



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

June 15, 2004

Warning Letter No. 2004-NOL-27

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Carl Cotten, Owner
Sheila P. Cotten, Owner
Perfect Tans and Spa
3441 Lebanon Road
Hermitage, Tennessee 37076

Dear Mr. & Mrs. Cotten:

During an inspection of Perfect Tans and Spa, located at the above referenced address, on April 7 - 9, 2004, United States Food and Drug Administration (FDA) investigator Carl A. Huffman III, determined that your business maintains and operates tanning beds. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). Our investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in conjunction with thirteen (13) tanning beds at your facility.

The inspection revealed that several of your tanning beds are adulterated within the meaning of Section 501(c) of the Act in that their strength differs from, or their quality falls below, that which they are represented to possess because they contain UV lamps which are different from the lamp types designated for use in these products by the manufacturers' warning labels. The Federal Performance Standard for Light Emitting Products set forth in Title 21, *Code of Federal Regulations*, Part 1040 (21 CFR Part 1040) requires that manufacturers' warning labels designate the ultraviolet lamp type to be used in any sunlamp product. See 21 CFR § 1040.20(d)(1)(vi). No documentation was provided to show that the UV lamps in use in certain tanning beds at Perfect Tans and Spa are compatible with the UV lamps recommended by the manufacturer and certified for use in the beds. Thirteen (13) tanning beds were found to lack compatible UV lamps.

The inspection revealed that your tanning beds were not compliant with the required labeling as follows:

1. Ten (10) of your [REDACTED] tanning beds contain [REDACTED] lamps, which are not the type lamps specified in the label for the beds nor are they equivalent lamps.

2. Two (2) of your [REDACTED] tanning beds contain [REDACTED] lamps, which are not the type lamps specified in the label for the beds nor are they equivalent lamps.
3. One (1) of your [REDACTED] tanning beds contain [REDACTED] lamps, which are not the type lamps specified in the label for the beds nor are they equivalent lamps.

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 applicable regulations.

You should take prompt action to correct these violations. 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/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to bring your business into compliance with the law. Your response should include each step that has been taken or will be taken to correct these violations and prevent their recurrence. If corrections cannot be completed within 15 working days, please state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217. If you have any questions, please contact Mr. Hayes at (615) 781-5389 extension 125.

Sincerely,



H. Tyler Thornburg
District Director
New Orleans District

Enclosure:
21 CFR Part 1040.20