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Inspections, Compliance, Enforcement, and Criminal Investigations

1/16/14



Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

January 16, 2014

WARNING LETTER

VIA UNITED PARCEL SERVICE

Dear Dr. [REDACTED]:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at Advanced Magnetic Research Institute International, LLC (AMRI), from August 20 2013, to September 10, 2013, by an investigator from the FDA San Francisco District Office. This inspection was conducted to determine whether your firm's activities and procedures as sponsor for three clinical studies complied with applicable federal regulations. This letter also requests prompt corrective action to address the violations cited. The three studies reviewed were:

- "A Randomized Sham-Controlled Clinical Study to Evaluate the Effects of the Magnetic Molecular Energizer on Chronic Low Back Pain"
- "A Randomized, Sham-Controlled Clinical Study to Evaluate the Effects of the Magnetic Molecular Energizer on Diabetic Peripheral Neuropathy"
- "Patient Evaluation Using Magnetic Molecular Energizer"

The Magnetic Molecular Energizer (MME) is a device as that term is defined in 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 diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions, Premarket Approval applications, and Premarket Notification submissions are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the district office revealed several violations of 21 Code of Federal Regulations (CFR) Part 812 - Investigational Device Exemptions, which concerns requirements prescribed under section 520(g) of the Act, 21 U.S.C. § 360j(g). At the close of the inspection, the FDA

investigator presented an inspectional observations Form FDA 483 for your review and discussed the observations listed on the form with you. The deviations noted on the Form FDA 483, and our subsequent review of the inspection report, are discussed below:

1. Failure to obtain Institutional Review Board approval of the investigation [21 CFR 812.2(b)(1)(ii)]

To meet the abbreviated requirements for investigational device exemptions for devices that are not significant risk devices, sponsors are responsible for obtaining Institutional Review Board (IRB) approval. For an investigation of a device other than a significant risk device, the sponsor must present the reviewing IRE with a brief explanation of why the device is not a significant risk device and then obtain IRB approval of the investigation. This approval must be maintained.

You failed to maintain IRB approval for the MME device investigations after February 2, 2008. Your failure to maintain IRB approval is a serious violation of your responsibilities as a sponsor and placed study subject at increased risk of adverse health consequences. Without IRB approval, there is no assurance that the risks associated with the device and study procedures are minimized. These risks include the worsening of disease conditions or death due to inadequate or inappropriate treatment of several illnesses that the MME was purported to treat. These include congestive heart failure, cerebral palsy, Alzheimer's disease, and brain and spinal cord injuries.

2. Failure to comply with FDA regulations that prohibit promotion of an investigational device until after FDA has approved the device for commercial distribution and representation that an investigational device is safe or effective for the purposes for which it is being investigated [21 CFR 812.2(b)(1)(vii)].

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not promote or represent that an investigational device is safe or effective for the purposes for which it is being investigated. You have failed to adhere to this regulation. Examples of this include, but are not limited to, the following:

On your website, <http://www.amri-intl.com>, (and the brochure included on your website), the investigational device is being represented as safe and effective. The website states:

- "Research with the Magnetic Molecular Energizer (MME) offers hope for many diseases previously considered untreatable by conventional methods. It has thus far shown promise with a wide variety of ailments such as spinal cord injury, brain injury, stroke impairment, multiple sclerosis, muscular dystrophy, cerebral palsy, Parkinson's disease, Alzheimer's disease, congestive heart failure, and orthopedic conditions involving bone and joint repair."
- "The rate of healing can be accelerated to be much faster than the typical healing rate of the human body. For example, a bone fracture that typically requires 6-8 weeks to heal may require only a few days with MME treatment."
- "The safety of the induction of high strength magnetic fields was well established during toxicity studies performed for the FDA approval of the MRI."
- "Since extensive toxicity studies have already been conducted, MME research can focus on responses or benefits to an array of diagnosed conditions."
- "In general terms, MME treatment is painless, non-invasive, and does not have the allergy or interaction problems of multi-prescription medicating and does not carry the risks of more aggressive treatment methods such as experimental drugs or surgery. MME treatment is being actively researched, so that the full extent and limitations of this treatment method can be determined."

FDA considers these statements to constitute promotion of the MME device in violation of 21 CFR 812.7(a) since FDA has not cleared or approved the device. To represent the MME as safe and effective for an indication that is being investigated is a violation of 21 CFR 812.7(d). These claims could unduly influence physicians and study subjects to believe that the MME is safe and effective for the purposes for which it is being investigated.

3. Failure to maintain required records under § 812.140(b)(4) and make the reports required under § 812.150(b)(1) through (3) and (5) through (10) [21 CFR 812.2(b)(1)(v)].

As sponsor of an investigation you are responsible for maintaining specific records that are accurate, complete, and current, and preparing and submitting specific reports that are complete, accurate, and timely. You failed to adhere to the above-stated regulation. Examples of your failure to adhere to these requirements include, but are not limited to, the following:

- Records concerning many adverse device effects were not available for FDA inspection, nor were the unanticipated adverse device effects submitted to FDA as specified by this regulation. Specifically, you failed to report several serious adverse events including:
 - o breast cancer (6 months after MME),
 - o a death related to an undiagnosed cancer (4 months after MME),
 - o a death of unknown etiology (possible TIA 30 days after MME), and
 - o a subject who withdrew from the study and was also newly diagnosed with cancer.

Proper reporting of adverse effects according to FDA regulations is a critical step in ensuring the safety and welfare of study subjects.

You failed to provide records to indicate the name and address of the IRB that reviewed the above-stated studies, as required by 21 CFR 812.140(b)(4)(iv). Additionally, there were no records to indicate the extent to which the good manufacturing practice regulations in 21 CFR Part 820 were followed to manufacture the MME device, as required by 21 CFR 812.140(b)(4)(v).

The violations described above are not intended to be an all-inclusive list of problems that may exist with your clinical studies. It is your responsibility as a sponsor to ensure compliance with the Act and applicable regulations.

We recommend a teleconference to further discuss the Form FDA 483 observations and any corrective actions that you have implemented or plan to implement. Please contact Ms. Veronica Calvin within two weeks of receiving this letter to propose several dates and times for this teleconference.

Also, within 15 working days of receiving this letter, please provide documentation of the actions that you have taken or will take to correct these violations and prevent recurrence, and a plan to monitor the effectiveness of your corrective actions. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you. Your response should reference "CTS # EC130292/E001 and be sent to:

Attention: Veronica J. Calvin, MA
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
Building 66, Room 3508
Silver Spring, Maryland 20993-0002

A copy of this letter has been sent to FDA's San Francisco District Office, 1431 Harbor Bay Pkwy, Alameda, CA 94502-7070. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA-regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA-regulated device clinical research activities. These modules are located at the following website address: <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>¹.

If you have any questions, please contact Veronica Calvin at (301) 796- 5647 or Veronica.Calvin@fda.hhs.gov.

Sincerely yours,
/S/
Steven D. Silverman