



December 3, 2018

Zengar Institute Inc.
520 Island Rd.
Victoria, BC, V8S 2T6

RE: NeuroOptimal® Neurofeedback Systems and the FDA

To Whom This May Concern,

This is to confirm that on October 11, 2018, the FDA found NeuroOptimal® to be a General Wellness Product.

Here is the official statement from the FDA:

Pursuant to Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), you requested information regarding the regulatory requirements applicable to NeuroOptimal under the Act. Based on the information provided in your submission, we have determined that the NeuroOptimal is a general wellness product. In accordance with our guidance¹, CDRH defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use as defined in the guidance, and (2) present a low risk to the safety of users and other persons. A general wellness product has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition. Our determination that NeuroOptimal is a general wellness product is based on the following information provided in your submission: (i) the intended use of the product is for passive brain training for personal enrichment; (ii) noninvasively records brain activity to provide a brief interruption in the sound of media playing through earbuds. Therefore, we do not intend to enforce any applicable regulatory requirements under the Act, including premarket notification, and its implementing regulations for the NeuroOptimal.

Please feel free to reach out to us for any additional information.

Best Regards,

A handwritten signature in black ink, appearing to read "Samantha Diavatis".

Samantha Diavatis
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