



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 19 1997

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ref: OC: I1-1766

Mr. Reint T. Henkemans, President
ProSun Tanning Industries Incorporated /dba Hapro
2442 23rd Street North
St. Petersburg, Florida 33713

Dear Mr. Henkemans:

This letter is to advise you of violations of the Federal Food, Drug and Cosmetic Act (the Act) as amended and deviations from the electronic product performance regulations of the Act, Chapter C - Electronic Product Radiation Control (EPRC), encountered during an inspection of your manufacturing facility on September 11 and 12, 1997, by Messrs. Timberlake and Karos, and as determined by review of your firms sunlamp product reports.

Please be advised that sunlamp products manufactured on or after May 7, 1980, are subject to all the requirements of the Federal Performance Standard for Sunlamp Products under Title 21, Code of Federal Regulations (CFR), Part 1040.20. Your sunlamp products are medical devices and must be manufactured in accordance with Good Manufacturing Practices (GMP's) regulations for medical devices promulgated under Section 520(f) of the Act. The Food and Drug Administration (FDA) inspection and review of your product reports disclosed violations of the Act and the EPRC as follows:

Section	Brief Description
538(a)(1)	<p>The ProSun Tanning Industries, Incorporated /dba Hapro has introduced into commerce sunlamp products which fail to comply with the EPRC as follows:</p> <ol style="list-style-type: none"> 1. 21 CFR 1040.20(d)(1)(iv). The required warning label for some of the ProSun and Luxura model sunlamp products failed to include an adequate recommended exposure schedule because the maximum recommended exposure times (MRET) on the exposure schedules were not determined using the maximum erythelial times (Te) for the skin types II. The MRET's on the exposure schedules for all skin types shall not exceed the Te for skin type II. (Refer to the enclosed Policy Statement dated August 21, 1986). The MRET's on warning labels exceeds the Te in several instances as follows:

- a. The ProSun 2400 model series has a MRET of 30 and 15 minutes while the Goldarium S lamps Te = 26.6 minutes and the Hi Tan lamps Te = 13.3 minutes.
 - b. The ProSun 2800 model series has a MRET of 30 and 15 minutes while the Goldarium S lamps Te = 21.4 minutes, the Crystal Sun S lamps Te = 26.3 minutes and the Hi Tan lamps Te = 11.9 minutes.
 - c. The Luxura 48 model series has a MRET of 20 and 15 minutes while the Philips Professional 100 W lamps Te = 15.7 and 18.5 minutes, the Goldarium S lamps Te = 18.1 minutes, the Bellarium S lamps Te = 18 minutes and the Philips TL 160 W Professional R lamps Te = 11 minutes and the Bellarium SR 160 W lamps Te = 11.0 minutes.
2. 21 CFR 1040.20(e)(1)(i). The required user instructions for some of the sunlamp product models do not contain the reproduction of the label(s) required by 21 CFR 1040.20(d)(1) prominently displayed at the beginning of the instructions.
 3. 21 CFR 1002.30(a)(2). ProSun Tanning Industries, Incorporated /dba Hapro has failed to establish and maintain adequate records of results of tests for electronic product radiation safety:
 - a. The sunlamp product quality control procedures failed to ensure that the MRET's on the warning labels do not exceed the skin Type II Te's for each product.
 - b. The sunlamp products quality control procedures failed to ensure that the timers were tested to assure compliance with 21 CFR 1040.20(c)(2)(iii).
 - c. The sunlamp products quality control procedures failed to ensure that the correct labeling was affixed to the product and included in the user information.

The above-stated inspection revealed that ProSun Tanning Industries, Incorporated /dba Hapro has introduced into interstate commerce devices that are adulterated within the meaning of 501(h) of the Act., in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practices (GMP) for Medical Devices Regulations, as specified in 21 CFR 820 as follows:

1. Failure to have written procedures and checklists for finished device test/inspection to assure that the device specifications are met as required by 21 CFR 820.160. For examples, refer to the sunlamp products noncompliances with the performance standard listed under 538(a)(1).
2. Failure to have a device master records prepared, dated, and signed by a designated individual(s) which included or referred to the locations of the device specifications including appropriate drawings and component specifications, production process specifications including equipment specifications, production methods/ procedures, and quality assurance procedures as required by 21 CFR 820.181.
3. Failure to have written manufacturing specifications and processing procedures established, implemented and controlled to assure device conformance to its original design and/or approved changes to that design as required by 21 CFR 820.100.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

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

Section 538(a) of the Act, Chapter V, Subchapter C - EPRC, prohibits any manufacturer from certifying or introducing into commerce sunlamp products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish or maintain required records or to submit required reports. Failure to respond to this letter may be considered to be in violation of paragraph 538(a)(4) of the Act. The FDA is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to a civil penalty of up to \$1,000.00 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the

place of manufacture. In addition, if the product distribution was confined to specific geographic areas of the United States, please specify those areas.

1. Refutation- You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request- You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action- If you neither refute the noncompliances 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) to 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 described in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for the preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide an explanation for any delays and a reasonable target date for 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 the 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.

Further, 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 award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Your response should be sent to: Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville Maryland 20850 with a copy

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to the Florida District Office as follows: Food and Drug Administration, Investigations Branch, 7200 Lake Ellenor Drive Suite 120, Orlando, Florida 32809. If you have any questions contact Mr. Norman L. Timberlake or Mr. Manuel G. Karos at 301-594-4654.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill". The signature is written in black ink and is positioned above the printed name and title.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health