FDA says Zicam nasal spray can cause loss of smell

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(AP) -- Consumers should stop using Zicam Cold Remedy nasal gel and related products because they can permanently damage the sense of smell, federal health regulators said Tuesday.

The over-the-counter products contain zinc, an ingredient scientists say may damage nerves in the nose needed for smell. The other products affected by the Food and Drug Administration's announcement are adult and kid-size Zicam Cold Remedy Nasal Swabs.

The FDA says about 130 consumers have reported a loss of smell after using Zicam products since 1999.

"Loss of the sense of smell is potentially life threatening and may be permanent," said Dr. Charles Lee. "People without the sense of smell may not be able to detect life dangerous situations, such as gas leaks or something burning in the house."

The FDA said Zicam Cold Remedy was never formally approved because it is part of a small group of remedies that are not required to undergo federal review before launching. Known as homeopathic products, the formulations often contain herbs, minerals and flowers.

A warning letter issued to manufacturer Matrixx Initiatives on Tuesday asked the company to stop marketing its zinc-based products, but the agency did not issue a formal recall. Instead, regulators said Matrixx would have to submit safety and effectiveness data on the drug.

"The next step, if they wish to continue marketing Zicam intranasal zinc products, is for them is for them to come in and seek FDA approval," said Deborah Autor, director of FDA's drug compliance division.

The agency is requiring formal approval now because of the product's safety issues, she added.

Matrixx Initiatives is facing multiple lawsuits over the product, but says on its Web site: "No plaintiff has ever won a court case, because there is no known causal link between the use of Zicam Cold Remedy nasal gel and impairment of smell."

Representatives from the Scottsdale, Ariz.-based company, which saw its stock price plunge to a 52-week low after the FDA announcement, did not immediately return calls for comment Tuesday.

Health officials said they have asked Matrixx executives to turn over more than 800 consumer complaints concerning lost smell that the company has on file. A 2007 law began requiring manufacturers to report such problems, but FDA regulators declined to say Tuesday whether the company broke the law.

The 130 reports received by the FDA came entirely from physicians and patients, not the manufacturer.

Regulators said the relatively small number of complaints accounted for the agency's lengthy investigation.

"FDA doesn't take action against drug products without evaluating all of the circumstances surrounding the issues with the product," Lee said.

Shares of Matrixx Initiatives Inc. plummeted $10.71, or 55.7 percent, to $8.53 in afternoon trading.