CITIZEN PETITION

2013 SEP 30 A 9:10

September 26, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

The undersigned, Kevin Boulton, submits this petition under Sections 201(h) of the Federal Food, Drug, and Cosmetic Act (FDCA) and in the form required by 21 C.F.R. Section 10.30 Petitioner requests the Commissioner of Food and Drugs to recognize that Harmony Cone Ear Candles (HCEC), as defined in this petition, are not medical devices under § 201(h). Petitioner also asks that the agency hold a public hearing on this matter before making a definitive decision.

A. ACTIONS REQUESTED

Petitioner respectfully petitions the Commissioner of Food and Drugs to issue a declaratory order finding that Petitioner has standing, and that HCEC, as defined in this petition, are not "devices" under FDCA § 201(h).

Petitioner also requests a full, fair public hearing on all of the issues presented in this petition of right.

Petitioner respectfully requests that the Commissioner temporarily stay any regulatory enforcement action against any HCEC manufacturer, distributor or seller during the pendency of this action.

2013-8407

FDA-2013-P-1297

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B. STATEMENT OF GROUNDS

1. Petitioner's Interest

In the exercise of Petitioner's secured rights, Petitioner has regularly used HCEC for over twelve years and intends to continue using HCEC for personal comfort, as a relaxing technique and for a sense of wellbeing. Petitioner has never been harmed in any way from the proper and continued use of properly made HCEC. Petitioner has and exercises liberties and rights secured under the Constitution for the United States of America, including but not limited to, the right of choice regarding personal health, comfort, well-being, and happiness.

Petitioner is also the sole U.S. patent holder for a "Tip For Ear Candle", Patent No. US D592,749 S. which is used in a significant number of ear candles and in all of HCEC's. Petitioner also represents the families of Harmony Cone Ear Candles and handcrafted HCEC products. Petitioner and the families of Harmony Cone Ear Candles will be adversely affected by any FDA decisions and/or actions against HCECs manufacturing, marketing and sales unless the FDA properly rules/decides, that HCECs are not a medical device when no medical claims are used.

Significant numbers of people, including this Petitioner, regularly and freely choose to use holistic, alternative, and integrative modalities for personal wellness and physical comforts, including HCEC. As a result many practitioners, and doctors are conducting studies that explore the holistic and alternative wellness (mind-body-spirit) synergies, including those based upon bodily energy consumption, use and transfers. Petitioner has and intends to exercise his natural and personal liberty to pursue the knowledge of and to use such holistic, alternative and integrated modalities and techniques to secure and enjoy his personal comforts, health and a sense of wellbeing and happiness.

Petitioner maintains a firmly held belief that ear candles are an integral part of personal comfort, holistic lifestyle, and health security that is grounded in the integration of body, mind, and spirit energies. The term *"energy"*, as defined by Cyndi Dale, author of The Subtle Body, An Encyclopedia of Your Energetic Anatomy are subtle, or indiscernible, energies that create and sustain all matter. The physical world – the one that Petitioner can touch, smell, taste, hear, and

see, is constructed from, is effected by, and uses these energies, which are sometimes imperceptible through the five natural human senses. Petitioner has reason to believe that the perceived physical world and human body are created from organized, and interactive with, dynamic, and transferable systems of subtle energy that have yet to be proven, understood or even acknowledged by the currently approved medical sector. There are energies that we may not directly sense but can be cognitively perceived through effects or affects. These physically perceptible energies that are known in nature may not be recognized or approved by the AMA.

As a regular user, Petitioner finds that HCECs when used as a relaxation technique (as defined in this petition) are an integral component for the maintenance of personal comfort and sense of well-being because the Petitioner can perceive and/or feel the effects within his subtle energy body fields, in the form of relaxation, an improved sense of general wellbeing and pleasant sensations, even though the Petitioner may not fully understand the specifics of what has actually occurred or did not occur.

The Mayo Clinic has stated that relaxation techniques can reduce stress symptoms and help you enjoy a better quality of life, especially if you have an illness. The Mayo Clinic even goes so far as to state: "Relaxation is a process that decreases the effects of stress on your mind and body. Relaxation techniques can help you cope with every day stress and with stress related to various health problems, such as cancer and pain." https://www.mayoclinic.com/health/relaxation-technique/SR00007 HCEC is the primary relaxation technique Petitioner uses to maintain personal comfort, stress reduction and a sense of wellbeing, especially when Petitioner does not feel normal and optimal performance.

2. Ear Candles Defined

"HCEC," as used in this petition, means ear candles that are designed, manufactured, and marketed according to the following standards and other the Harmony Cone Trademarks:

1. The wax in the Petitioners conical candle is a high-quality wax that meets FDA standards for food-grade (paraffin) wax.
2. If it is a beeswax candle, the Petitioner's wax compound is made according to a specific ratio of ten parts food grade wax to one part bee's wax.

3. The safest ear candle found in the marketplace is made with 100% percent food grade wax;
4. All other components of HCEC are of the highest quality needed to meet HCEC requirements, including cotton muslin cloth and aromatherapy oils;
5. The ear candle that Petitioner uses and represents, HCEC, is made with a noticeable ½ inch wide strip that is clearly marked with the words "STOP HERE". The strip clearly indicates to stop burning the HCEC at a safe distance and then extinguish the flame in water.
6. The ear candle that Petitioner uses and represents, HCEC, has a US Patent No. US D592,749 S safety tip for the protection of the end user. Instructions for use and pre-cautionary statements are included with the candle, in product information handouts and on the website www.harmonycone.com; and
7. Labeling and promotional materials clearly state that the ear candle is only intended for relaxation, stress reduction, and wellbeing. The ear candle with the safety tip is not designed as or used for a medical device and no representations are made to that purpose and effect.

Properly made ear candles, like HCEC, contain only high quality food-grade (paraffin) wax. The wax specifications are generally within the following ranges: (1) a melting point of 148° to 154°, (2) a viscosity rate of 38 – 41, (3) oil content is less than .5%, and (4) the odor is zero. These self-imposed manufacturing requirements are likened to be comparable with FDA Title 21, Sections 172.886 & 178.3710. Furthermore, the wax supplier provides for regular testing of the wax to ensure that it meets the manufacture's safety and production requirements. (See Exhibits #1, #2, and #3)

Multi-step processing of wax provides clean, high quality products that are comparable to FDA requirements for use in food applications and in food packaging. Fully-refined paraffin wax is a non-reactive, non-toxic, colorless mixture of hydrocarbons that is solid at ambient temperature, thermoplastic in nature, and effective as a moisture barrier and clean-burning fuel. Food grade waxes are harder, with lower oil contents (usually less than an oil content of 1.0 mass percent or less), and white in color. The quality is determined by the extent of the refining process, the more refined, the less particulates are created when burned. Food grade wax produces less smoke and

burns slower. Due to its very nature, few substances will chemically react with or bind to paraffin wax, thus making it a convenient and safe raw material to use in various applications. (See Exhibit #4).

The manufacturer also sets specific parameters for the wax compound used in beeswax ear candles. Properly made ear candles, like HCEC, do not contain 100% bee's wax and contain no soy wax, as these waxes drip excessively and are not as environmentally friendly as some may believe. (See Exhibits #5 and #6). To ensure against dripping, properly made ear candles either have 100% high grade food quality wax or if they are using beeswax, the compound mix ratio would be 10 parts of food grade paraffin wax and one part high-quality bee's wax.

The organic cotton muslin cloth, used in HCEC and represented by the Petitioner, also meets self-imposed manufacturing standards for quality and for consumer safety. The cotton muslin cloth that is used in the HCEC is unbleached and in a minimally-processed state with the least amount of chemicals being used in its manufacturing process. The manufacturing process provides an organic and thicker material that does not have dyes, starch or bleach. The cloth in each HCEC is cut from, clean cotton, preferably organic, and uses approximately 53 square inches of cloth to increase the burn time while at the same time reducing the amount of particulates being released while burning the candle. (Exhibit #7)

To ensure additional safety, each HCEC is marked with a colored strip that is one half (½) inch wide and imprinted with the words, "Stop Here". The strip label instructs the user exactly how far to burn the candle down. At this burn line label the user extinguishes the flame into water. (Exhibit #8).

An additional safety feature is the safety tip, which is the only patented safety tip in the United States. (Exhibit #9). The Petitioners patented safety tip is inserted into the HCEC after it has been handcrafted. (At which time, the product makers are also trained to identify any potential issues with the structure of the ear candle.) The safety tip is specifically designed and manufactured to fit snugly into the tapered end of the candle. The mounting teeth on the safety tip, locks the tip into place thereby securing its placement and intended function. The safety tip

prevents any possible debris or residue from entering the ear. The air flow continues through the funnel or tube above the tip as noted in Exhibit 9, providing a slower burn and safer product use.

