January 16, 2014

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

CITIZEN PETITION

The undersigned submits this petition to respectfully request that the Commissioner of Food and Drugs instruct the Center for Devices and Radiological Health (CDRH) to refrain from taking any form of further administrative action that directly, or indirectly, affects a specific type of consumer product that CDRH (1) acknowledges is not a “device,” as this term is defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FDCA), and (2) refers to as “Personal Sound Amplification Products.” As part of this request, I believe that it is appropriate and necessary for the Commissioner to instruct CDRH to withdraw its November 7, 2013 draft guidance document entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products--Draft Guidance for Industry and Food and Drug Administration Staff” and cease all attempts to expand the scope of the generic type of device known as “hearing aid” as this term is used in 21 CFR 801.420, 21 CFR 801.421 and Subpart D of 21 CFR Part 874 – Ear, Nose and Throat Devices.

While I believe that aspects of CDRH’s current guidance document entitled “Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on February 25, 2009, exceeds the authority of the Food and Drug Administration (FDA) in that it negatively impacts the availability of a consumer product, the release of this guidance document has particular historical significance in that for the first time since enactment of the Medical Device Amendments of 1976 to the FDCA, FDA acknowledged that not all wearable sound amplifiers fall within FDA jurisdiction. It is on this basis that I have elected not to request that the 2009 guidance document be withdrawn at this time.

A. Action requested

The Petitioner requests that the Commissioner order CDRH to:

1. Refrain from taking any form of further administrative action that directly, or indirectly, affects a specific type of consumer product that CDRH (1) acknowledges is not a “device,” as this term is defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FDCA), and (2) refers to as “Personal Sound Amplification Products;” and

and cease all attempts to expand the scope of the generic type of device known as “hearing aid” as this term is used in 21 CFR 801.420, 21 CFR 801.421 and Subpart D of 21 CFR Part 874 – Ear, Nose and Throat Devices.

B. Statement of grounds

The factual and legal ground on which the petitioner relies is presented below. The basis for the Petitioner’s request relates to limitations on FDA authority that are being disregarded; a misapplication of the concept of “intended use;” no scientific evidence supporting CDRH’s actions; a lack of transparency; and issuance of a misguided draft guidance document for public comment. My perspective on all of these issues is presented below.

CDRH ACTIONS APPEAR IN DISREGARD OF THE LIMITATIONS ON FDA AUTHORITY

The Food and Drug Administration (FDA) derives its authority from the Federal Food, Drug, and Cosmetic Act (FDCA) and, in the case of medical devices, this authority originates from the definition of a device found in section 201(h) of the FDCA. The definition of device is as follows:

\[(h) \text{ The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—}\]

\[(1) \text{ recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,}\]

\[(2) \text{ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or}\]

\[(3) \text{ intended to affect the structure or any function of the body of man or other animals, and}\]

\[\text{which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.}\]

In the context of what FDA commonly refers to as “hearing aids,” it is interesting to consider these products in the context of the FDCA definition of a “device.” While they are universally accepted to be instruments, apparatus, implements, machines, or contrivances, it can be argued that hearing aids do not fit within the remainder of the statutory definition. They are not recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them. If “hearing impairment” is the
condition for which they are used, they are not used in the diagnosis of the condition, nor can they cure, mitigate, treat or prevent a disease that contributes to hearing loss. Further, hearing aids do not affect the structure or function of the body of man. While some interested persons may take the position that hearing aids mitigate hearing impairment and/or affect the function of the human body, neither is true. Hearing aids do not lessen the severity or intensity of hearing impairment; they simply amplify sound to compensate for the hearing impairment, no different than a hearing impaired individual requesting someone to speak louder, or turning up the volume on a radio or television. Likewise, the function of the human ear is unaffected by wearing a hearing aid. While a hearing-impaired individual may find it easier to function while wearing a hearing aid, the true benefit may actually be felt by others in the immediate vicinity of the hearing-impaired person. In reality, society is often the real beneficiary of any individual’s ability to personally amplify sound to their liking.

