U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

ProSun International, LLC 8/15/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751
Telephone: 407-475-4700
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-38

August 15, 2011

Tom Henkemans
President/CEO
ProSun International, LLC
2442 23rd Street North
Saint Petersburg, FL 33713

Dear Mr. Henkemans:

During an inspection of your firm located in Saint Petersburg, Florida, on March 9, 2011, through March 14, 2011, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Skin Rejuvenation or Collagen Bed and Sun Tanning Products. 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 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 (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

Your response to the FDA 483 dated April 18, 2011, was not reviewed because it was not received within fifteen business days of issuance. The response may be evaluated along with any other written material provided in response to the violations cited in this Warning Letter. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). For example, your firm failed to implement design control procedures, E204-002, in the design and development of the Skin Rejuvenation Beds Models "ASR" and "SR."

2. Failure by management with executive responsibility to review the sustainablility and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20 (c). For example, no management review meetings have been conducted since 2003.

3. Failure to establish procedures for quality audits and failure to conduct such audits to assure that 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 quality audits have been completed since 2003.

4. Failure to maintain complaint files and establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm failed to adequately implement its Complaint Handling Procedures - S2 14-001. Your firm did not consider service calls related to malfunctioning digital timers on all models of commercial sun tanning beds and skin rejuvenation beds as customer complaints and these calls were not investigated as such.

5. Failure to establish and maintain adequate 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 did not document supplier approval. There are no records of annual supplier evaluations. Your firm did not maintain supplier records for approval and annual evaluations, as required by its established procedures: Purchasing Procedure, P206-001; Approved Supplier List, P306-001, and Vendor Qualification Procedure, P306-003.

6. Failure to establish adequate procedures for acceptance of incoming product, as required by 21 CFR 820.80(b). For example, testing records for timers received on March 27, 2009; April 9, 2009; April 17, 2009; and May 28, 2009, only included a computer printout of the final data as the original raw data of the testing conducted and acceptance data for each of the timers were not maintained.

7. Failure to establish adequate procedures for identify training needs, ensuring all personnel are adequately trained to perform their assigned responsibilities, and documenting personnel training, as required by 21 CFR 820.25(b). For example, during the inspection, an FDA investigator observed an employee of your firm installing the electrical wiring from the ballasts to the UV tube holder circuits of a tanning bed; however, when the FDA investigator reviewed your firm's training sheets, there was no record documenting the employee had undergone training to perform that particular task.

The FDA also learned that your firm is marketing skin rejuvenation equipment in the United States without the required marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

According to your firm's website, http://www.prosun.com/skin_rejuvenation.php[1] :

"Jade and Onyx series beds have a variety of options available for skin rejuvenating red light phototherapy. This technology has been medically proven to

reduce the signs of age, such as wrinkles, fine lines, and crow's feet . . . . Activates fibroblast cells which create collagen and elastin."

Your firm's labeling also make claims relating to "skin-rejuvenation," "anti-aging," and "the production of collagen and elastin to revitalize and rejuvenate the skin."

These claimed intended uses cause your firm's All Skin Rejuvenation and Skin Rejuvenation Beds to be 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) of these products 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 devices are also misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce them into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). 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 you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html[2]. The FDA will evaluate the information you submit and decide whether your 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 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.

Please notify this office in writing within fifteen 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 (including any systemic corrective actions) 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.

Our inspection also revealed that your firm failed to comply with requirements of 21 CFR 1040.20. For example, the digital timers installed in your tanning beds do not comply with 21 CFR 1040.20(c)(2)(iv) in that you received numerous complaints about timers automatically re-setting after the end of a tanning session. The service calls related to this malfunction were not reported to the quality unit for investigation since the manufacturer states that this is a known malfunction if the power input to the unit falls outside the 210 – 230 V range. However, there is no mention in the User Manual explaining that this specific malfunction can occur.

In addition, you firm failed to comply with requirements for reports and record keeping (Title 21 CFR § 1002). 21 CFR 1002.13 requires that manufacturers submit annual reports to CDRH providing the volume of products produced, sold or installed. Your firm did not submit annual reports for 2006-2008 and 2010. These reports are due annually by September 1 of each year and shall cover the 12-month period ending on June 30 preceding the due date of the report.

In order to address the requirements of 21 CFR 1040.20, respond in writing using one of the options listed below:

1. Refutation. Under 21 CFR 1003.11(a)(3), you may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request. Under 21 CFR 1003.30(a), you may request an exemption from user and dealer/distributor notification requirements (21 CFR 1003.10(b)). If exempted from such notification, you are not required to correct the violative products (under 21 CFR 1004.1(a)). Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31) and the information required under 21 CFR 1003.20.

3. Purchaser Notification and Corrective Action. If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) for approval showing how you will fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

   a. Notification Letter. Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letters sent to purchasers and dealers must also be sent to the FDA. We recommend that you submit a draft of this letter to us for review.

   b. Corrective Action Plan (CAP). Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4. Such a plan must expeditiously correct the failure to comply with the performance standard and must be approved as set out in 21 CFR 1004.6.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Section 538(a) of the Act, Chapter V, Subchapter C Electronic Product Radiation Control prohibits any manufacturer from certifying or introducing into commerce sunlamp products which do not comply with the performance standard. It is also a prohibited act to fail to establish and maintain required records and to fail to submit required reports. Be advised that failure to respond to this letter may be considered to be a violation of section 538(a)(4) of the Act, 21 U.S.C. § 360oo(a)(4). FDA is prepared to take regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in section 539 of the Act, 21 U.S.C. § 360pp. Persons who violate section 538 of the Act are subject to civil penalties of up to $1,100 per violation and up to a maximum penalty of $355,000 without further notification by the FDA.

In summary, to address these violations you must:

1. Submit a complete description explaining how you will address the timer noncompliance required by 21 CFR 1040.20(c)(2)(iv).

2. Submit annual reports covering all models of sunlamp products entered into commerce for years 2006-2008 and 2010 in order to bring your annual reporting up-to-date as required by 21 CFR 1002.13. Annual reports must include any communications with customers, service personnel, dealers, distributors, or regulatory agencies that reference radiation safety or radiation emissions.

Your response should be sent to [Andrea H. Norwood, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, FL 32779. Refer to the Unique Identification Number (CMS Case 188053) when replying. If you have any questions about the content of this letter please contact: Andrea H. Norwood at 407-475-4724.

Finally, you should know that 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 Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout 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 actions to correct the violations and to bring your products into compliance.

Sincerely,

Elizabeth W. Ormond
Acting Director, Florida District

Links on this page:

1. http://www.prosun.com/skin_rejuvenation.php
2. http://www.fda.gov/cdrh/devadvice/3122.html