Each package of HCECs includes step-by-step instructions for proper consumer use and safety precautions. (Exhibit #10) The instructions and precautions are in clear narrative form and available on the Internet. Ear candles are intended to be and are marketed as modalities for natural wellness rather than for the treatment, diagnosis, prevention, cure or mitigation of any disease or to affect the structure or function of the body. For this reason, the descriptions of HCECs that appear in their labels and labeling comply with the law. In addition, instructions for use and educational materials conveying the information about properly made ear candles, which are not subject to the provisions of the FDCA governing medical devices, as set forth below in this petition, also comply with the law. Petitioner firmly believes that HCECs website should be allowed to freely provide demonstration videos online to show interested consumers about the proper and safe use with proper and clear instructions instead of having consumers rely upon 'YouTube' videos from other sources that can provide inaccurate information and directions. The instructions can clearly convey that HCEC are only to be used in the outside opening of the ear.

The packaging, instructions, and promotional materials clearly and conspicuously state that HCEC are intended only to be used for personal relaxation, stress reduction, balancing and/or wellbeing. The product packaging, instructions, and promotional materials clearly and conspicuously state that ear candles are not intended for removal of ear wax and are not a cure for any disease or infection. Petitioner believes that if there was a uniformity of relevant product information and an understanding of claims being circulated on the internet, in particular, that there would be a clear consensus that HCEC are not medical devices. Petitioner believes that there is a direct correlation between the fact that HCECs has no Adverse Events Reports (AERs) or liability claims (unlike some product manufacturers) because of their quality standards, safety features and clear, concise, instructions.

Additional comprehensive instructions and information should be allowed to be provided on the manufacturer's website, which may answer additional consumer questions and provide

additional information for the product's application. The website-needs to seek to freely communicate and educate the public about ear candles and to thereby eliminate misnomers about ear candles (i.e., the myth that ear candles are used for removing ear wax). (Exhibit #11)

3. Ear Candles Are Not "Devices"

Under FDCA § 21 U.S.C. 321(h) "device" is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

> (1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) Intended to affect the structure or any function of the body of man or other animals, and
>
> Which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

HCECs are not designed, manufactured, distributed, or sold as a medical instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article. The product is not made to, does not, and cannot physically perform any functions as a medical "device."

HCECs also fail to fall within the meaning of a "device" under 21 U.S.C. § 321(h) because: (1) HCECs are not recognized in the official National Formulary or the U.S. Pharmacopeia, or any supplement to that publication; (2) HCECs are not intended to diagnose, cure, mitigate, treat, or prevent disease; (3) HCECs are not intended to affect the structure or function of the body, and (4) do not achieve the product's intended purpose through chemical action, and (5) are not metabolized to achieve a medicinal purpose.

Petitioner uses and believes HCECs to be a natural calming and energetic modality leading to improved wellness via stress reduction and relaxation principles. HCECs are relaxing to the Petitioner and encourage a synergistic wellbeing. Many people, including Petitioner, find ear candles to be a useful and beneficial part of their effort to maintain such synergistic balance. Petitioner does not believe that HCEC cures or treats any disease or illness but rather encourages Petitioners body to relax which provides the opportunity for the body to naturally improve its own wellbeing through a synergistic and holistic approach. Petitioner does not believe or support that there is a medicinal purpose for HCEC or that the product should be used in a medical context.

HCEC are not intended to, and Petitioner makes no claim that the HCEC product is intended to, diagnose, mitigate, treat, cure, or prevent disease. *See* 21 C.F.R. § 101.93(g)(2). Labeling and promotional materials for HCEC state that ear candles are used for relaxation, stress reduction, and/or a spiritually energetic balancing of the mind, body and spirit, which encourages synergistic wellbeing while reducing stress.

Furthermore, HCEC are safe for consumers when used according to the instructions. HCECs pose a significantly lower risk of harm and injury than other products on the market involving combustion or other forms of heat. For example, the temperature of the center of the flame of a household candle averages are 1400°C. Whereas the average flame of the ear candle is at 700 to 900 °C. This is due to its laminar diffusion flame. The fuel comes from the wax vapor, while the oxidizer is air; they do not mix before being introduced (by *diffusion*) into the flame zone.

