Inspections, Compliance, Enforcement, and Criminal Investigations

Leisure Products, Inc. 11/20/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217
Telephone: (615) 366-7801
FAX: (615) 366-7802

November 20, 2012

WARNING LETTER NO. 2013-NOL-03

UNITED PARCEL SERVICE
DELIVERY SIGNATURE REQUESTED

Joseph Parham, President
Leisure Products, Inc.
1044 Fordtown Road
Kingsport, Tennessee 37663-3210

Dear Mr. Parham:

During an inspection of your firm located in Kingsport, Tennessee, on January 24 and 25, 2012, an investigator with the U.S. Food and Drug Administration (FDA) determined your firm manufactures and distributes sunlamp products. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 United States Code (USC) 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 to affect the structure or any function of the body.

The inspection revealed these devices are adulterated under Section 501(h) of the Act [21 USC 351 (h)], because 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 requirements of the Quality System regulation found at Title 21, *Code of Federal Regulations* (CFR), Part 820.

We received a response from **(b)(6)**, dated January 31, 2012, concerning our investigator's observations noted on the FORM FDA 483 (FDA 483), List of Inspectional Observations, issued to your firm. We have addressed this response below in relation to each of the noted violations. These violations include, but are not limited to the following:

1. Failure to establish and maintain corrective and preventive action procedures, as required by 21 CFR 820.100(a). For example, there are no written Corrective and Preventive Action procedures.

   We reviewed your firm's response and concluded it was not adequate. The response states information pertaining to quality issues and sources of nonconforming products is being compiled and will be reviewed for trends. However, the response lacks information to ensure

corrective and preventive action procedures will be established and a systemic corrective action is not addressed in your response.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, there are no written complaint procedures.

We reviewed your firm's response and concluded it was not adequate. Although the response states complaint procedures are being established, there is no indication the software to be installed on the service technicians computers has been validated. In addition, a systemic corrective action is not addressed in your response.

3. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a). For example, in-process and finished device testing is not documented and there are no in-process or finished device acceptance activity procedures.

We reviewed your firm's response and concluded it was not adequate. Although the response indicates your firm intends to establish in-process and final acceptance procedures and acceptance criteria, the procedures were not available for review to ensure compliance with the QS regulation and a systemic corrective action was not provided.

4. Failure to establish and maintain procedures to ensure all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, no purchasing control procedures and quality requirements for suppliers were available for review.

We reviewed your firm's response and concluded it was not adequate. The purchasing control procedures were not available for review, the quality requirements were not discussed and a systemic corrective action was not addressed in your response.

5. Failure to establish and maintain adequate procedures for quality audits and conduct such audits to assure the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, no internal audits have been conducted.

We reviewed your firm's response and concluded it was not adequate. Although a procedure to conduct internal quality audits is being developed, the response lacks information to ensure your quality system will be evaluated to ensure it complies with the quality system requirements and to determine the effectiveness of your firm's quality system. In addition, a systemic corrective action was not addressed.

6. Failure to identify through suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria, as required by 21 CFR 820.86. For example, there no records maintained to indicate the acceptance status of product to indicate the conformance or nonconformance of product throughout manufacturing.

We reviewed your firm's response and concluded it was not adequate. Although your firm's response states procedures to ensure control of the production activities will be established, it is not clear how this will be done and whether or not these procedures will include acceptance status of conforming and nonconforming product. In addition, a systemic corrective action was not provided.

The inspection revealed items of noncompliance with the Act, Subchapter C, Electronic Product Radiation Control, Section 538(a) [21 USC 360oo(a)].

1. Failure to ensure certification of the sunlamp products is based upon a test of the individual article, in accordance with the standard, or upon a testing program which is in accordance with good manufacturing practices, as required by 21 CFR 1010.2(c). For example, no certification testing was observed and management could not provide documentation of any testing performed. Management could not provide testing data for the irradiance ratio used to develop the recommended exposure schedule for any sunlamp products.

We reviewed your firm's response and concluded it was not adequate. The response only states you are designing a method to test finished sunlamp products for conformance to the Performance Standards. The response lacks information to describe how the testing ensures products meet the Performance Standard requirements.