The purpose of discussing “hearing aids” in the context of section 201(h) of the FDCA is not to argue that they are not within FDA’s jurisdiction, but rather to point out that the agency needs to be very careful and deliberate when exercising its authority in this area. While I do not object to reasonable FDA regulation of wearable sound amplifiers, designed and labeled for use in patients diagnosed with hearing impairment, any expansion of FDA regulation of wearable sound amplifiers beyond these very limited circumstances may be subject to legal challenge, but more importantly places FDA directly between consumers and consumer products that simply allow them to have some limited control over the amplification of sounds in their immediate environment.

A review of the history of FDA regulation of hearing aids reveals the specific circumstances that have justified the imposition of FDA regulatory requirements. Dating back to March 1974, when the Secretary of Health Education and Welfare (HEW) established the Intradepartmental Task for on Hearing Aids through the notice and comment rule-making associated with the promulgation of 21 CFR 801.420 and 21 CFR 801.421 in February 1977, the focus was on the availability of hearing aids from a “hearing healthcare team” comprised of physicians, audiologists and hearing aid dispensers; all focused on meeting the needs of hearing-impaired individuals. It is obvious from the regulatory history that FDA’s interests are ensuring that patients with hearing impairment, as determined by a physician, audiologist or hearing aid dispenser, were fitted with hearing aids that were likely to compensate for their medical condition. Throughout the regulatory history, there is simply no evidence that FDA considered the general availability of wearable sound amplifiers, or even determined that it had the authority to regulate such products, until February 2009 when the agency issued a guidance document that differentiated personal sound amplifiers from hearing aids and stated that personal sound amplifiers are not medical devices, subject to FDA regulatory requirements.
CDRH ACTIONS ARE BASED ON A MISAPPLICATION OF THE CONCEPT OF INTENDED USE

It is critically important for the Agency to understand that FDA’s definition of “hearing aid” focuses on persons with impaired hearing, as do the words chosen by the agency to identify a hearing aid. If this was not the case, an innumerable number of consumer products would fall under FDA jurisdiction. In fact, rapid advances in technology have resulted in an explosion of consumer products that are “wearable” sound amplifiers, with many appearing identical to “hearing aids.” Just consider the myriad of wearable Bluetooth® products that amplify sound from audio and video sources and cell phones. These products all afford users the opportunity to amplify and control sound, including many users with decreased hearing.

If FDA-regulated hearing aids are intended for persons with impaired hearing, Agency scientists and clinicians may ask how a person knows that they have impaired hearing and are eligible for an FDA-regulated hearing aid. The condition is either detected by a member of the hearing healthcare team, or is confirmed by a member of the team confronted with a person suspecting that they have acquired a hearing loss. In either case, the FDA regulatory paradigm ‘strives to ensure’ that hearing healthcare team members provide their patients with hearing aids that can compensate for their specific hearing loss and, in the dispensing process, do not overlook medically treatable diseases or conditions. This measure is accomplished through FDA’s hearing aid-specific labeling regulations, and not FDA premarket review, as hearing aids are regulated as class I devices, exempt from premarket review. Through the labeling regulations, FDA mandates requirements for “professional and patient labeling” and “conditions for sale” for hearing aids. While the merits of these regulations deserve investigation and their effectiveness can be debated, they unquestionably impose substantial regulatory burden on hearing aid dispensers and patients, and contribute to the cost of today’s hearing aids. While I am not challenging the cost/benefit of 21 CFR 801.420 and 21 CFR 801.421 in this petition, any indiscriminate expansion of the regulatory burden associated with these regulations on manufacturers and distributors of

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1 Refer to 21 CFR 801.420(a)(1)
2 Refer to 21 CFR 874.3300
products that are not medical devices is a substantial part of the foundation for this petition.