HCEC has had no liability claims of any type, including claims for physical injuries, in the entire 21 years that it has been in business.

4. Foreign Markets and Implementation Of General Safety Protocols

Petitioner declares and reiterates that HCEC do not fall within the scope and purview of FDA statutes and regulations regarding medical "devices." It is worthwhile to consider examples from other countries. Notably, HCECs are legally sold in markets outside of the United States, where

pre-approval for their sales is not required since they are not deemed to be medical devices. In markets outside of the United States, HCECs are held to a classification of General Safety Protocols for manufacturing, safety controls for ear candles and proper consumer instructions and information which are sufficient to provide reasonable assurance of their intended use and consumer safety. All safety protocol requirements can be and are reasonably observed by HCEC. HCEC has had no adverse events reports or liability claims in any other country.

Notably, as of August, 2012, the respective health agencies of Brazil, Australia, and the United Kingdom have all determined that ear candles and/or HCECs are not medical devices when no medical claims are made in connection therewith. In the U.K., the Medicines and Healthcare Products Regulatory Agency (MHRA) has determined that CE certification is no longer necessary, and since 2010, has not treated ear candles as medical devices requiring approval when no medical claims are made. Furthermore, after reviewing Harmony Cone's ear candle packaging and labeling, MHRA has specifically determined that Harmony Cone ear candles are not medical devices. (Exhibit #12.) Similarly, Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil recently ruled in 2012 that Harmony Cone's ear candles are for relaxation purposes only and, as such, are not medical devices and require no certification. (Exhibit #13.) Additionally, the Therapeutic Goods Administration of Australia has also determined that ear candles are for relaxation and wellbeing purposes, and as such, are only registered as "other therapeutic goods".[1] (Exhibit #14.)

In the European Union, HCEC is only subject to General Safety Protocols under Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety. The Directive imposes a general safety requirement on any product put on the market for consumers or likely to be used by them, including all products provided in connection with a service. In the E.U., a product that is intended to have a toiletry or cosmetic purpose is not a medical device if the principal intended purpose is not a medical purpose, even if the

[1] "'Other therapeutic goods' are therapeutic goods that are not regulated specifically as medicines or medical devices." Australian Government, Department of Health and Aging, Therapeutic Goods Administration (http://www.tga.gov.au/industry/otg.htm).

product may be used for the prevention of disease as a secondary purpose.[2] Examples include but are not limited to tooth brushes, hand cleansing wipes, or hot water bottles.[3]

In the E.U., a safe product is one which poses no threat or only a reduced threat in accordance with the nature of its use and which is acceptable in view of maintaining a high level of protection for the health and safety of the consumer.

In the United States, HCEC is cognizant of and maintains the Quality (control) System of an ear candle manufacturer as an indication of the required end result rather than specifically prescribing how a manufacturer is to comply with any new regulations. *See* FDA, Center for Devices and Radiological Health, Medical Device Quality Systems Manual: A Small Entity Compliance Guide (Dec. 1996). New regulatory standards do not need to prescribe in detail how a manufacturer must produce a specific 'device' or in this case the ear candle product. *See* F.R. vol. 61, No. 195, at 52602-52603 (Oct. 7, 1996). Any Quality System regulation need only specify general objectives rather than methods, since one method would not be applicable to all manufacturers. *See* FDA Guide to Inspections of Medical Device Manufacturers, at page 2 (Dec. 1997).

The current restrictive actions of Respondent FDA are in restraint of and have adverse impacts upon foreign trade, especially trade with countries with which the United States has free trade agreements, such as the Uruguay Round Trade Agreement, and adversely impacts Petitioners' patent and intellectual property rights.

5. Ear Candles Are Safe Modalities for Natural Wellness

HCECs are properly designed and manufactured and when used only for their intended purpose, are safe for holistic practice and in-home use. When an ear candle is made with high quality wax and a 1 to 10 ratio composition of beeswax to food grade wax, high quality muslin cloth

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[2] *See* "Medical Devices: Guidance Document," European Commission, MEDDEV 2. 1/1, April 1994, at pages 3, 5, 6 ("Definition of 'medical devices'") (http://ec.europa.eu/health/medical-devices/files/meddev/2_1-1___04-1994_en.pdf).