2. Failure to ensure sun lamps are in compliance with the Performance Standards contained in 21 CFR 1040.20. For example, there are no records relative to any testing performed, such as irradiance ratio limits and timer settings.

We reviewed your firm's response and concluded it was not adequate since it does not appear to address how your firm will perform testing to ensure product compliance with the sun lamp Performance Standard requirements.

Failures to comply with the regulations covering records and reports were observed and include the following:

3. Failure to submit an annual report for the Solar Wave Series sunlamp products, as required by 21 CFR 1002.13. For example, no reports have been submitted as required for your finished products since your submittal of an initial report for some sunlamp products in 2006, namely the Solar Storm Series.

We reviewed your firm's response and concluded it was not adequate. There was no information to ensure the annual report you are creating meets the requirements for annual reports. Additionally, we not received annual reports from Leisure Products as of the date of this letter.

4. Failure to submit a required supplemental report, prior to the introduction of the product into commerce, for a new or modified model within a model or chassis family, as required by 21 CFR 1002.11. For example, new models of the same series for both the Solar Wave and Solar Storm sunlamp products, as well as modified models in both series, have been introduced since filing your initial report in 2006 for the Solar Storm sunlamp products.

We reviewed your firm's response and concluded it was not adequate. There was no information to ensure the supplemental reports you are creating meet the requirements for supplemental reports. Additionally we have no record of receiving supplemental reports from Leisure Products as of the date of this letter.

Our inspection revealed your firm's sunlamp products devices are misbranded under Section 502(t)(2) of the Act, [21 USC 352(t)(2),] because your firm failed or refused to furnish material or information respecting the device, as required by or under Section 519 of the Act, [21 USC 360i], and 21 CFR 803 - Medical Device Reporting (MDR). Significant violations include, but are not limited to, the following:

Failure to develop, maintain and implement written MDR procedures, as required by 21 CFR 803.17. For example, no written MDR procedures were available during the inspection.

We reviewed your firm's response and concluded it was not adequate. Although MDR procedures are being developed there is no information available to ensure the procedures will meet the adverse event reporting requirements in 21 CFR 803, and a systemic corrective action was not provided.

Under Section 510 of the Act [21 USC 360], manufacturers of medical devices are required to annually register with the FDA. In September 2007, Section 510 of the Act was amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) to require domestic and foreign device establishments to submit their annual establishment registration and device listing information to FDA by electronic means [Section 510(p) of the Act [21 USC 360(p)] during the period beginning October 1st and ending December 31st of each year. Our records indicate your firm has not fulfilled annual registration and listing requirements for fiscal year 2012.

Therefore all of your firm's devices are misbranded within the meaning of Section 502(o) of the Act [21 USC 352(0)], because the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act (21 USC 360) and were not included in a list required by Section 510(j) of the Act [21 USC 360(j)].

Your response was not adequate since it does not indicate you have registered your firm and listed your devices with the FDA.

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, quality control testing program disapproval, seizure, injunction, and/or civil penalties. Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the QS 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 (15) business days from the date you receive this letter of the specific steps you firm has taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Your response should include detailed distribution records in your response to indicate (a) which models you currently have in stock, and, (b) which models and how many of each model was shipped from your place of manufacture over the previous five years. You should also include documentation of the correction and/or corrective actions (including any systemic corrective actions) that your firm has taken to address compliance with FDA requirements. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Kari L. Batey, Compliance Officer, United States Food and Drug Administration, 404 BNA Drive, Building 200, Suite 500, Nashville, Tennessee 37217. If you have any questions about the content of this letter, please contact Ms. Batey at (615) 366-7808. A copy of your response should be sent to Patrick Weixel, Postmarket Team Lead, United States Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, Room 66-4545, Silver Spring, Maryland, 20993.

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

Sincerely,

/S/

Patricia K. Schafer
District Director
New Orleans District

Enclosure: FDA 483 dated January 25, 2012

cc: **(b)(6)**
(b)(6)

Leisure Products, Inc.
1044 Fordtown Road
Kingsport, Tennessee 37663-3210

Page Last Updated: 12/17/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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