Given that it is not design or technology that differentiates FDA-regulated and unregulated wearable sound amplifiers, but rather “intended use,” it is critical that clear criteria exist to define what is regulated and what is not regulated. The FDA concept of intended use is defined in 21 CFR 801.4, and in this context involves “the objective intent of persons responsible for labeling devices.” Although labeling is mentioned in this regulation, “objective intent” is to be determined from virtually anything that a manufacturer or distributor does or says regarding the use of a “device.”

In the case of consumer products, 21 CFR 801.4 has no applicability. In fact, even within the domain of FDA regulated devices, 21 CFR 801.4 only applies to 21 CFR 801.5, 21 CFR 801.119 and 21 CFR 801.122. While FDA often cites the definition of intended use in connection with wearable sound amplifiers, the regulation does not apply to consumer products, or to 21 CFR 801.120, 21 CFR 801.122 or 21 CFR 874.3300. For consumer products that may have a subset of users that use the product in relation to a disease or medical condition, the fact that this relationship is known cannot constitute evidence that the objective intent of the manufacturer or distributor triggers FDA regulation. It is this mindset within the agency that I find objectionable. For a reasonable outcome, there has to be evidence of the manufacturer’s or distributor’s intent for the product to compensate specifically for impaired hearing. While not entirely consistent with the intent of section 513(i)(1)(E)(i) of the FDCA, it may be appropriate for FDA to restrict any determination that the intended use for a sound amplifier is specific to persons with impaired hearing to the product’s labeling. Given that it is known that wearable sound amplifiers will be sold to some consumers with hearing impairment, it is inevitable that manufacturers and distributors of wearable sound amplifiers will engage in communications with hearing-impaired persons. It is just as unreasonable for FDA to determine that such communication with a hearing-impaired person constitutes evidence that the product is a “hearing aid,” as a similar communication between a golf cart manufacturer and a person with a disability establishes that the golf cart is a powered wheelchair (21 CFR 890.3860).

While the concept of “intended use” may have specific regulatory meaning, applying the concept in an unregulated environment can have untoward consequences. For example, closed captioning was initially intended for hearing-impaired persons. In this regard, the technology that automatically transcribes and projects communications could have fallen under FDA’s purview and been a regulated device. If the technology was subject to the same arcane requirements as hearing aids, its availability would have been restricted and consumers would have had to have a medical examination, or be given an opportunity to waive an examination, to have access to closed captioning technology. This regulatory paradigm would have stifled development of the technology to the point that consumers with normal hearing would not enjoy the benefits of the technology to understand actors’ accents or speech in a foreign language.
CDRH OFFERS NO EVIDENCE OF A PUBLIC HEALTH PROBLEM ASSOCIATED WITH THE COMMERCIAL DISTRIBUTION OF UNREGULATED WEARABLE SOUND AMPLIFIERS

While FDA prides itself on being an evidence-based regulatory body, CDRH has not presented any scientific evidence that suggests the existence of a public health problem associated the commercial distribution of unregulated wearable sound amplifiers. While the Center acknowledges that it has no authority over these products, unless intended for use by the hearing impaired, it has not presented any scientific evidence to support its attempt to redefine the line that differentiates regulated and unregulated products. The only basis that I have found that could justify the Center’s actions is revealed in the section entitled “CDRH ACTIONS LACKS TRANSPARENCY” (below).

If no evidence of a public health problem exists with unregulated wearable sound amplifiers, the Center should, at a minimum, demonstrate the public health benefit that regulation as a hearing aid will afford consumers. Without such evidence, it will be difficult to justify restricting product availability by requiring detailed and technical professional and patient labeling to accompany product, and insisting that purchasers have (1) medical evaluations, (2) an opportunity to sign a waiver, or (3) refuse to sign a waiver.

