July 23, 2020

Kelly Roman
[redacted]

[redacted]

Re: Citizen Petition- Docket Number FDA-2020-P-0893

Dear Mr. Roman:

This is an interim response to the petition dated February 17, 2020, filed by the Food and Drug Administration (FDA) on February 18, 2020. In the petition, you requested:

1. Withdraw the Final Order regarding Cranial Electrotherapy Stimulator (CES) Devices (December 20, 2019; 84 FR 70003); and

2. Convene a new Neurological Devices Panel of the Medical Devices Advisory Committee to review all available valid scientific evidence of safety and effectiveness pertaining to CES devices, including evidence from direct current (DC) CES devices, also known as transcranial direct current stimulation (tDCS) devices intended to treat anxiety, depression and/or insomnia, so that the Panel may render a recommendation to FDA regarding the device's appropriate regulatory classification.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Joshua Chetta of our Office of Policy at (240) 402-4910.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2020.07.23 11:56:55 -04'00'

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