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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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Refer to: CFN 1125220

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4040

November 19, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Glenda Hughes-Turner, Owner  
Two Thumbs Up Tanning  
810 University City Avenue, Suite G  
Blacksburg, Virginia 24060

Dear Ms. Hughes-Turner:

During an inspection of your Blacksburg, Virginia facility on October 30 and 31, 1997, violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) were observed. Our investigator inspected the Super Sundash R40 tanning bed 1, Sundash ZR-32 tanning bed 2, Sundash R26B tanning beds 3 and 4, Sundash R26P tanning beds 5 and 6, Sundash R32P tanning beds 7 and 9, TanAmerica VIP/SLC tanning bed 8, and Cyber-Dome CO52 tanning bed 10. Significant items of noncompliance with the Federal Performance Standards for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations (CFR), Part 1040.20, were documented.

These items of noncompliance render tanning beds 2, 3, 4, 5, 6, 7, and 9 adulterated within the meaning of Section 501(c) of the FD&C Act, in that the quality of the sunlamp products fall below that which they purport to possess. The beds contain UV lamps other than those designated by the manufacturer, and there is no documentation available to establish that those lamps are compatible with those designated by the manufacturer. In addition, tanning beds 7 and 9 have timers that were modified to allow up to 20 minutes of exposure that is not compatible with the manufacturer's labeled maximum exposure time of 10 minutes.

The inspection also revealed that the sunlamp products present in your establishment are misbranded within the meaning of Section 502(f) of the FD&C Act, in that instruction manuals for all beds are not available to provide users with adequate directions for use in such a manner as is necessary for protection against potentially harmful exposure to ultraviolet radiation.

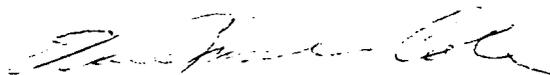
Ms. Glenda Hughes-Turner  
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The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that electronic sunlamp products in use at your facility meet applicable performance standards and are in compliance with the provisions of the FD&C Act. You should take prompt action to correct these violations. Failure to do so may result in regulatory action, including seizure, injunction and/or civil penalties, without further notice. A copy of the Federal Performance Standards for Sunlamp Products and the FDA-483, List of Observations, issued on October 31, 1997, are enclosed for your reference.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Elaine Knowles Cole  
Director, Baltimore District

Enclosures