DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 20, 2020

Kelly Roman
Co-Founder & CEO
Fisher Wallace Laboratories, Inc.
515 Madison Avenue, 22nd Floor
New York, NY 10022

Sent via email to: kelly@fisherwallace.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requests the following:

(1) withdraw the Final Order regarding CES Devices (the "Final Order"), 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 CES devices, also known as transcranial direct current stimulation ("tDCS") devices intended to treat depression, anxiety and/or insomnia, so that the Panel may render a recommendation to FDA regarding the device's appropriate regulatory classification.

Your submission was received by this office on 02/18/2020 and it has been assigned docket number FDA-2020-P-0893. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2020.02.21 11:14:42 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)