



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

Judith A. Monroe, M.D.
State Health Commissioner

DATE: June 16, 2009
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program
SUBJECT: Zicam Cold Remedies

SUGGESTED

ACTION: FDA Advisory; FDA is warning consumers Not to use certain Zicam Cold remedies; Recommend notification to establishments that may carry these products via phone, fax or e-mail.

From the information provided by FDA, People who have experienced a loss of sense of smell or other problems after use of the affected Zicam products should contact their health care professional. The loss of sense of smell can adversely affect a person's quality of life, and can limit the ability to detect the smell of gas or smoke or other signs of danger in the environment.

FDA NEWS RELEASE

For Immediate Release: June 16, 2009
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Consumer Inquiries: 888-INFO-FDA

FDA Advises Consumers Not To Use Certain Zicam Cold Remedies
Intranasal Zinc Product Linked to Loss of Sense of Smell

The U.S. Food and Drug Administration today advised consumers to stop using three products marketed over-the-counter as cold remedies because they are associated with the loss of sense of smell (anosmia). Anosmia may be long-lasting or permanent.

The products are:

- Zicam Cold Remedy Nasal Gel
- Zicam Cold Remedy Nasal Swabs
- Zicam Cold Remedy Swabs, Kids Size (a discontinued product)

The FDA has received more than 130 reports of loss of sense of smell associated with the use of these three Zicam products. In these reports, many people who experienced a loss of smell said the condition occurred with the first dose; others reported a loss of the sense of smell after multiple uses of the products.

“Loss of sense of smell is a serious risk for people who use these products for relief from cold symptoms,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research (CDER). “We are concerned that consumers may unknowingly use a product that could cause serious harm, and therefore we are advising them not to use these products for any reason.”

People who have experienced a loss of sense of smell or other problems after use of the affected Zicam products should contact their health care professional. The loss of sense of smell can adversely affect a person’s quality of life, and can limit the ability to detect the smell of gas or smoke or other signs of danger in the environment.

The FDA has issued Matrixx Initiatives, maker of these Zicam products, a warning letter telling it that these products cannot be marketed without FDA approval.

“Companies have an obligation to the public to demonstrate to the FDA that their products are safe, particularly when there is evidence they may be causing serious adverse events, and they are marketed for minor, self-limiting conditions like the common cold,” said Deborah M. Autor, director of CDER’s Office of Compliance.

Health care professionals and consumers are encouraged to report adverse events (side effects) that may be related to the use of these products to the FDA’s MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

--Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

--Regular Mail: use FDA postage paid form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

--Fax: 800-FDA-0178

--Phone: 800-FDA-1088

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm166834.htm>