

Wow! Incredible! Amazing!

Dear Retailer,

Our position is that ear candles are not a medical device. Ear Candles are a holistic modality that helps one relax and begin to heal. We disagree with the FDA's request to register ear candles as a medical device.

However, we are *shocked* at the most recent turn of events. As many of you know there is a letter circulating indicating that their product (aka ear candles aka incense candles) have been approved by the FDA and they are the only one to be approved. They stated that this approval came in November of 2009. Please note the letter issued by the FDA November 2009 stated the following: ([click here for actual letter http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202305.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202305.htm)).

FDA requests that White Egret, Inc. immediately cease marketing, promoting and distributing White Egret ear candles. This includes the removal of White Egret ear candles and references to ear candling from your website www.whiteegretearcandles.com.

We received your undated response to the Inspectional Observations, Form FDA 483 (FDA 483) from the law firm of Emord & Associates, P.C. on or about November 6, 2009. **The adequacy of your response to the FDA 483 cannot be determined at this time. In your response, your attorney states that as of November 1, 2009, you have stopped selling all products labeled as ear candles and that you will permanently discontinue the manufacture, distribution, and sale of ear candles and of all products associated with, or concerning, use of candles for affecting the body's structure or function.** Your response will be verified during the next scheduled inspection.

You should take prompt action to correct the violations addressed in this letter. **Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.** Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

This means ear candles and any product that is concerning a candle, including incense candles.

This is obviously not an approval letter of any ear candle product, including incense candles or any candle that affects the body's structure or function.

We are responding to this public letter to help further protect our Retailers. At Harmony Cone Ear Candles, our families and I have done the following to Legally and Properly protect ear candles and your Right to continue to provide them to your customers:

1. We are the founders of Holistic Candles and Consumers Association. This alliance of 8 ear candle manufacturers (not including White Egret and Wallys) and consumers has been formed in order to:

A. Fight the FDA: We have filed a first ever injunction against the FDA for violating our rights to manufacture, use and educate consumers regarding ear candles.

B. To establish much needed standards to avoid any further litigation with the FDA, including but not limited to burn line labels, wax controls, marketing claims, research and science.

2. We have generated an online petition against the FDA which has collected over 8,000 signatures so far.

3. We have met with our Leaders in Congress, including Ron Paul, who personally wrote a letter to the FDA on our behalf. Other members of the alliance have met with their Representatives and have written similar letters. [Click here for letter - http://www.globalhealthfreedom.org/?p=5485](http://www.globalhealthfreedom.org/?p=5485)

4. We are working hand in hand with a team of Counsel, including Jim Turner with Citizen for Health, Ralph Fucetola, The Vitamin Lawyer, and Larry Becraft and others. We have expended over thousands of dollars, personally, to protect our category and our industry's Right to Speech and Choice.

In response to the public letter indicating premier research and approval, please note that Harmony Cone Ear Candles was the first to introduce :

- a. the highest food grade wax in the marketplace,
- b. burn line labels
- c. online videos to educate your consumers
- d. real science and efficacy reports supporting the proper usage of ear candles.
- e. the only PATENTED safety tip

In conjunction, we are the ONLY ear candle manufacturer to have on staff a former FDA agent to ensure the implementation of GMP compliant systems. We also are the ONLY ear candle manufacturer to write a Citizen Petition to the FDA to help protect our category with science and research during our legal case.

The FDA has been held at bay by our efforts! We are winning!

(click here to view our legal documents online!)

<http://www.healthfreedomusa.org/?p=5210>

Therefore, please continue to support us and our families. We are fighting for you. Join our Alliance, circulate our petition, encourage any other ear candle manufacturers to join our Battle against the FDA, DONATE money to our law firm (www.swankin-turner.com)

The FDA wants to stop all ear candle manufacturers!

Please note this is a serious matter. On March 26, 2010, Kevin Boulton, representing the families of Harmony Cone and attorney, Larry Becraft personally appeared at the FDA office located in Atlanta, Georgia, in response to the FDA Warning Letter and for the purpose of having a scheduled meeting with FDA officials regarding the manufacture, marketing, distribution and sale of ear candles by Harmony Cone.

The FDA sent 3 agents from the Atlanta office and included 8 Department heads from the Washington DC office:
Atlanta office: Serene N. Ackall, Spring Randall, and Fulton Varner

Washington, D.C. office: Mr. Craigs acting as Legal Director of the Office Of Compliance
Mr. Ian acting as Legal Deputy Director of Division of Ophthalmic, Neurological, and ENT Devices
Debra Demeritt, acting as Office of Compliance
Robert Gatling, acting as Program Operations Staff, Office of Device Evaluation (?)
George Kroehling, acting as Deputy Director, Division of Enforcement A
Eric Mann, acting as Clinical Deputy Director, Division of Surgical, Orthopedic, and Restorative Devices
James Saviola, acting as Ophthalmic, Neurological, and ENT Devices analysis
Larry Spears, acting as Deputy Director for Regulatory Affairs, Office of Compliance

WOW!!! I think the FDA is serious about this matter.

During the March 26, 2010 meeting in Atlanta, Georgia, FDA agent Larry Spears, while acting as FDA Deputy Director for Regulatory Affairs, Office of Compliance, asserted that:

"Okay we can see that you have had some issues with the webmaster that you have that is neither here nor there I don't know what is on there today, things like ear infections, swollen glands, I would also like to mention to reiterate that this is **not an approved device** and that we are not going to approve any ear candles for use in the market from any company so I just want to make sure that you understood that this is our position and we look forward to your response so from today in two weeks and we will evaluate that response and make decisions on what we are going to do, going forward, ... "

On March 26, 2010, during the same meeting in Atlanta, GA, FDA agent Fulton Varner stated that:

"I just want you to understand that the FDA still considers ear candling a medical device. **You can change whatever you want to you, you can change the colors, you can make non claims or not what it is. It is still an ear candle and that is where they are coming from. I just want you to understand that what you claim that it is or not, it's what they believe."**

So as you can see it is VERY IMPORTANT that we fight the FDA. The ONLY people that are protected from the FDA's tyranny at this point are the members of this Alliance that are in litigation with the FDA.

It is a necessity to Stand Up and Fight for Our Rights. Now is not the time to confuse and spread misinformation about ear candles (incense candles, votive candles, household candles, etc). Please realize that we are not just fighting the FDA. We are also fighting Pfizer. Pfizer purchased Wyeth who received approval for Prevnar 13, the new vaccine against ear infections, and 13 streptococcus pneumonia. We are battling against the FDA and the billion dollar industry that pushes vaccines. Pfizer predicts Prevnar 13 to be as large of a profit maker as Lipitrol. "there's your sign!" (link to Pfizer story).

We need truth on our side so that we can prevail against the FDA. We need you, the Retailer to know the truth and stand by our side. Do not forget:

If people let government decide what foods they eat and what medicines they take, their bodies will soon be in as sorry a state as are the souls of those who live under tyranny. – Thomas Jefferson

We will stand for what is Right and Just with Integrity and Principle.

As always, thank you for your support.

Dr. Harmony