A1 Engineering 11/19/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

November 19, 2015

WL# 8-16

Mr. Anthony Picciano, CEO
A-1 Engineering
9450 7th St.
Rancho Cucamonga, California 91730

Dear Mr. Picciano:

During an inspection of your firm located in Rancho Cucamonga, California, conducted from March 02, 2015 through March 18, 2015, an investigator from the

United States Food and Drug Administration (FDA) determined that your firm manufactures and distributes the Neurotris SX-Series Machines and Neurotris PICO Toner. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

To date, we have not received a response from you concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. Noted violations include, but are not limited to, the following:

1. Failure to maintain device master records as required by 21 CFR 820.181. For example, your firm has not created device master records for the Neurotris SX-Series Machines.

2. Failure to establish and maintain device history records as required by 21 CFR 820.184. For example, your firm does not maintain procedures defining the contents of device history records. In addition, the documentation that you provided during the inspection as your device history records for the SX-Series Machines did not include the primary identification label and labeling used for each production unit or complete acceptance records.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, your firm does not maintain approved procedures to document requirements for in-process or receiving acceptance activities during the manufacturing process.

4. Failure to evaluate potential suppliers on the basis of their ability to meet specified requirements and to document such evaluations, as required by 21 CFR 820.50(a)(1). For example, you provided no documentation of evaluations for any of your firm's component and parts suppliers.

5. Failure to maintain complaint files as required by 21 CFR 820.198(a). For example, your employee responsible for investigating complaints does not document

investigation activities using the complaint investigation form referenced in your firm's Investigation of Complaints SOP **(b)(4)**. You also stated to the investigator that your employee documents retesting related to complaints on the inspection checklist, which is not maintained as part of your firm's complaint files.

6. Failure to establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment and to document maintenance activities as required by 21 CFR 820.70(g)(1). For example, you stated your firm had no calibration records for its Fluke digital multimeter; Simpson Analog VOM; Owon Oscilloscope; and Sorenson Digital Power Supply.

7. Failure to establish Quality System procedures and instructions as required by 21 CFR 820.20(e). For example, your firm's management did not sign or date the Quality Manual, **(b)(4)**; Investigations of Complaints, **(b)(4)**; or Corrective and Preventive Action System, **(b)(4)**. In addition, your firm could not provide copies of the following procedures listed in your firm's Quality Manual: Device Master Record, **(b)(4)**; Supplier Evaluation and Monitoring, **(b)(4)**; Production Work Order and History Record, **(b)(4)**; Product Identification and Traceability, **(b)(4)**; Labeling and Packaging, **(b)(4)**; In-Process Inspection, **(b)(4)**; Final Acceptance Inspection, **(b)(4)**; and Measuring and Monitoring Equipment, **(b)(4)**.

In addition, FDA has reviewed labels and marketing materials for the Neurotris SX-Series Machines and PICO Toner collected from your firm during the March 2015 inspection. Based on this review, FDA has determined that the Neurotris SX-Series Machines and PICO Toner 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) for these devices as described and marketed.

The Neurotris SX-Series Machines and PICO Toner are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction these devices into interstate commerce for commercial distribution, intended for a use different from the intended use of a legally marketed device in the generic type of device described at 21 CFR 890.5660 (Therapeutic Massager) without submitting a premarket notification to FDA as required by section 510(k), 21 U.S.C. § 360(k).

Your firm has registered as a manufacturer and listed its devices as electric therapeutic massagers under 21 CFR 890.5660. Devices classified under 21 CFR 890.5660 (Therapeutic Massager) are exempt from premarket notification unless they exceed the limitations on exemption at 21 CFR 890.9(a). However, there is evidence that the Neurotris SX-Series Machines and PICO Toner are intended for uses that

are different from those of legally marketed devices classified under 21 CFR 890.5660 (Therapeutic Massager). Generic devices of this type are intended for medical purposes, such as to relieve minor muscle aches and pains. However, your firm is marketing the devices for different intended uses, including, but not limited to, wrinkle reduction, facial lifting, neck tightening, increased ATP production, increased collagen and elastin, improved circulation, skin tightening, cellulite reduction, enhancement of biological processes, hydrolysis of triglycerides, improving sun damaged skin and skin pigmentation, iontophoresis, fat reduction, and muscle building and toning. Examples include:

Your Neurotris Facial & Body Sculpting Systems brochure makes the following claims:

- Regarding the SX-Series facial sculpting systems, the brochure states, “Results seen are:
  - Wrinkle Reduction
  - Toning
  - Tightening
  - Facial Lifting
  - Neck Tightening
  - Increase in ATP Production
  - Increases in Collagen
  - Increases in Elastin
  - Improved Skin Texture
  - Improved Circulation . . . .”

- Regarding the SX-Series body sculpting systems, your brochure states “Benefits are Seen Immediately and Results are Cumulative:
  - Inch Loss
  - Fat Reduction
  - Muscle Toning
  - Skin Tightening
  - Lifting of Sagging Areas
  - Cellulite Reduction
  - Enhances Biological Processes . . . .”

- “The SX-50 Microcurrent Body Sculpting System has 5 preset programs that utilize

ultra-high definition signals to stimulate hydrolysis of triglycerides while simultaneously increasing muscle tone."

- "[W]e added an additional protocol for intense muscle building making the SX-101 our extreme body system. Results seen: Extreme muscle building, skin tightening, muscle toning, inch loss, reducing fat and cellulite, lifting sagging areas, and enhances biological processes."

- "The SX-3800 features output accessories for both facial & body sculpting Level 1. Expected benefits are: Improve facial and neck muscle tone, lifted jowls and eyebrows, reduction and elimination of fine lines and wrinkles, improved facial circulation, . . . lymphatic drainage, product penetration, [and] improving sun damaged skin and skin pigmentation . . . ."

- Regarding the Neurotris PICO Toner, your brochure states, "Benefits are Seen Immediately and Results are Cumulative:
  - Stimulates Production of Collagen and Elastin
  - Improves Circulation & Lymphatic Drainage
  - Reduce Fine Lines and Wrinkles
  - Tightens Pores & Sagging Skin
  - Improves Overall Tone
  - Facial Lifting . . . ."

- The Customer Testimonial section of your brochure states, "No more headaches, no more sinus issues, no more pain in my jaw line. . . . [M]y vision has gotten better . . . . I have gotten my smile back and it has even healed previous nerve damage from a past surgery!"

- The Customer Treatment Results section of your brochure states, "Reduce the appearance of stretch marks, cellulite, scarring and dimpling with this relaxing treatment. . . . See benefits in skin tightening, lifting sagging areas, muscle toning, hydration and overall appearance of the skin. . . . See a reduction measured in inches and dress sizes. This is a great treatment for post pregnancy issues!"

Because there is evidence that the Neurotris SX-Series machines and PICO Toner are intended for uses that are different from those of legally marketed devices classified under 21 CFR 890.5660, they exceed the limitations described in 21 CFR 890.9(a) and are not exempt from premarket notification.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/defau The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Our office requests that A-1 Engineering immediately cease activities that result in the misbranding or adulteration of the Neurotris SX-Series Machines and PICO Toner, such as the commercial distribution of the devices for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected. A follow up inspection will be required to assure that corrections and/or corrective actions are adequate.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

CAPT Daniel Cline, Acting Director
Compliance Branch
Food and Drug Administration
Los Angeles District Office
19701 Fairchild

Irvine, CA 92612

Refer to the identification number [CMS #457666] when replying. We remind you that only written communication is considered as official. If you have any questions about the content of this letter, please contact Dr. Raymond W. Brullo, Compliance Officer, at 949-608-2918 or raymond.brullo@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
LCDR Steven Porter, Acting Director
Los Angeles District

Cc:

David M. Mazzera, Ph.D., Chief
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Food and Drug Branch
1500 Capitol Avenue MS 7602
PO Box 997435
Sacramento, CA 95899-7435
Attn: FDA Correspondence

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