March 7, 2022

Kevin Boulton
(b) (6)
[redacted]

Re: Citizen Petition – Docket Number FDA-2013-P-1297

Dear Mr. Boulton,

This letter responds to the above referenced citizen petition, received on September 30, 2013, and filed with the U.S. Food and Drug Administration (FDA or Agency) on October 25, 2013. In your petition, you request that the FDA issue a declaratory order recognizing that Harmony Cone Ear Candles (HCEC) as defined in the petition are not "devices" under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). In accordance with 21 CFR § 10.30(e), and for the reasons set forth below, we deny your petition as submitted.

I. Requested Action

Your petition presents information intended to support your proposal that the Agency issue a declaratory order finding that you have standing and that HCEC do not meet the statutory definition of devices under section 201(h) of the FD&C Act. You specifically note that the term "HCEC," as used in the petition, refers to "ear candles that are designed, manufactured, and marketed according to the following standards and other Harmony Cone Trademarks…." In the petition, you describe yourself as a regular user of HCEC, as "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," and that you "represent[] the families of Harmony Cone Ear Candles and handcrafted HCEC products." You additionally state that you have "regularly used HCEC for over twelve years and intend[ ] to continue using HCEC for personal comfort, as a relaxing technique and for a sense of wellbeing." Your petition further notes that, "(l)abeling 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." You also request a public hearing on your petition and a temporary stay on any regulatory enforcement action against any HCEC manufacturer, distributor, or seller while the Agency considers your petition.

II. Decision Summary

A. Statutory and Regulatory Requirements

Section 201(h) (21 USC § 321(h)) of the FD&C Act defines a "device" as an instrument,

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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. The term "device" does not include software functions excluded pursuant to section 520(*o*) of the FD&C Act.

FDA's regulations specify that the term "intended uses" or similar words refers to "the objective intent of the persons legally responsible for the labeling of an article (or their representatives)." 21 CFR § 801.4 states that:

> The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for a device approved, cleared, granted marketing authorization, or exempted from premarket notification based solely on that firm's knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

FDA's regulations governing citizen petitions state that any person may petition the Agency to take or refrain from taking any form of administrative action, and that the Commissioner shall rule upon each petition that is properly filed, "taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by the statute." 21 CFR §§ 10.30(a), (b)(3), (e)(1).

B. Rationale for Decision

As an initial matter, it is not necessary for the Agency "to issue a declaratory order finding that Petitioner has standing." Any person (including a person who is not a citizen of the United States) may file a citizen petition. *See* 21 CFR § 10.30(a). To the extent that your petition requests that the Agency recognize your standing in federal court, that would be outside the scope of FDA's citizen petition regulation.

Second, in response to your request that FDA issue a declaratory order finding that HCEC do not meet the statutory definition of devices in section 201(h) of the FD&C Act, FDA denies your petition because the Agency is declining, at least at this time, to use FDA's limited resources to address your request, as discussed in more detail below. In reaching this decision, FDA has taken into account the resources and the overall work of the Agency and the relative priority of the requested declaratory order. *See* 21 CFR § 10.30(e)(1). Given the scope of FDA's responsibilities, the Agency must make choices regarding how to use its limited resources, and it evaluates its options in terms of various factors, such as the public health benefit, statutory directives, other means that could address a matter, and the relative urgency.

As mentioned above, whether a product is a device within the meaning of section 201(h) of the FD&C Act depends on its intended use. In determining the intended use of a product, FDA considers any relevant evidence, including statements and circumstances surrounding the manufacture and distribution of a product, among other evidence. *See* Regulations Regarding "Intended Uses," 86 FR 41383, 41386 (Aug. 2, 2021). For example, the Agency may consider statements made by the manufacturer on the product's label, accompanying labeling, promotional statements, and advertising, among other sources. FDA may also find it relevant to consider how the manufacturer has modified its statements over time and what consumers understand about changes to the manufacturer's claims.

In this case, determining the intended use of HCEC would be a resource-intensive task. Determining the intended use of HCEC would likely entail considering the manufacturer's current and past statements about these products, consumer understanding about those statements, and any changes that have occurred over time. The Agency might also find it important to consider the circumstances in which HCEC are distributed and used to determine whether such activities provide additional evidence about the intended uses of HCECs, such as whether the intended uses of HCEC advertised on other websites may be imputed to the manufacturer. Although you provided information you believe is relevant to determining whether HCEC are devices, FDA would need to verify that information, and determine whether there is additional relevant information. Moreover, the information you submitted, even if accurate and complete, may have changed since you submitted it. In addition, regardless of a manufacturer's intent, a subsequent packer, distributor, or seller may have a different objective intent. All of this requires the Agency to devote additional resources that FDA believes are better used for other Agency work. Additionally, were the Agency to respond to this petition by issuing a declaratory order, the objective intent of the manufacturer and others may change after that. The declaratory order requested would also apply to a single product and so would not necessarily have broad implications. Other firms or users of other products may make similar inquiries for different ear candle products with different facts about their intended uses, and were FDA to address one product, it could be harder to decline similar requests, which would require the Agency to commit additional resources to this type of effort.

Given the scope of FDA's responsibilities and the relatively narrow public health impact of your petition because it is focused on the facts of a single product that could change over time, we believe it is better to use FDA's limited resources for more pressing public health matters and FDA's various legal obligations.

You also request that the Commissioner "temporarily stay any regulatory enforcement action" against HCEC during the pendency of your petition. Requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures. *See* 21 CFR § 10.30(k). The Agency also considers a request to not initiate enforcement actions to be outside the scope of a citizen petition, and consequently denies your request to stay any potential enforcement action against any HCEC manufacturer, distributor, or seller. The FDA notes, however, that the request is also moot, because it did not initiate enforcement relating to HCEC during pendency of the petition.

Finally, because FDA is declining to devote resources to determining whether HCEC are a "device," a public hearing on your request is similarly unwarranted. Nonetheless, as with all citizen petitions, the public was able to submit comments to the docket for this petition.

III. Conclusion

For the reasons discussed above, FDA is denying your petition requests.

If you have any questions, please contact Mr. Madhusoodana Nambiar by e-mail at madhusoodana.nambiar@fda.hhs.gov or 301-796-5837.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2022.03.07 14:25:10 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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