



10/19/97
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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED LETTER
RETURN RECEIPT REQUESTED

WARNING LETTER
97-DT-20

September 30, 1997

Mr. Andre J. Boulet, Owner
Golden Tanning, Inc.
32653 Cherry Hill
Westland, MI 48185

Dear Mr. Boulet:

An inspection of your tanning salon was conducted on August 6, 7, 11, and 13, 1997 by FDA Investigator Deanna Lampley. The inspection found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) which include significant items of noncompliance with the Federal Performance Standards for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20).

A number of tanning units do not comply with 21 CFR 1040.20(c)(2)(ii) in that the maximum timer interval exceeds the manufacturer's recommended maximum exposure times as indicated on the labeling for the following tanning units:

- Room 2 Mega Sun, Tanning Bed, Serial # MS.3337
- Room 3 Sun Industries, Suntana, Tanning Bed, Serial # 388
- Room 5 5N - Sun Industries, Tanning Booth, Serial # 190
 5S - Sun Industries, Tanning Booth, Serial # 194
- Room 10 Sun Industries, Suntana, Tanning Bed, Serial # 246
- Room 11 Mega Max, Tanning Bed, Serial # MS.3367
- Room 13 Sun Industries, Tanning Booth, Serial # 184
- Room 14 Mega Sun, Tanning Bed, Serial # MS.3336
- Room 15 Sun Industries, Tanning Booth, Serial # 189
- Room 16 Sun Industries, Tanning Booth, Serial # 187
- Room 17 Sun Industries, Tanning Booth, Serial # 191
- Room 18 18AN - Sun Industries, Tanning Booth, Serial # 183
 18BS - Sun Industries, Tanning Booth, Serial # 180

These tanning units are also adulterated within the meaning of Section 501(c) and misbranded within the meaning of Section 502(a) of the Act in that the units are labeled as complying with 21 CFR 1040.20 when in fact they do not comply with the standard.

Page 2

Warning Letter 97-DT-20

Golden Tanning, Inc.

Westland, MI 48185

A number of tanning units do not comply with 21 CFR 1040.20(e)(1) in that user/owner's manual which contain adequate instructions for use, and technical and safety information were not available for the following tanning units:

Room 3	Sun Industries, Suntana, Tanning Bed, Serial # 388
Room 5	5N - Sun Industries, Tanning Booth, Serial # 190
Room 9	Sun Industries, USA TAN, Tanning Bed, Serial # 433
Room 10	Sun Industries, Suntana, Tanning Bed, Serial # 246
Room 15	Sun Industries, Tanning Booth, Serial # 189
Room 16	Sun Industries, Tanning Booth, Serial # 187
Room 17	Sun Industries, Tanning Booth, Serial # 191

These tanning units are also adulterated within the meaning of Section 501(c) of the Act in that the units are labeled as complying with 21 CFR 1040.20 when in fact they do not comply with the standard.

This inspection also noted that the ultraviolet lamps were found in the following tanning units which were not compatible with the lamps specified for the tanning units. No documentation was available to show that the lamps were equivalent to the specified lamps.

Room 2	Mega Sun, Tanning Bed, Serial # MS 3337
Room 5	5N - Sun Industries, Tanning Booth, Serial # 190
Room 7	ISM, Black - Tanning Bed, Serial # A665
Room 8	ISM, White - Tanning Bed, Serial # A600
Room 12	ISM, White - Tanning Bed, Serial # Unknown
Room 14	Mega Sun, Tanning Bed, Serial # MS
Room 15	Sun Industries, Tanning Booth, Serial # 189
Room 16	Sun Industries, Tanning Booth, Serial # 187
Room 17	Sun Industries, Tanning Booth, Serial # 191

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.

You must respond in writing within 15 working days of the receipt of this letter. In responding you have the following options:

- A. Refutation - You may submit your views and evidence to establish that the alleged noncompliance or defect does not exist.

NOTE: Should your refutation not be accepted, you may request a Regulatory Hearing to state your views in accordance with 21 CFR 1003.11(a)(3).

- B. If you determine that the noncompliance or defect is caused by the factory-based

Page 3

Warning Letter 97-DT-20

Golden Tanning, Inc.

Westland, MI 48185

manufacturer, you must notify him of the noncompliance and send documentation of such notification to this office.

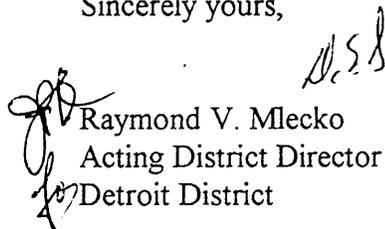
- C. If you can establish that the system is compliant, and that the alleged noncompliance or defect does not exist or does not relate to the safety of the product, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 days of the receipt of this letter.
- D. Make the necessary corrections, and provide a written description of your corrective action to this office.

Failure to promptly correct these violations can result in regulatory action being taken by the Food and Drug Administration without further notice. These actions include but are not limited to seizure, injunction and/or civil penalties as provided for in Sections 303 and 539 of the Act.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. 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 directed to Mr. David M. Kaszubski, Compliance Officer, 1560 East Jefferson Ave., Detroit, MI 48207 (Telephone: 313-226-6260 Ext 185).

Sincerely yours,


Raymond V. Mlecko
Acting District Director
Detroit District