

Let the Truth be Told

Dear Loyal Retailer:

As many of you know, the FDA has made an aggressive move against ear candles. I apologize for our delay in responding to all of the inquiries, however, I believe that after you read what has happened you will understand that we have been extremely busy.

What has happened since February 17, 2010:

Ear Candles and ear candling have been used for hundreds of years as an all natural remedy for the relief of several body ailments. The FDA has recently sent Warning Letters to 17 manufacturers (including ourselves, Wallys Natural and White Egret, who also received an Import Alert letter) to stop the production and sale of ear candles in the US. The FDA sights three reports of adverse events and a document referred to as the "Seelys' study".

As is discovered, the FDA's "Seely Study" is in fact not a study at all, it is merely an early 1990's unofficial survey of a handful of ear nose and throat doctors who claim ear candles can cause harm to the ear drum via melted wax. As we all know, ear candles have improved substantially since then with higher quality raw materials eliminating these initial concerns documented in Seelys' study.

Interestingly enough, the same day that the FDA launched an all out war on ear candle manufactures in an effort to kill the industry it approved the controversial Prevnar 13 vaccine. However, during their clinical they had 3 deaths!

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM206264.pdf>

Dr. Harmonys Position:

At the forefront is that our position at Harmony Cone Ear Candles has always been...

Ear candles do NOT remove wax or anything ELSE from the body. And, as such, ear candles are NOT a medical device.

My team and I have worked tirelessly to dispel the rumors and untruths that plague this very useful holistic and relaxing modality. It is so important to remember not everything is conventional... not everything needs or "should" be resolved with drugs- this has been proven time and time again – for nature is the cure...

What is the FDA's position:

The FDA thinks that ear candles are a medical device. This is a result of most manufacturers selling ear candles as ear wax removers.

Currently, the FDA is trying to prevent manufacturers from using the word 'EAR' with candle. This includes videos, instructions, literature, marketing, etc. **To be clear, Ear Candles are not household candles, incense candles or anything else but an ear candle.** Unlike our competitors, this current FDA position challenges our ethics and integrity.

The FDA *insinuates* that there is a list of injuries that have occurred or could occur when using ear candles. The FDA also insists that studies prove that ear candles are ineffective. But I have to challenge this assertion. What studies were done and by whom? How long were these studies conducted and under whose supervision? How much time and money was allotted for these studies? ***But the most important question of all was what were they testing?*** The only studies done by opponents were to test for wax removal. So, of course, their conclusion would be that ear candles are ineffective.

We are only aware of ONE documented case of a burnt ear drum due to an ear candle. Of course, the same week that the FDA attacks a natural, holistic product we find out that the FDA's criminal complicity with industry has led to 83,000 excess heart attacks from the now recalled drug Avandia. Of course, that is on top of Vioxx which caused some 140,000 heart attacks and there are so many other regulatory failures that you cannot blame this problem on ineptitude.

What is interesting to me is that I have personally ear candled nearly 10,000 people over 5 years and have NEVER had an injury.

FDA countradictions:

I have to concede that on one point *only* the FDA is correct: SOME people make outrageous claims that are atrocious. There are companies that misrepresent the history of ear candling, for example, by using the Hopi name, to market their product, or state that the product purifies the blood, strengthen the brain, or can even 'cure' cancer! How ridiculous! (But interestingly enough these companies did not get served Warning Letters!)

It is our desire that the FDA should focus its energy on those who would make such unproven claims. But instead the FDA is trying to destroy an opportunity to help the body help itself... which is what we feel ear candles actually do, holistically - and quite well if you listen to the millions of users.

We are sympathetic to the FDA's pursuit of erroneous claims, however, let's not attack an entire industry- let's pursue those who make false claims individually.

So why does the FDA continue to make an assault upon natural holistic modalities? First I have to ask why are drugs that kill millions or people placed on the market everyday - legally? How do drugs like Vioxx, Avandia or Premarin even get approval? Why are heroes like David Graham (an employee/whistle blower at the FDA) ostracized and offered bribes to be silent by his fellow peers? It is simple - money. Funny thing about mother nature though - you cannot trademark it and you cannot patent it ... therefore it is hard to back it with lots of money. This is why holistic and natural remedies are often the focus of overreaching authorities.

