U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Xanacare Technologies, LLC 10/28/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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October 28, 2014

UPS Overnight

WARNING LETTER

Mr. Thomas C. Siirola
Manager & CEO
Xanacare Technologies, LLC
9185 E. Kenyon Avenue, Ste. 270
Denver, CO 80237-1857

DEN-15-01-WL

Dear Mr. Siirola:

During an inspection of your firm located in Denver, CO on July 31 through August 4, 2014, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures the SimulCare II, a therapeutic lamp/nerve stimulator/massager. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)], this product is a device 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 is intended to affect the structure or function of the body.

The inspection revealed that this device is 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, its manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP)

requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish adequate procedures for design changes, as required by 21 CFR 820.30 (i). Specifically, your firm's Design Control procedure, SOP-101, Rev. 00 CN #001, requires supporting documentation in the form of engineering studies, analyses, verification or validation for any changes that affect the form, fit or function of a component. No records of identification, validation or verification, review, or approval were available for design changes to the SimulCare resulting in the SimulCare II. The changes included new digital controls, **(b)(4)**, new power unit casing, updated user manual and labeling, and a change to the **(b)(4)**. The SimulCare II was released for distribution in December 2013.

2. Failure to ensure that suppliers and contractors were evaluated and selected based upon their ability to meet specified requirements, as required by 21 CFR 820.50(a)(1). Specifically, your firm utilizes various suppliers for components of your devices, including PCBs, cable assembly/power unit, and custom pads. No documented evaluation of these suppliers was available. Additionally, no supplier agreements were available delineating any specified requirements for components or quality agreements.

3. You have not established procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100, and including procedures for requirements such as:

   a. the identification of sources of quality issues to ensure that all potential quality issues are identified;

   b. the analysis of sources of quality data to identify existing or potential quality issues;

   c. the investigation of the cause of nonconformities related to product, processes, and the quality system; and,

   d. the verification or validation of corrective and preventive actions to ensure the actions are effective and do not adversely affect the finished device.

4. Failure to establish procedures for Device History Records (DHR), and failure to maintain DHRs for each batch, lot, or unit as required by 21 CFR 820.184. Specifically, no DHRs were maintained for approximately **(b)(4)** SimulCare II devices manufactured between December 2013 – August 2014.

5. Failure to maintain complaint files as required by 21 CFR 820.198(a). Although your Complaint Handling procedure, SOP-103, Rev. 00, CN#106, outlines the processing of complaints, your firm failed to record and document investigation of oral complaints related to burnt-out microchips/nonfunctioning devices following use of non-rechargable batteries (2), burning sensation with use of device following icing (1), and texture of the conductive gel (several). The complaints related to the conductive media resulted in a change to that component via CN #020 in November 2010.

6. Failure to establish procedures for acceptance or rejection of incoming products, and failure to maintain documentation of acceptance or rejection of incoming materials, as required by 21 CFR 820.80(b). For example, your firm receives components such as PCBs, cable assembly/power unit, and custom pads. 21 CFR 820.80(b) requires incoming product to be inspected, tested, or otherwise verified as conforming to specified requirements; however, your firm had no documentation of any inspections, tests, or other verification to demonstrate that all component shipments met their specified requirements.

7. Failure to establish and maintain procedures for finished device acceptance, as required by 21 CFR 820.80(d). Specifically, your firm has no written procedures outlining the acceptance criteria for finished device evaluation and acceptance for the SimulCare II. Approximately **(b)(4)** SimulCare II units have been manufactured and released since December 2013 without documentation demonstrating that all units met the acceptance criteria, and were duly authorized for release by a designated individual, as specified in 21 CFR 820.80(d).

8. Failure to establish a procedure for quality audits, and to conduct and document quality audits, as required by 21 CFR 820.22. Although your Quality Manual, QA Man, Rev. 00, CN #017, states that quality audits are required annually, your firm has no procedures in place for these audits and no evidence was available to demonstrate that any quality audits have been conducted.

To date, we have received no written response to the form FDA-483, Inspection Observations, issued at the close of the inspection to Mr. Thomas D. Liston, Production Manager.

In addition to the above, our inspection also revealed that the SimulCare II is 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)]. The SimulCare II is also misbranded under section 502(o) the Act [21 U.S.C. § 352(o)] because your firm made major changes or modifications to the device and did not notify the agency of its intent to introduce the device into commercial distribution as required by section 510(k) of the Act [21 U.S.C. § 360(k)] and 21 CFR 807.81(a)(3)(i).

Specifically, the SimulCare II was cleared under K083202; however, your firm's promotion of the device provides evidence that the device was modified including a change from analog knobs utilized to control the strength and duration of therapy to digital button controls now utilized for the same function. Although the intended use of the device was unaffected, the change required new labeling, **(b)(4)**, and a new design of the power unit casing. The changes to the SimulCare Kit Device Master Record/Device History Record indicated that in addition, the labeling on the power unit, the **(b)(4)**, and the User Manual were also updated in this change. These changes constitute a major change or modification which could significantly affect the safety or effectiveness of the device; therefore, these changes require a new premarket notification submission, as required by 21 CFR 807.81(a)(3)(i).

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 CFR 807.81(b)). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm (/MedicalDevices/default.htm)**. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

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 Waning 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.

Please notify this office in writing within fifteen business days from the date you received 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: Food and Drug Administration, Denver District, DFC, Bldg. 20, 6th Avenue and Kipling Street, P.O. Box 25087, Denver, CO 80225-0087, Attention: Sarah A. Della Fave,

Compliance Officer. If you have any questions about the contents of this letter, please contact Ms. Della Fave at (303) 236-3006.

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 product(s) into compliance.

Sincerely,
/S/
LaTonya M. Mitchell
District Director

cc:
Mr. Thomas D. Liston
Production Manager
Xanacare Technologies, LLC
9185 E. Kenyon Avenue, Ste. 270
Denver, CO 80237-1857