November 12, 2019

VIA EMAIL AND OVERNIGHT MAIL

Blake Bevill, Medical Device Program Division Director
U.S. Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, FL
[redacted]

Attention: Allegations of Regulatory Misconduct Branch
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
WO Bldg. 66 RM 3523
10903 New Hampshire Ave
Silver Spring, MD 20993
CDRHDeviceAllegations@fda.hhs.gov

Re: Neurocore, LLC's Unapproved Medical Device

Dear Mr. Bevill:

We write to file a complaint with the U.S. Food and Drug Administration against Michigan-based "brain training" company Neurocore, LLC[1] for its marketing, use, and sale of unapproved medical devices.

Neurocore markets, sells, and uses neurofeedback equipment (a type of biofeedback device) to allegedly form and strengthen new brain connections and pathways ultimately resulting in the "non-invasive treatment" of "ADHD and ADD, stress disorders, anxiety, panic attacks, Asperger's, depression, headaches, migraines, concussions, some forms of memory concerns, and sleep issues."[2] *See* https://www.neurocorecenters.com/neurofeedback; https://www.neurocorecenters.com/neurofeedback-training. Thus its equipment is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h) because it is intended for use in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

While biofeedback equipment is a Class II device, it is only exempt from FDA premarket notification procedures "when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use."

See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5050; *see also* FDA Warning Letter to EEG Info, dated Aug. 16, 2012, available at https://www.fdalabelcompliance.com/letters/ucm319506. Not only does Neurocore's equipment fail to meet these conditions, but equipment similar to Neurocore's that is used solely to assist in the diagnosis of ADHD, rather than treat it, required premarket approval. *See* https://www.accessdata.fda.gov/cdrh_docs/pdf11/K112711.pdf.

Neurocore's In-Center Neurofeedback Equipment


Neurocore's At-Home Neurofeedback Equipment

See https://www.neurocorecenters.com/neurofeedback; http://www.neurocorecenters.com/blog/neurofeedback-at-home; https://www.neurocorecenters.com/blog/difference-between-biofeedback-and-neurofeedback.

For the foregoing reasons, TINA.org urges the FDA to open an investigation of Neurocore's use of unapproved medical devices and take appropriate enforcement action.[3]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq.
Legal Director
Truth in Advertising, Inc.

Bonnie Patten, Esq.
Executive Director
Truth in Advertising, Inc.

Cc: Mark Murrison, CEO, Neurocore

[1] Neurocore is headquartered in Michigan at 201 Monroe Ave. NW, Suite 300, Grand Rapids, MI 49503 (Phone: (800) 600-4096).

[2] Neurocore also uses its equipment during its initial brain diagnostic assessments, which are one-time two-hour appointments that consist of questionnaires, biofeedback tests (heart rate, blood pressure, and breathing pattern), and a quantitative electroencephalography reading that maps electrical functions in the brain. *See* https://www.neurocorecenters.com/blog/neurocores-frequently-asked-questions. Rather than being conducted by psychiatrists, psychologists, neurologists, or other neurofeedback experts, such medical assessments are done by social workers.

Similarly, Neurocore's neurofeedback treatment sessions are administered by technicians, rather than psychiatrists, neurologists, or other medical experts.

[3] TINA.org has also notified the Federal Trade Commission of Neurocore's use of unsubstantiated disease-treatment claims in its marketing materials. *See* https://www.truthinadvertising.org/wp-content/uploads/2019/11/11_12_19-Neurocore-complaint-letter-to-FTC.pdf.