In accord with President Obama’s Executive Order 13563 -- Improving Regulation and Regulatory Review, it seems appropriate for CDRH to undertake a retrospective analysis of 21 CFR 801.120 and 21 CFR 801.122 to determine if they are “… outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.” Given that these regulations are over 35 years old, they are ideal candidates for retrospective analysis. Evidence that they do not represent reasonable and up-to-date regulation can be readily observed in the language appearing in the mandatory statement that all prospective hearing aid users must be afforded an opportunity to sign (21 CFR 801.421(a)(2)(iii)). The mere fact that a hearing aid is the only medical device where purchasers are expected to acknowledge (by signing a written statement) that the Agency has made a determination of what is in their best interest, suggests that these regulations are what the President envisioned when he issued Executive Order 13563 and, therefore, are prime candidates for retrospective review.

An additional perspective that puts the public health significance of hearing aids in context and further supports that 21 CFR 801.120 and 21 CFR 801.122 are prime
regulations for retrospective review, is the classification of standard air-conduction hearing aids. Following the FDA Modernization Act of 1997, FDA examined all class I devices that were subject to premarket notification (510(k)) requirements to determine whether they met statutory criteria for continuing to impose 510(k) requirements. For class I devices, the law mandated that they were exempt from section 510(k) unless the device is intended for a use which is of substantial importance in preventing impairment of human health or that it presents a potential unreasonable risk of illness or injury (a.k.a. the “reserved criteria”). Following a thorough evaluation, FDA concluded that hearing aids did not meet the reserved criteria and that they should not be subject to any premarket review. I believe that this conclusion supports my position that there is no basis to change any aspects of FDA’s current regulation of hearing aids, particularly by restricting access to unregulated wearable sound amplifiers, and that the current labeling regulations that apply to hearing aids should be examined and withdrawn, unless there is evidence that they contribute to public health.

Furthermore, FDA has a responsibility to consumers. FDA’s current regulation of hearing aids is burdensome and contributes to the high cost of hearing aids. The proposed guidance will restrict consumer access to products that might improve listening and communication ability in a variety of situations, and limit access to wearable sound amplifiers at affordable prices. It is ironic that FDA proposes to restrict the availability of wearable personal sound amplifiers at a time when the National Institutes of Health is awarding National Research Service Awards to investigate how to deliver more affordable and accessible hearing care (Calendar No. 128 113TH CONGRESS 1ST SESSION S. 1284 [Report No. 113–71]. The current hearing aid labeling regulations, as well as the proposed guidance document, are out of step with the current healthcare climate in the US. In addition, the Affordable Care Act encourages consumers to take more responsibility for their own and their family’s health and wellness. Quite simply, consumers want less regulation and more freedom to choose products that assist them in their daily lives and promote better quality of life.

**CDRH ACTIONS LACK TRANSPARENCY**

I believe that CDRH’s current efforts to expand the scope of hearing aids to encroach on the domain of wearable sound amplifiers have been spurred by special interest groups. I was present at a meeting when Dr. Eric Mann, then Chief of the ENT Branch, in CDRH’s Office of Device Evaluation (ODE), addressed the Hearing Industries Association (HIA) early in 2009. Dr. Mann stated that the Agency had “drawn a bright white line” between what the Agency regulates and what it does not regulate. He indicated that FDA regulates hearing aids; it does not regulate personal sound amplifiers. The term “PSAP” (personal sound amplification product) was first used by FDA in its 2009 Guidance for Industry and FDA staff. That document declared PSAPs to be non-medical products, which FDA does not regulate. Since that guidance was issued, there has been opposition to the sale of personal sound amplifiers from the hearing aid industry and from professional organizations.
I am aware that in April, 2012, the Counsel to the HIA wrote to Mr. Steven Silverman, Director of the Office of Compliance, CDRH, claiming “flagrant disregard” by multiple companies on the labeling of personal sound amplifiers. In that letter the HIA called for FDA to update the 2009 Guidance and “tighten and enforce the limits of claims” made by manufacturers of personal sound amplifiers. In August, 2012, the Academy of Doctors of Audiology, American Speech-Language-Hearing Association and International Hearing Society (collectively referring to themselves as “Hearing Health Organizations”) also sent a letter to Mr. Silverman asserting that vendors may be targeting consumers with impaired hearing, regardless of how they otherwise describe the product. Their letter stated, “We urge the FDA to make the guidelines mandatory, as well as provide additional examples of what constitutes PSAPs and to make it clear that such products should only be marketed to those who are not hearing impaired,” and they indicated a willingness to work with FDA in developing regulations, guidelines, and standards that will protect consumers. In June, 2009, the President of the American Academy of Audiology wrote to Dr. Eric Mann stating that the Academy believed an absence of regulation of wearable sound amplifiers “could lead to unsafe, careless, and ill-advised use of such devices, which could result in a detriment to the consumer’s overall hearing health.”

