Citizen Petition

Revised July 31, 2024

The undersigned submits this petition under Section 3060(a) of the 21st Century Cures Act (Cures Act) section of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to take action to enforce proper regulation of "wellness" devices.

A. Action Requested

The undersigned requests the Commissioner to take the following actions:

1. Enforce Regulation:

Ensure that ALL neurostimulation wellness products claiming to “cure” or “treat” medical conditions are subject to the same regulatory standards as FDA approved neurostimulation medical devices.

Neurostimulation wellness products are a category of electronic devices designed to deliver electrical or magnetic stimulation to the nervous system with the objective of promoting general well-being or addressing certain non-medical conditions. These devices often claim to enhance mood, improve sleep quality, reduce stress, boost cognitive performance, and increase relaxation.

Some neurostimulation wellness products may claim benefits for conditions like anxiety, depression, or pain management, although these claims are not supported by clinical evidence.

These products are often marketed for personal use and are typically available without a prescription. However, wellness neurostimulation products are distinct from FDA approved neurostimulation devices used in clinical settings. The latter which are rigorously tested and approved for treating specific medical conditions.

2. Remove Non-Compliant Products:

Remove from the market any neurostimulation wellness products that are making unsubstantiated medical claims. Neurostimulation wellness products *may* enhance well-being and *may* help to manage minor conditions. However, due to their varying levels of scientific support and regulatory oversight, consumers are put in a position where they must exercise caution and critically evaluate claims made by manufacturers.

3. Amend Advertising Practices:

Require companies selling neurostimulation wellness products to amend their advertising and promotional materials to eliminate any false or misleading medical claims.

B. Statement of Grounds

This petition is submitted to highlight industry concerns regarding the misbranding and sale of neurostimulation wellness products in the United States that make false and misleading medical claims. Specifically, devices such as auricular Vagus Nerve Stimulation (aVNS), Transcranial Direct Current Stimulation (tDCS), and Cranial Electrotherapy Stimulation (CES) which are currently marketed as capable of curing or treating serious medical conditions, despite lacking FDA approval or clearance for

these claims. These products are easily accessible online and heavily promoted on social media platforms like Meta/Facebook and Instagram, reaching a broad audience without adequate regulation.

According to Section 201(h) of the Food, Drug & Cosmetic Act, a medical device is defined as any instrument, apparatus, implement, machine, or related article intended for use in diagnosing, curing, mitigating, treating, or preventing disease in humans. Therefore, ALL neurostimulation products or devices making therapeutic claims should fall under this definition and should be regulated accordingly.

Representative companies that comply with the U.S. Code of Federal Regulations (CFR) have demonstrated, or are in the process of demonstrating, that their products are safe and effective for the intended uses. These companies adhere to rigorous performance testing, including EMC/electrical safety testing, shelf-life testing, software validation, and biocompatibility testing, ensuring their devices meet FDA-recognized regulatory standards.

We urge the FDA to take decisive action to protect consumers by regulating these wellness products and enforcing compliance with existing laws and regulations.

C. Environmental Impact

Petitioner is categorically excluded from this requirement

D. Economic Impact

Economic impact information will be submitted upon request of the Commissioner.

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 that are unfavorable to the petition.

Daniel Powell (Jul 31, 2024 08:28 CDT)

Daniel Powell, CEO

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Enclosure: Original Petition dated 10/15/2023

24.07.31 Updated Petition Letter

Final Audit Report 2024-07-31

Created:	2024-07-31
By:	Kelly Jackson (kelly.jackson@sparkbiomedical.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAANQ8_ih5bNxMGKtVPUBjM1cP-TKK82Upy

"24.07.31 Updated Petition Letter" History

Document created by Kelly Jackson (kelly.jackson@sparkbiomedical.com)
2024-07-31 - 1:20:58 PM GMT

Document emailed to Daniel Powell (daniel.powell@sparkbiomedical.com) for signature
2024-07-31 - 1:21:55 PM GMT

Email viewed by Daniel Powell (daniel.powell@sparkbiomedical.com)
2024-07-31 - 1:26:19 PM GMT

Document e-signed by Daniel Powell (daniel.powell@sparkbiomedical.com)
Signature Date: 2024-07-31 - 1:28:18 PM GMT - Time Source: server

Agreement completed.
2024-07-31 - 1:28:18 PM GMT