[3] *Id.* at 5.

(preferably organic), the patented safety tip, and the "Stop Here" demarcation all work to ensure maximum user safety. Properly made and used ear candles, like HCEC, are considerably safer than a hot water bottle, which is not a medical device.

Contrary to misnomers, HCECs are not made for or intended for use in removing earwax, also known as cerumen. Rather, HCECs are made for and intended to be used for relaxation, stress reduction, and part of a synergistic wellbeing. Similar to some therapeutic mental control practices, relaxation techniques (meditation, deep breathing, mindfulness, time-outs, self massage, music, sunshine, etc.) or some types of physical exercises, HCECs relaxe the body's subtle energy field which, in turn, allows the body to relax into a state of readiness to experience balanced awareness, wellbeing and a reduction in stress. This is sometimes called relaxed wakefulness which is similar to meditation. HCECs are a means to facilitate relaxation and thus a pathway to a more complete and secure state of mind, body, and spirit.

HCECs are not intended to and do not create any vacuum within the outer ear opening. The product does not promote or cause the evacuation of earwax (cerumen), and the product does not extricate any other material substances from the ear. (Exhibit #15)

Contrary to some common misperception, HCECs are not a fire hazard. HCECs are safe when used as instructed and with a modicum of common sense. To date, there has only been one fire purportedly caused by an ear candle (not an HCEC) use. (Exhibit #16) Ear candles are used with someone being awake and aware and are easily extinguished or put out with a small amount of water. In contrast, regular household candles are responsible for an estimated 23,600 residential structure fires each year and cause 1,525 civilian injuries, 165 fatalities, and $390 million in direct property loss. (Exhibit #17). This data was published by the US Department of Homeland Security and the US Fire Administration, based on fire data from 2002 to 2004.

Furthermore, Adverse Events Reports (AERs) for ear candles are both rare and questionable as substantiating evidence. Notably, HCEC has had no AER's. Of over approximately 20,000,000 ear candles that have been sold, there have been only four (4) substantive AERs—where there may have been a nexus between the adverse event and the ear candle worthy of investigation.

Assuming that these alleged injuries actually occurred, and that the harm or injury is shown to be attributable to ear candle uses, which has not yet been determined, this presents an injury rate ratio of only .00000002. Furthermore, FDA's earlier finding that ear candles are unsafe may be based upon misleading data, inadequate or erroneous information, or insufficient evidence, as stated below. (Exhibit #18, #19 and #20).

In FDA's Adverse Event number 396380 (dated April 12, 2002), after purportedly using a Lee's candle, the unknown complainant reported "that ear wax candles are dangerous to use." There was no indication of any injury or any reason for the conclusion that ear wax candles are dangerous. (Exhibit #21)

In FDA's Adverse Event number 760688 (dated August 21, 2006), after using a Wallys Ear Candle, the allegedly injured person claimed that she felt a burning sensation in her right ear. The purported consumer and user did not file any claims with or against the manufacturer of the ear candle manufacturer and the candle was not available for examination by the reporting doctor or by the FDA. The reporting doctor alleged that after a "follow-up one week later the tympanic membrane was examined and a perforation was identified." (Exhibit #22)

In FDA's Product Problem Report number 1013928, (dated August 10, 2007), the opinion that the reported product was "life threatening" is unsupported by sufficient facts and evidence. "Sinusitis" or "earwax" are not generally associated with "life threatening" events. The manufacturer of the product is unknown as well as the purported person or persons who advertised the product to "cure sinusitis and clean earwax." There is no indication that the allegedly injured person followed any instructions for use of the product or used common sense with regard to using it. The reporting party did allege that they were burned from using this product. As stated in the report, the complaining party was not a health professional, did not report the matter to FDA, and did not report the matter to the manufacturer. (Exhibit #23)

In FDA's Adverse Event number 97032, (dated December 20, 2007), there is no indication that the allegedly injured person followed any product instructions for use or used the ear candle for its intended purpose. The complainant noted that her boyfriend had hot wax go into his ear and

burn a hole through his eardrum. According to the FDA's Adverse Events Report, there was no visit to a doctor, report sent to the manufacturer, nor any follow up with the FDA. The FDA report also indicates that the consumer used the ear candles to clear out ear wax but does not state that there was a representation that the product was intended to be used for that purpose. (Exhibit #24)

In FDA's Adverse Event Report and Product Problem Report number 1276183, (dated December 7, 2008), it is stated that the patient allegedly used the ear candle according to instructions on the package, and while using the product to "clean" their ears, had a hole burnt into his eardrum by an ear candle. The complaining party did not return the ear candle to the unnamed manufacturer or to the retailer. The ear candle was not available for evaluation. There is no clear indication whether the alleged wax residue was earwax (cerumen) or candle wax. The report-was not sent to the manufacturer. The AER indicates that the patient underwent surgery; yet no product liability claims were filed against the unnamed ear candle manufacturer. (Exhibit #25)

There is only one documented case of a burned ear drum. This report was purportedly documented by Richard Harris at Brigham Young University where a 55 year old female lay midwife had used ear candles and the wax dripped into the ear canal and burned the tympanic membrane. She had been using ear candles to remove cerumen from her ear "for a number of years." It is unclear what information or instructions were given on the product package, and whether or not representations were made therein that the ear candle product was actually produced and marketed to remove cerumen (earwax). (Exhibit #26)

In FDA's Adverse Event number 102991 (dated June 24, 1997), there is no indication that any ear candle was used, much less any injury suffered. This report does not seem to qualify as an actual Adverse Events Report (AER) or as a Product Problem Report (PPR).

These few examples of Respondent agency's reports on ear candles as a product and as related to adverse events are not sufficient to warrant the actions of the FDA to completely prohibit the manufacturing, distribution and sale of ear candles to consumers.

Therefore, upon closer review of the few AERs and PPRs on file in the agency records, some common themes emerge:

1. There is no clear indication that these consumers actually followed instructions for product use.
2. There is no clear indication that these consumers used the ear candle for its intended purpose.
3. There is some indication that the ear candles were used for unintended purposes, namely, removal of cerumen (earwax).
4. There is no clear indication that these consumers attempted to contact any manufacturer allegedly involved.
5. There is no clear indication that these consumers filed any claims or commenced any suits for damages.
6. There is no clear indication that Respondent FDA initiated and completed a follow-up investigation into any AER report before relying upon the agency report records; and,
7. Ear candles are not "life threatening" and did not cause any permanent physical damage or impairment to these few consumers when the product was improperly used.

The safety of the HCECs has never been an issue. The limited number of Adverse Events Reports, as well as indications therein that the allegedly injured persons failed to use the ear candles for their intended purpose and failed to follow directions for use, suggest that ear candles are a safe modality for natural comfort, wellbeing, stress reduction, and happiness when used for their intended purpose and when instructions for use are followed. HCECs are not medical devices or medicine and should not be used as medical devices or medicine. The above examples of FDA's Adverse Events Reports, while lacking acceptable evidentiary support, indicate that the purported injuries likely resulted from inferior raw materials or failure to properly employ safety protocols. Therefore, general safety protocols, raw material standards, safety tips, burn line labels, proper explanation, and proper marketing are all key to protecting the consumer.

6. Ear Candles Manufacturers and Current Good Manufacturing Practices.

Responsible manufacturers of properly made ear candles, like HCEC, whose products are sold in foreign countries and the USA, can and do implement basic general safety protocols to ensure consistent quality and safety measures and other protocols for safe consumer use of HCEC products. HCEC, as a manufacturer can and does employ a thorough and well-documented system of good manufacturing practices that includes at a bare minimum implementation and oversight of the following examples: Customer complaint forms for Consumer Safety and Injury (Exhibit #27), and Marketing and Education Issues Complaint Forms (Exhibit #28) as most complaints are about the misconception that ear candles pull wax out of the ear.

7. Ear Candles Comply with Labeling Requirements

HCECs are not medical devices or medicine and are properly labeled and described as they contain proper consumer instructions, factual information, manufacturer location, and the list of material ingredients. Labeling containing general safety protocols is adequate for a non food items, non medical devices or non drugs. This is more than adequate when compared to a common household candle that is used for aromatherapy, mood ambiance or for relaxation purposes. (Exhibit #29)

C. CONCLUSION

HCECs are not "devices" within the meaning of FDCA, § 201(h) because: (1) ear candles are not recognized in the official National Formulary or the U.S. Pharmacopeia, or any supplement to them; (2) ear candles are not intended to diagnose, cure, mitigate, treat, or prevent disease; (3) ear candles are not intended to affect the structure or function of the body, and (4) do not achieve the product's intended purpose through chemical action, and (5) are not metabolized to achieve that purpose. As such, HCECs do not fall within the definition, scope and purview of the statute and regulatory scheme on "devices."

