



VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-00-23

February 1, 2000

Reint T. Henkemans, President
ProSun Tanning Industries, Inc.
2442 23rd Street North
St. Petersburg, Florida 33713

Dear Mr. Henkemans:

We are writing to you because on December 28-29, 1999 and January 4, 2000 FDA Investigator Ernest A. Clausnitzer collected information that revealed serious regulatory problems involving tanning beds which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820).

QUALITY SYSTEM REGULATIONS

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulations. These violations include, but are not limited to the following:

1. Failure of management with executive responsibility to establish a quality policy and objectives to ensure that a quality policy is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20 (FDA 483, Items 1 a/c).
2. Failure to establish procedures for conducting quality audits to assure that the quality system is in compliance with the quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22 (FDA 483, Item 1 d).

3. Failure to control and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70. For example, handwritten assembly schematics, not bearing management approval, used in assembly operations, wiring procedures not readily available to assembly personnel and assembly history records completed prior to the completion of the assembly operation (FDA 483, Items 2 a/d).
4. Failure to maintain complaint files as required by 21 CFR 820.198. For example, management review and evaluation of complaints and service reports to determine whether the complaint represents an event which requires a Medical Device Report to FDA is not documented (FDA 483, Item 3 b).

MEDICAL DEVICE REPORTING

The inspection also revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act in that there was a failure to furnish material or information required by or under section 519 of the Act respecting the devices as follows:

5. Failure to develop, implement and maintain written Medical Device Reporting (MDR) procedures as required by 21 CFR 803.17 (FDA 483, Item 3 a).

The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of these violations. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

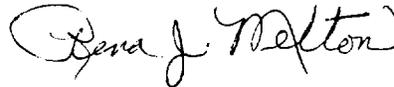
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation showing that corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in cursive script that reads "Reva J. Melton". The signature is written in black ink and is positioned above the typed name.

Reva J. Melton
Acting Director
Florida District