These are three examples of letters of which I am aware that were sent to FDA in response to the 2009 Guidance. While correspondence from industry stakeholders and professional groups is not unusual, it is inappropriate for FDA to act on such correspondence without making the correspondence, as well as any other bases for their actions, public. In reviewing the correspondence, I believe that the only valid point that any individual or group can make is regarding labeling. Any other comments are patently self-serving and are obviously intended to influence FDA to restrict the availability of legally marketed consumer products that may meet a user’s needs and expectations and to interfere with the free market rights of companies doing business legally and ethically within all regulatory guidelines. For the manufacturers of wearable sound amplifiers (including PSAPs and other assistive listening systems) that are not labeling their products as hearing aids or specifically marketed for use by hearing-impaired persons, any restrictions on how these companies describe and distribute their products is not under FDA jurisdiction and is unequivocally contrary to free enterprise.
THE CDRH DRAFT GUIDANCE IS MISGUIDED

It has been CDRH’s stated position that PSAPs are not for use by hearing-impaired individuals and through its recent draft guidance document, the Center is now expanding this position to further state that personal sound amplifiers “are not intended for everyday use in multiple listening situations.” To ensure that PSAPs are not used by hearing-impaired consumers, all consumers would have to undergo a medical evaluation; a step not even required to currently purchase an FDA-regulated hearing aid. Given that personal sound amplifiers are not devices under FDA jurisdiction, CDRH has no authority to restrict the frequency, duration, or environment in which PSAPs are intended to be used, or dictate how PSAPs are actually used by the consuming public. Furthermore, any limitations on the functionality of a personal sound amplifier are outside the agency’s jurisdiction and will only unnecessarily restrict consumers who may want to purchase a personal sound amplifier for any number of uses. Most importantly, the proposed narrower definition of what a personal sound amplifier can and cannot be used for restricts a consumer’s right to purchase a wearable sound amplifier for any of the situations listed in the draft guidance, irrespective of hearing ability.

The draft guidance adds language that significantly restricts the use of personal sound amplifiers. Note the differences (in bold italics) between the 2009 Guidance and the 2013 draft guidance.

PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss. Examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations). Examples of listening situations that are typically associated with and indicative of hearing loss include: difficulty listening to another person nearby, difficulty understanding conversations in crowded rooms, difficulty understanding movie dialogue in a theater, difficulty listening to lectures in an otherwise quiet room, difficulty hearing the phone or doorbell ring, or difficulty listening situations in which environmental noise might interfere with speech intelligibility. Products making these or similar claims should not be considered PSAPs. In addition, products that are sold as an “over the counter” alternative or substitute for a hearing aid should not be considered PSAPs. Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the FD&C Act. As such, there is no regulatory classification, product code, or definition for these products. Furthermore, there are no requirements for registration of manufacturers or listing of these products with FDA.
In generating the draft guidance document, CDRH fails to accept that listening ability in all situations can be improved with the use of a personal sound amplifier because the product improves *audibility*. Amplifying speech so that it is audible (and thus, more intelligible) is not just reserved for hearing aids or persons with hearing loss. Normal-hearing persons often want amplification ‘in difficult listening situations in which environmental noise interferes with speech intelligibility.’