Properly made and used ear candles pose no threat of harm or injury to the physical body of the consumer or to their health.

Even Eric Mann, M.D., Ph.D., clinical deputy director of FDA's Division of Ophtlamic, Neurologic and Ear, Nose, and Throat Devices states: "FDA believes that there is no valid scientific evidence for any medical benefit from their use." Petitioner agrees that ear candles are not medical devices as they are not intended to be used for medical purposes. (Exhibit #30)

Incorrect information (obtained from misinformed persons and organizations) about the intended use of ear candles should not be used in determining whether properly made and properly marketed ear candles are medical devices.

Modern medical practice has adequate examples of synergistic placebo effects that benefit some people without exposing the consumer to harmful or injurious risks. Modern medical practice also has adequate example of FDA approved drugs and devices that were misused based upon the consumer's misguided or uninformed beliefs. Personal beliefs and choice of actions, whether informed or uninformed, are natural and personal liberties. Providing consumers with carefully made products and adequate information on the intended and proper use of HCEC's product substantially reduces any potential risk while allowing consumers the right to choose.

Petitioner, Kevin Boulton, exercised freedom of choice and has used and represented HCECs for several years without any adverse impacts or consumer injury events. In addition, Petitioner holds the valid and recognized patent on a safety tip for ear candles that is intended to eliminate or greatly lessen any likelihood of consumer risk. Petitioner will be adversely impacted by any FDA decision and/or order to cease and desist all production, manufacturing and sales of ear candles. As such, Petitioner has a substantive interest and standing in this matter.

Ear candles, like HCEC, when properly designed, manufactured, marketed, and used – are safe for consumer use. HCECs ear candles are designed and intended to and should not be used to diagnose, cure, treat, or prevent disease; and are not intended to affect the structure or function of the body; Therefore, ear candles are not "devices" under FDCA § 201(h).

In addition, no ethical manufacturer represents ear candles to have the capacity to cure or treat any disease or to affect the structure of functions of the physical body of man or other animals. The product is not designed or intended to remove cerumen, also known as earwax. Proper product labeling, information brochures, and demonstrations would eliminate those misnomers and promote safe consumer use.

Petitioner avers that Ear Candles are not designed or intended "for a use in supporting or sustaining human life or for a use that is of substantial importance in curing or preventing any impairment of human health, Petitioner avers that ear candles do not present a potential or unreasonable risk of illness or injury for those who properly use said product. The intent of proper ear candle use is to facilitate a traditional relaxation technique (allowing a personal synergistic balance within the mind, body and soul), a reduction of stress, calmness and peace in ones' own energy field, which can and does promote a sense of comfort, wellbeing, and happiness. Petitioner uses HCEC since petitioner is endowed by the Creator with certain unalienable Rights, that among them are Life, Liberty and the pursuit of Happiness. HCEC are a part of this pursuit.

Petitioner reiterates his request for a public hearing on the matter contained in this Citizen Petition.

Respondent FDA should consider all relevant facts and alternatives when making any decision regarding the manufacturing, marketing, distribution, and sales of ear candles.

D. ENVIRONMENTAL IMPACT

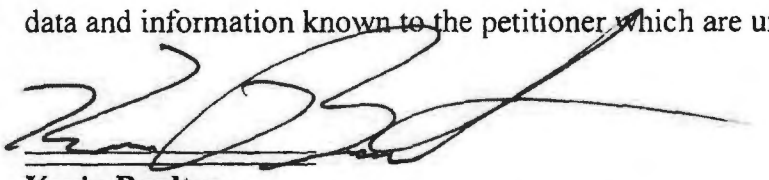
There will be no known adverse environmental impact from the granting of this petition.

E. ECONOMIC IMPACT

There will be a positive economic impact from the granting of this petition by increasing awareness and creating a safer product for the marketplace.

F. 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.



Kevin Boulton,
For himself and representing the families Harmony's Candles

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Sui Juris, Jus Soli, Jus Sanquinis, Jure Divino

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James Turner
Swankin & Turner
1400 16th St. NW
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