Ear candle companies have come under fire for marketing violations under the "guise" that ear candles are medical devices. We are being accused of not having the proper paperwork for a medical device. However, this is confusing as on the one hand the FDA states that the ear candle is a medical device, but then they state it has no therapeutic value. So I have to ask, how can something be called a medical device if it has no therapeutic value according to the FDA and Health Canada? **Once again, it is our position that ear candles are holistic and NOT a medical device... and they certainly do not remove wax.**

It is important to note that the FDA has made it very clear that even if we did complete our 'paperwork' that they would not approve ear candles. Period, end of the discussion. (see FDA's position – [click here](#))

What action are we taking at Harmony Cone Ear Candles?

1. We are leading 7 other smaller manufacturers in the fight against the FDA (Wallys Natural nor White Egret chose to participate. Nor have we received any support from any organization other than Natural Solutions Foundation, www.healthfreedomusa.org).
2. We have formed the first ever ear candle alliance designed to establish standards in safety, raw materials and marketing claims.
3. We have co-created a petition for everyone to sign on line and in stores with Natural Solutions Foundation, <http://www.healthfreedomusa.org/?p=4790>
4. We have visited our Congressman and continue to visit with them, and

5. We have led the Alliance in conjunction with our legal team and have filed an Injunction against the FDA. This injunction was filed April 11, 2010.

We are hoping to win this war against the FDA. However, as we all know this will take lots of time and money.

SUMMARY:

As we all know, what the FDA is failing to consider is that as a holistic modality, the allopathic evaluations on ear candles simply cannot measure the relaxing holistic energy that accompanies natural wellness applications. Why has the FDA not used the leading manufacturers as a resource for information? We make, use, and distribute the product to millions. WE have the data and the knowledge. We have the documentation. I, myself, have worked with doctors all over the world researching and studying the effects of ear candles. Where was our participation in the FDA's decision? Our input? Our involvement?

As a result of the FDA's shenanigans and unjust behavior, we have expended over \$50,000 dollars in the fight to stop the FDA. Obviously, we cannot continue to expend this kind of money and stay in business (and then the FDA wins anyways). Also, once we realized that a vaccine had been released we knew that our fight against the FDA also included the billion dollar vaccine industry – Wyeth, Merck, GlaxoSmithKline, etc.

Please click here to donate: [fundraiser letter here](#).

Future Consequences of the FDA's actions:

For the past 19 years we have worked diligently to establish self regulated standards to avoid any potential injury from ear candles. The families that are handcrafting Harmony Cone ear candles ALWAYS use a very specific, expensive, and pure grade wax. We work diligently with our vendors to ensure melting points, viscosity, vapor rates and oil content. We do this never having any injury claims. Again we support standards. And this principle should be applicable to all industries.

If the FDA prevails, ear candles will become a 'black market' item that is not regulated or controlled by peer pressure and educated consumers. Consumers will begin using raw materials and items that are quick burning and unsafe to use. This will surely give the FDA some real concern with injuries. However, there will be absolutely no self regulation and injuries will be high when retailers and consumers purchase inferior ear candles made with inferior raw materials.

More importantly, the FDA's pursuit of an entire industry by means of limited, erroneous, or unsubstantiated claims off-handedly threatens jobs. They are not just denying consumers a natural choice, but more importantly, thousands of jobs- at a time when our country needs jobs- and needs manufacturing. Harmony Cone is an American made product, made by people with disabilities, retirees, single mothers, home school families, the GLBT community, and Native Americans. Do not deny us and

them the opportunity on the basis of here say and without undeniable well researched facts. Now is not the time to make sweeping laws without taking into account the repercussions of those actions.

The FDA's actions could result in thousands of jobs lost, millions of tax dollars lost and actually cause ear candle injuries.

How can you help?

Continue to buy Harmony Cone Holistic Candles so that we can fight and defend all of our Rights to choose our personal method of healing.

Sign the Petition at: http://salsa.democracyinaction.org/o/568/p/dia/action/public/?action_KEY=2521 and get your customers to sign the petition.

Donate money to our legal campaign. Please send funds to Jim Turner at 1400 16th Street, NW, Suite 101, Washington, DC 20036 Phone: (202) 462-8800 Fax: (202) 265-6564. [Fundraiser letter – click here](#)

Please make checks out to Holistic Candles and Consumers Association. As a retailer, become a plaintiff as a party against the FDA and our injunction file April 9, 2010.

At Harmony Cone Ear Candles, we believe that we are put here to serve others, to help others, to make available natural resources to those who chose a natural path. Lofty as that may be... We live our life in service not just other people but to the earth we live on.

Thank you for your time, patience, and understanding

Dr. Harmony and the families of Harmony Cone Ear Candles.