Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: December 19, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Matrixx Initiatives Recall

SUGGESTED ACTION: **Unclassified Recall; 1 lot of Zicam® Extreme Congestion Relief nasal gel after finding a small amount of *Burkholderia cepacia* in a single sample of the product taken from the affected lot; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The product was distributed to retailers nationwide throughout the United States. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

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

Contact:
Consumer:
1-877-942-2626
602-385-8861

Media:
Elinor Polack, Edelman
212-704-4528

FOR IMMEDIATE RELEASE - December 18, 2012 - 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.

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[1].

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.htm[2]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[3]. 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.

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RSS Feed for FDA Recalls Information[4] [what's this?[5]]

Photo: Product Labels[6]