U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

Date: August 19, 2020

TO: Moses Durazo

magnethealing@gmail.com - Durazo Medical Biomagnetism and Neuro-Alignment
1615 French Street, Suite 101
Santa Ana, CA 92701

RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet www.savememagnets.com on June 12, 2020 and August 17, 2020, respectively. We also reviewed your social media pages at www.facebook.com/savememagnets/, www.twitter.com/SaveMeMagnets, and www.instagram.com/savememagnets, where you direct consumers to your website, www.savemagnets.com and/or to your Amazon or Square websites, www.amazon.com/stores/page/62703517-18D50481B-94A0-A1C90412CBBF and savememagnets.square.site to purchase your products.

FDA has observed that your websites offer "Biomagnetism Magnetic Therapy DIY Kits" (which include sets of ceramic grade magnets encased in plastic and washers to hold the magnets in place over clothing) for sale in the United States. Based on our review, the "Biomagnetism Magnetic Therapy DIY Kits" are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19[1] in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h).

Our review of your websites revealed statements that establish that the "Biomagnetism Magnetic Therapy DIY Kits" are intended for the prevention, diagnosis, mitigation, and/or treatment of COVID-19, including:

- "Worried about CORONAVIRUS? Biomagnetic Solutions Exist" [www.savememagnets.com]
- An image of a man holding your product with the text "PANDEMIC WEAPON OF CHOICE" [www.savememagnets.com]
- "2 Quick Start Kits… If you happen to get coronavirus or any other infection, you will need these tools and instructions!" [www.savememagnets.com]

[1] As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

- A YouTube video posted by "SaveMeMagnets" titled "How to Scan for the C-Virus Using SaveMeMagnets - Biomagnetic Pair – with specialist Moses Durazo" contains the caption "Scanning for Coronavirus" and shows a person placing your firm's product on the body of another person while a speaker states "So the way, biomagnetically, we do this, which is to place a negative field of magnet to the body part where we scan for that virus" and "Now put this [magnet] on the urethra . . . . This leg becomes shorter than the other. So this would tell us that she's carrying the virus." [https://www.youtube.com/watch?v=iJaIzzLNtDc&feature=emb_err_woyt/]

- "Cómo controlar el CORONAVIRUS con el Par Biomagnético" (*translation:"How to control the CORONAVIRUS with the Biomagnetic Pair"*) [March 13, 2020 post on www.twitter.com/SaveMeMagnets]

- An image of a man holding your product with the text "MY PANDEMIC WEAPON OF CHOICE," is accompanied by the following text "Ready for battle! #savememagnets #magnetichealing . . . #coronavirus #pandemic" [April 11, 2020 Facebook post at www.facebook.com/savememagnets, and April 11, 2020 Instagram page post at www.instagram.com/savememagnets]

The "Biomagnetism Magnetic Therapy DIY Kits" are offered for sale and distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, these products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). These products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of the product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded.

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3] Therefore, FDA is taking urgent measures to protect consumers from certain

[2] Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx). The declaration has been renewed for an additional 90 days twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21.aspx).

[3] President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel

products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sell products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

On June 6, 2020, FDA sent an email to your firm requesting basic information regarding the devices offered for sale on your websites (including your firm's contact information and a description of your products' technology and intended use). On June 9, 2020, your firm responded, but did not provide the requested information. Rather, you argued in your response that your products are not subject to FDA regulation because your firm is a private membership association that "only deals with private members within a First and Fourteenth Amendment Private Membership Association in the private domain."

Your argument is without merit. Even assuming that your firm is a private membership association (which has not been established), courts have rejected the proposition that such entities are exempt from FDA regulation. *See Lytle v. HHS*, 612 F. App'x 861-62 (8th Cir. 2015) (rejecting the argument that FDA lacks regulatory jurisdiction over medical devices distributed in non-commercial transactions through private membership associations); *see also U.S. v. Allgyer*, No. 11-02651, 2012 WL 355261, at *4 n. 15 (E.D. Pa. Feb. 3, 2012) (finding that party's so-called "private membership agreement" was "merely a subterfuge" to unlawfully evade FDA regulation); *U.S. v. Travia*, 180 F. Supp. 2d 115, 120-21 (D.D.C. 2001) (rejecting argument that the Act does not apply to "private behavior"). Consequently, as described above, your "Biomagnetism Magnetic Therapy DIY Kits" are devices under section 201(h) of the Act and are subject to FDA regulation – regardless of whether those devices are offered for sale to the public or to members of a purported private membership association.

You should take immediate action to correct the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your product(s) or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your product(s) as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the product(s) in violation of the Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov** describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in

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Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

violation of the Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products. Once you have taken corrective actions to cease the sale of your unapproved, uncleared, and unauthorized product(s) for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that the product is not in violation of the Act, include your reasoning and any supporting information for our consideration.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov.

In addition, it is unlawful under the Federal Trade Commission Act (FTC Act), 15 U.S.C. 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, at rcleland@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Carlos L. Pena -S

Carlos Peña, Ph.D., M.S.
Director
Office of Health Technology 5 (OHT5): Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

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Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission