



DEPARTMENT OF HEALTH & HUMAN SERVICES

m 899N

Public Health Service

HFI-35
6/3/97
CJF

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 8 1997

WARNING LETTER

Ref:OC:I1-1748

via Federal Express

Mr. Joseph C. Bommarito, President
International Tanning Equipment
Division of J&B Products, Ltd.
2201 South Michigan Avenue
Saginaw, Michigan 48602

Dear Mr. Bommarito:

This is to notify you that the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) **hereby disapproves the certification and testing program for all models of sunlamp products manufactured by International Tanning Equipment, Division of J & B Products, Ltd.** Introduction of sunlamp products by International Tanning Equipment, Division of J & B Products, Ltd. and/or any other related firm into commerce after receipt of this letter is prohibited by Section 538 of Subchapter C - Electronic Product Radiation Control (EPRC, formerly the Radiation control for Health and Safety Act of 1968) of Chapter V of the Federal Food, Drug and Cosmetic Act (the Act).

Please be advised that sunlamp products manufactured on or after May 7, 1980, are subject to all requirements of the Federal Performance Standard for Sunlamp Products under Title 21, Code of Federal Regulations (CFR), Part 1040.20. It is unlawful for manufacturers: (1) to introduce products into commerce if they fail to comply with the standard; (2) to fail to submit reports as required by 21 CFR 1002; (3) to fail to issue product certification; (4) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h). The grounds for this disapproval are that International Tanning Equipment, Division of J & B Products Ltd., has introduced into commerce sunlamp products for which no product reports were submitted and for which the timer systems exceeds the maximum recommended exposure times (MRET's) established by product testing.

An inspection of your sunlamp product manufacturing operations was conducted on January 29, 30, and February 6, 7, and 12, 1997, by Investigator Deanna Lampley of our Detroit District Office. This inspection covered the compliance of your products with the Performance Standard for Sunlamp Products 21 CFR 1040.20. Sunlamp products are also devices as defined by Section 201(h) of the Act.

The inspection revealed that your firm is manufacturing and introducing into commerce sunlamp products based upon a false and misleading certification in that no product report has been received for the HEX Classic, HEX II or TAN 30 suntan booths which incorporate the B-29 Smart Lamp,

and the Hex II/Wolff System with Cosmolux or Solarium Reflector Lamps. The inspection further disclosed violations of the Act and EPRC as follows:

Section Brief Description

538(a)(1) International Tanning Equipment, Division of J & B Products, Ltd., has introduced into commerce sunlamp products which fail to comply with the EPRC as follows:

1. 21 CFR 1010.2(c): International Tanning Equipment, Division of J & B Products, Ltd's. certification testing program is not in accordance with good manufacturing practices in that it did not assure that its products complied with the sunlamp product performance standard.
2. 21 CFR 1040.20 (d)(1)(iv): Evaluation of the spectral irradiance output test data for your firms sunlamp products collected during the inspection revealed that the maximum timer interval(s) and exposure schedule(s) for the referenced sunlamp products were not established in accordance with these data results. According to the Optronic Laboratories, Inc., measurement report dated November 30, 1995, the maximum exposure time(s) are as follows:

Model	UV Lamp Designation	MRET (min.)		
		top	center	lower
HEX II	(46 lamps = 38 / B52RFR73/VHO & 8 / HEX FASHION TAN B52FRF73/VHO)	11.45	10.00	8.50
TAN 30	(containing 30 / B-29RFR74/VHO lamps)	15.86	15.13	14.42
HEX CLASSIC	(40 / Bellarium SR RA1-160W lamps)		13.12	

3. 21 CFR 1040.20(c)(2)(ii): Based on spectral irradiance output test data collected by the investigator during the inspection the referenced sunlamp products are equipped with timers which exceed the maximum timer interval established by the test data noted above.
4. 21 CFR 1040.20(e)(1)(i): The required user instructions for all 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.