**SUMMARY**

Wearable sound amplifiers and listening products are not medical devices. There are hundreds of unregulated wearable sound amplifiers available to consumers. Common examples include in-ear earphones and Bluetooth® headsets. Today’s smartphones with a variety of headsets have mobile applications (apps) that are available to amplify sound for any number of reasons a user chooses. These products have no limits on their functionality other than what is necessary to ensure consumer safety, similar to any other personal audio product.

The companies that sell personal sound amplifiers and assistive listening systems should be allowed to describe situations in which their products are effective, even if the situations overlap with the functionality of FDA-regulated hearing aids, as long as they do not label their products as hearing aids and specifically target hearing-impaired persons.

**C. Environmental impact**

(A) The Petitioner claims categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter, as well as an environmental assessment under 25.40 of this chapter.

**D. Economic impact**

While the Commissioner has not requested an assessment of the economic impact of CDRH’s actions, or my requests that the Center refrain from taking certain administrative actions and withdrawal a draft guidance document, it is my position that CDRH’s actions warrant the conduct of a formal Regulatory Analysis as described in Office of Management and Budget Circular A-4 dated September 17, 2003. Because of the significance of CDRH’s imminent regulatory actions, I believe that in accordance with Section 6(a)(3)(c) of Executive Order 12866, *Regulatory Planning and Review*, a thorough regulatory analysis would be very helpful and would contribute to the appropriate outcome. The basis for my assertion is as follows:

There is a rapidly growing industry for wearable technology of all kinds. These products promote wellness, which is good for consumers and good for the economy. If regulations suppress that growth, jobs and income will be negatively impacted.
Statistics on the National Institutes of Health (NIH) website indicate that an estimated 17% of American adults report some form of decreased hearing, with the average price of a digital hearing aid about $1500, and top-of-the-line devices costing $3000-$5000. On the same webpage, NIH reports that only one-fifth (20%) of people who could benefit from a hearing aid seek intervention. Reasons include the perceived versus actual benefits, cost, stigma, and value (benefit relative to price) of hearing aids, as well as the person’s accessibility to hearing healthcare.

A sizeable segment of the American population is unemployed. Most do not have the means to purchase expensive wearable technology. Better access to affordable products could lessen the burden on families, improve communication and potentially make it possible for someone to re-enter the workforce. Consumers might choose to use a personal sound amplifier on the job in addition to social and recreational settings. Job performance is better when listening and communication are improved.

Barriers to access to wearable sound amplifiers may create psychosocial problems, which can translate to economic impact. When communication is improved, people are less withdrawn, less irritable, less tense, depressed or lonely.

According to a 2005 national survey by the Better Hearing Institute (BHI), more than 31 million Americans in non-institutional settings acknowledged a hearing loss. Of those, only 37% were at retirement age. The majority is either school age or in the work force. A May, 2007 BHI report indicated that only 23% of hearing-impaired Americans are being helped with hearing instruments, which is the solution for 90-95% of people with decreased hearing. Of the 77% of people who do not want hearing aids, some might benefit from enhanced hearing in certain situations, much like reading glasses which are used throughout the day when needed.

Kirkwood reported on Hearing Health Matters.org that Bernstein Research reported a wholesale world market for hearing aids at $5.4 billion on sales of 10.8 million hearing aids sold in 2012; 29% of that figure was sold in North America. In March, 2013, the Bernstein group projected long-term growth of 3%-6%. An earlier report by iData Research (2011) indicated that the U.S. market for hearing aids plus audiology instrumentation was over $6 billion.

The personal sound amplifier industry is in its infancy and it is projected to grow. The battery industry also benefits from more consumer electronics products in use. FDA’s attempt to narrowly define and thus regulate a category of consumer products that provide personal sound amplification is a poor use of government resources. CDRH should cease the expenditure of all agency resources on activities related to products that are not under FDA jurisdiction (e.g., PSAPs) and focus its efforts on products that it does regulate (e.g., hearing aids) and prioritize its efforts based on public health significance and device classification (class I lowest and class III highest).
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.

Gail Gudmundsen, AuD

References: