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.



Zicam® Extreme Congestion Relief Lot 2J23 Exp 09/15

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.

- **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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

#