F.D.A. Warns Against Use of Popular Cold Remedy

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By GARDINER HARRIS

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Federal drug regulators warned consumers to stop using Zicam, a popular homeopathic cold remedy, because it could damage or destroy their sense of smell.

The action is an early indication that the Obama administration is likely to take far more aggressive enforcement actions against drug companies than the Bush administration did.

The Food and Drug Administration received 130 reports from consumers and doctors of people losing their sense of smell after using one of the Zicam nasal products, which include Zicam Cold Remedy and Zicam Cold Remedy Swabs. The reports date to 1999, when Matrixx Initiatives of Scottsdale, Ariz., first introduced the products.

In 2006, Matrixx paid $12 million to settle 340 lawsuits from Zicam users who claimed that the product destroyed their sense of smell, a condition known as anosmia. Hundreds more such suits have since been filed.

Although the F.D.A. took no action during the Bush administration, Dr. Margaret A. Hamburg, who was named the agency commissioner by President Obama, said the incidence of anosmia associated with Zicam “strikes us as a fairly large problem.”

The agency issued its consumer alert even though Matrixx refused to recall its products, a highly unusual event. In a news release, Matrixx said it had suspended shipments of Zicam and would reimburse customers who wanted a refund.

“Matrixx Initiatives stands behind the science of its products and its belief that there is no causal link between its intranasal gel products and anosmia,” the release said. “For this reason, Matrixx Initiatives believes that the F.D.A. action is unwarranted and will seek a meeting with the F.D.A. to review the company’s product safety data.”

Matrixx had $101 million in sales last year, of which $40 million came from Zicam products. Because Matrixx has called Zicam a homeopathic product, the company was not required to seek agency approval before selling it.

The F.D.A. does not have the power to order product recalls but must rely on manufacturers to do so voluntarily. Bills now moving through Congress would give the agency that power. Bush

administration appointees said the F.D.A. did not need mandatory recall authority because companies always withdrew unsafe products when asked.

But the government sometimes negotiated for days or weeks before companies agreed to recalls, leading many more consumers to be put at risk. And the Zicam case demonstrates that aggressive enforcement action can lead to disagreements.

An F.D.A. warning letter sent to Matrixx on Tuesday states that Zicam Cold Remedy intranasal products “may pose a serious risk to consumers who use them” and are “misbranded.” Such language would normally describe a recall alert. The products have no proven benefits.

Matrixx has received more than 800 reports of Zicam users losing their sense of smell but did not provide those reports to the F.D.A., said Deborah M. Autor, director of compliance in the agency’s drug center. The law requires producers of approved drugs to forward to the F.D.A. all reports of product-related injuries, but Ms. Autor declined to say whether this reporting requirement applied to Matrixx.

“This disabling loss of one of the five senses may be long lasting or even permanent in some people,” Ms. Autor said. “People without the sense of smell may not be able to detect dangers such as gas leaks or smoke. They could lose much of the pleasure of eating, adversely impacting the quality of life.”

Dr. Charles E. Lee, a compliance officer in the agency’s drug center, said zinc could be toxic to nerve receptors in the nose. In the 1930s, intranasal zinc was tested as a poliopreventative, and some patients suffered anosmia, Dr. Lee said.