

Petition Content and Format

(Date) MARCH 1, 2007

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

CITIZEN PETITION

The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to _____ (issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action).

A. ACTION REQUESTED

1. If the petition requests the Commissioner to issue, amend or revoke a regulation, give the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.
2. If the petition requests the Commissioner to issue, amend or revoke an order, include a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.
3. If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, state the specific action or relief requested.

B. STATEMENT OF GROUNDS

A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.

C. ENVIRONMENTAL IMPACT STATEMENT

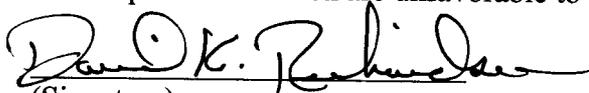
Give an environmental impact analysis report in the manner specified in 21 CFR 25.42. (Claim for categorical exclusion under 21 CFR 25.30, 25.31, 25.32, 25.33, or 25.34 or an environmental assessment under Sec. 25.40 of this chapter.)

D. ECONOMIC IMPACT STATEMENT

The following information is to be submitted only when requested by the Commissioner following review of the petition: a statement of the effect of the requested action on 1) cost (and price) increases to industry, government, and consumers; 2) productivity of wage earners, businesses, or government; 3) competition; 4) supplies of important materials, products, or services; 5) employment; and 6) energy supply or demand.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.


(Signature)

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February 20th, 2007

Commissioner of the US Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Dear Mr. Commissioner:

I am a 43 year old packaging equipment salesman living in Greensboro, North Carolina. In July 2005, I experienced a single use of ZICAM™ Nasal Gel and immediately lost my senses of both taste and smell. The product's main ingredient is zinc gluconate and is promoted as a homeopathic by the manufacturer. Whether it was the heavy sniffing from the cold I had at the time or the force from the projection of the gel as it left the applicator, I inhaled the product. A short time later after researching the curious loss of these two senses I learned of the correlation with ZICAM™. Upon inspection of the bottle which contained the actual gel I noticed no mention of the potential for long term adverse effects. The only information the manufacturer conveys is not on the actual container. Rather, there is a minor reference on the outer disposable packaging advising the user to avoid inhalation or "irritation may occur". This simple statement grossly understates the potential risk for damage to the olfactory nerve cilia. Furthermore, there is no procedure recommended for immediate nasal irrigation should the product be inadvertently inhaled. I have used other natural / homeopathic products in the past for things such as irregular sleep patterns and have accepted that while such a product's effectiveness might be questionable, its safety would not be. I now realize that I have erroneously assumed that at least some modicum of consumer safety protection was in place for such products. Based on the number of active law suits and grievances against ZICAM™ my experience is not isolated. Furthermore, since the terms "*homeopathic*" and "*natural*" are often associated together, as well as these products being available over the counter at drug and retail stores. I contend that the commonly accepted implication is that they are inherently safe.

I understand that during the 1990's congress enacted legislation that exempted homeopathic products from requiring more stringent governmental regulation by your agency. Like most Americans, I covet my civil liberties to make choices about many of the products I use. However, based on my recent experience I would argue that exempting a product like ZICAM™ from regulation exposes a major flaw. ZICAM's manufacturer, Matrixx LLC, has proven to me that we cannot assume that given their own volition, a manufacturer will necessarily perform such testing or provide appropriate warnings of potential serious danger. Particularly, if they realize that they will not be held accountable by an authoritative body. I am aware that Great Britain's Parliament has recently enacted such legislation for homeopathic products for this very reason.

I have enclosed just a few of the many available supporting documents that give credence to the danger of ZICAM™ nasal gel. Tragically, Matrixx LLC has attempted to hide behind the tenuous argument that their product is not intended to reach into the upper nasal cavity. I submit to you that the mere fact that the product is introduced into any portion of the nasal cavity should warrant prudent judgment on the part of the manufacturer to provide adequate warning and associated first aid procedures. In fact, it is my contention that such risk from a one time use of this over the counter product should preclude it from being administered by anyone other than a professional. Better yet, it should not be administered in the nasal cavity at all. The fact that the difference in the potential for damage is separated by only a few millimeters is far too great a risk to expect the average consumer to be responsible for. Particularly if they are not even aware of this risk. Yet, despite multiple recorded incidents of ZICAM™ related complaints Matrixx has refused to institute a more strongly worded warning. As you will find in the attached Matrixx press release, they attempt to give scientific credence to the safety of their product. What needs clarification in this document is whether or not the “Scientific Advisory Board” referred to has ever received compensation from Matrixx? If this is in fact the case, it should create a reasonable doubt for accepting their findings carte blanche. The manufacturer further attempts to mitigate the potential exposure to the upper nasal area by using such terms as “egregiously misused” and “extraordinary overdose” in an effort to persuade the reader why such contact with these nerves should not happen. Upon closer examination of the references at the end of this document, the astute reader will find that several are generic in nature and do not address zinc gluconate. Those that do are focused on the theoretical premise of reducing the duration of the common cold, not on zinc’s exposure to the olfactory cilia. Finally, they appear to have been published prior to the associated damage first being recognized and recorded in connection with ZICAM™. This should not be surprising since in the year 2003 ZICAM™ had only recently been introduced and the subsequent negative consumer feedback had yet to accumulate.

Adding to the lack of information made available to the consumer, it has also been noted that because of its similar if not identical design, the ZICAM™ applicator can easily be confused with that of other prescription and non-prescription nasal inhalation products. *(Note: Since the time of my use in 2005, the manufacturer has redesigned the applicator tip to make it less likely for the gel to be as easily projected up the nose. However, Matrixx has never admitted the potential for permanent damage to the senses as the reason why they made this design change).* I am reminded of other manufacturers such as W.R. Grace and R.J. Reynolds who effectively ignored known safety issues for many years and continued to allow their dangerous products of Asbestos™ and tobacco to be sold to the unsuspecting public. It was only after years of litigation and eventually being forced by legislation before these companies reluctantly announced warnings on their products or removed them from the market. Tragically, unlike these two examples which required years of exposure, ZICAM™ can do it’s damaged with only a one time single pump application. To date from what I can find thus far, there is no known cure for this damage. I am aware of one other zinc gluconate product under the trade name of COLD-EEZE™, which caused similar damage. It was voluntarily taken off the market by the manufacturer. Matrixx LLC on the other hand, appears to have taken the position of choosing short term profits over self induced responsibility. Consumer complaints against ZICAM™ have been documented as early as 2003, yet this has not been enough for Matrixx to follow the lead of COLD-EEZE™ and voluntarily pull the product.

Mr. Commissioner, my paramount request in submitting this petition is to require FDA sanctioned third party independent scientific analysis of zinc gluconate's reaction to human olfactory cilia tissue. Such validation should build upon the previous work of such studies as that by Doctors Jakek, Linschoten and Murrow in 2004. Additional studies from 1934, 1937, 1976, 1978, 1982 and 1997 seem to also support the 2004 findings. If your commission agrees that there is a scientific correlation found between zinc gluconate and the loss of taste and smell as these previous independent studies show, then please use your influence to promptly remove ZICAM™ from the market place. Of secondary and less pressing importance is to see additional safety standards set for the homeopathic industry as a whole. In the current environment which appears to be devoid of many tangible consumer safeguards, this industry can essentially ignore safety. As a consumer who may never have the privilege of smelling fresh cut grass or tasting my favorite food. I ask you to please do something to prevent others from sharing the same unnecessary and unfortunate experience.

Respectfully,



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