

## Drugs in the News 6/17/09 – Homeopathic Zicam Cold Remedy Nasal Gel and Zicam Cold Remedy Swabs Removed from the Market Due to Reports of Anosmia

The Food and Drug Administration (FDA) issued a Warning Letter to Matrixx Initiatives, Inc. (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm>) on June 15, 2009 concerning the safety of the company's homeopathic drugs Zicam Cold Remedy Nasal Gel and Zicam Cold Remedy Swabs and reports of anosmia (loss of sense of smell). These reports indicated that users experienced a long lasting or permanent loss of smell. The immediate safety concern is the inability to detect gas leaks, fire, or spoiled food.

In 2006, the company paid \$12 million to settle lawsuits with 340 people who suffered anosmia after using Zicam. The FDA notes in the Warning Letter that there is evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans.

Zicam Cold Remedy intranasal products are promoted as homeopathic drug products. Homeopathy is a 19<sup>th</sup> century alternative medicine belief system in which the more dilute the drug the more potent the product. Homeopathy has a cloudy history in U.S. drug law. The Homeopathic Pharmacopeia was recognized in 1938 Food, Drug, and Cosmetic largely due to the efforts of Senator Royal Copeland of New York and homeopathic physician.

The Zicam intranasal products are labeled as containing Zincum Gluconicum 2X (zinc gluconate). The X is the Roman numeral for 10 and 2X a 1-to-10 dilution repeated two times.

The FDA regulates homeopathic drugs in several different ways from other drug products. Manufacturers of homeopathic drugs are deferred from submitting New Drug Applications (NDAs) to the FDA. Homeopathic drugs are exempt from Good Manufacturing Practice (GMP) requirements related to expiration dating and from finished product testing for identity and strength. Homeopathic drugs in solid oral dosage form must have an imprint that identifies the manufacturer and indicates that the drug is homeopathic. The imprint on conventional products, unless specifically exempt, must identify the active ingredient and dosage strength as well as the manufacturer.

Homeopathic drugs are not exempt from the provisions of the Food, Drug, and Cosmetic Act. Matrixx Initiatives, Inc. claims that Zicam Cold Remedy intranasal products "reduces" the "duration of the common cold" and the "severity of cold symptoms," including specifically "sore throat • stuffy nose • sneezing • coughing • congestion." These claims make these products drugs, as defined by the Food, Drug, and Cosmetic Act, because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body of man or other animals.

Health professionals should counsel consumers on two points about Zicam and homeopathic drugs. One, Zicam intranasal products should not be used because of the risk of anosmia. Two, the safety and efficacy of homeopathic drugs have not been evaluated by the FDA based on high quality randomized clinical trials.