538(a)(4) International Tanning Equipment, Division of J & B Products, Ltd., has failed to provide Product Reports/Supplemental Reports, as required by 21 CFR 1002.10 and 1002.11, for models "HEX II, HEX II WOLFF SYSTEM", "HEX CLASSIC", and/or "TAN 30" sunlamp products and any other sunlamp products incorporating "B52RFR72,73/VHO", "HEX FASHION TAN B52FRF73/VHO", "B29 Smart lamp 72,74/VHO", "COSMOLUX VHR NAI-15-160W" and/or "BELLARIUM SR RA1-160W" sunlamps.

538(a)(5)(B) International Tanning Equipment, Division of J & B Products, Ltd., has issued a certification when such certification is not based on a testing program that assures the sunlamp products comply with all applicable standards. Nor is such certification based upon a test or testing program in accordance with good manufacturing practices, as required by 21 CFR 1010.2(c), and the issuer, in the exercise of due care, has reason to know that such certification is false and misleading in a material respect.

The above-stated inspection revealed that International Tanning Equipment, Division of J & B Products, Ltd., 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 Regulation, as specified in 21 CFR Part 820 as follows:

1. Failure to investigate the failure of the device to meet performance specifications after a device has been released for distribution, and to make a written record of the investigation including conclusions and follow-up, as required by 21 CFR 820.162. For example, the complaint record book and part replacement files noted at least 10 tanning booth timer failures without any record of an evaluation or investigation into the failures.
2. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures, as required by 21 CFR 820.20(b).
3. Failure to have signed and dated device master records for production process procedures, quality assurance procedures, packaging and labeling specifications, and device specifications, as required by 21 CFR 820.181.
4. Failure of the device master record to include device specifications, including component specifications, as required by 21 CFR 820.181(a). For example the device master record lacks written specifications for the specific lamp types placed in the following tanning booths: the Hex Classic Booths manufactured with the B-29 Smart Lamps, the Hex II Booths manufactured with the Wolff Bellarium Bulbs and B-29 Smart Lamps, and the Tan 30 Booths manufactured with B-29 Smart Lamps.
5. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, no documentation is available to show that finished product testing was done on Tan 30 Tanning Units manufactured on 2/27/96 (Serial Number T-5743-2-96), 4/2/96 (Serial Number T-5729-2-96), and 2/29/96 (Serial Number T-5722-1-96).
6. Failure of the device master record to include quality assurance procedures and specifications, as required by 21 CFR 820.181(c). For example, no written testing procedures are available for the Phototherapy Booth timer, or for the recording of the amp meter readings for finished product testing of the ballasts.

7. Failure to have a formal approval procedure for any change in the manufacturing process, as required by 21 CFR 820.100(b)(3). For example, two different warning labels are available for production of the Hex Classic Booth and the Hex II Booth using the B-29 Smart Lamp bulbs which have different maximum exposure times (10 minutes and 15 minutes):
8. Failure to routinely calibrate measurement equipment and to maintain records of calibration, as required by 21 CFR 820.61. For example, the test calibration procedure calls for testing the amp meters every 6 months, and no documentation is available to show that any calibration has been done. The calibration procedure calls for testing the insulation tester (hot box) every 6 months, and the Insulation Tester, Serial Number 7652, has not been calibrated since 1991 and the Insulation Tester, Serial Number 94148, has not been calibrated since 1994. The test calibration procedure calls for testing the stop watch used for finished product testing every 3 months, and the stop watch was last calibrated over 5 months ago.

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 and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a 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 for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 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 geographical 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).

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) 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 prescribed 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 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 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.

You must submit all the information required under 21 CFR parts 1002.10, 1002.11 and 1040.20 such that CDRH can determine that International Tanning Equipment, Division of J & B Products, Ltd., is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices. The CDRH will advise you whether or not your submittal is satisfactory and when you may resume introduction of certified products into commerce.

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 to the Detroit District Office as follows: Mr. David M. Kaszubski, Compliance Officer, Food and Drug Administration, 1560 East Jefferson Avenue, Detroit, Michigan 48207. If you have any questions please contact Mr. Norman L. Timberlake at (301) 594-4654.

Sincerely yours,



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