December 15, 2024

Daniel Powell
Spark Biomedical, Inc.
18208 Preston Road
Suite D9 531
Dallas, Texas 75252

Sent via email to: daniel.powell@sparkbiomedical.com

Re: Docket Number FDA-2024-P-3761

Dear Petitioner:

This letter responds to your petition, dated July 31, 2024, that requests FDA: (1) "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"; (2) "Remove from the market any neurostimulation wellness products that are making unsubstantiated medical claims"; and (3) "Require companies selling neurostimulation wellness products to amend their advertising and promotional materials to eliminate any false or misleading medical claims." FDA sent you an acknowledgement letter on August 7, 2024.

We have carefully reviewed your petition and have interpreted your requests, enumerated above, to be requests for FDA to investigate types of devices such as auricular Vagus Nerve Stimulation (aVNS), Transcranial Direct Current Stimulation (tDCS), and Cranial Electrotherapy Stimulation (CES), communicate to those device manufacturers that they are not in compliance with the law, and remove noncompliant products from the market by initiating enforcement actions and related regulatory activities. Requests for the agency to initiate enforcement actions and related regulatory activity are not within the scope of FDA's citizen petition procedures. *See* 21 CFR 10.30(k); *see also* 21 CFR 10.30(b)(3) (limiting the scope of citizen petitions to FDA to requests to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action"); 21 CFR 10.3(a) (defining "administrative action").

FDA has interpreted 21 CFR 10.30(k) as covering not only situations where enforcement action is requested, but where related regulatory activities, such as investigations prior to the issuance of a Warning Letter or a recall, are required to determine whether subsequent enforcement actions may be taken. Such matters are within the discretion of the agency.[1]

Therefore, we are denying your petition as not within the scope of FDA's citizen petition procedures.

We appreciate the information that you provided. Such information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that we enforce. We take complaints seriously, and we will evaluate this matter to determine what follow-up action is appropriate. Decisions with respect to initiating enforcement actions are generally made on a case-by-case basis.

If you have any questions about this response, please contact Samantha Loh Collado of the Office of Policy at samantha.lohcollado@fda.hhs.gov.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2024.12.15 15:22:14 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health

[1] *See* Heckler v. Chaney, 470 U.S. 821, 835 (1985) ("The [FD&C] Act's enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised."). *See also* Administrative Practices and Procedures, Notice of Proposed Rule Making, 40 FR 40682, 40683 (Sept. 3, 1975) (preamble to proposed rule establishing FDA's citizen petition procedural regulations, stating that "any enforcement activity in preparation for or incidental" to the referral of apparent violations to United States attorneys for the institution of criminal and civil proceedings "is solely within the discretion of the Commissioner and is not subject to petitions or other action by interested persons outside the agency," and that "matters related to the agency's law enforcement role are not included" in the definition of "administrative action" under the citizen petition procedural regulations).