



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

Telephone (201) 331-2907

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

October 7, 1997

WARNING LETTER

RELEASE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Lisa Wolfson, Owner
Diamond Tanning
Routes 24 & 206
Chester, New Jersey 07930

REVIEWED BY

RUB
C.C.

10/9/97
DATE

FILE NO.: 98-NWJ-01

Dear Ms. Wolfson:

Field examination of your tanning salon on August 21 and 22, 1997 by FDA Investigator Keith Schwartz revealed violations of the Federal Food, Drug and Cosmetic Act (the Act). Our investigator documented 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) in conjunction with suntan products in your facility.

The field examination found that the suntan bed (Room #1) in your facility to be adulterated within the meaning of Section 501(c) of the Act in that frayed wiring was exposed from the suntan bed, and the maximum exposure setting is greater than the maximum exposure setting recommended by the manufacturer.

In addition, suntan beds located in Rooms #2-5 do not allow the user to terminate radiation emissions. The ultraviolet lamps installed in the beds in Rooms #1-5 are not those required by the labeling and no documentation regarding the lamps' compatibility was available.

The field examination also revealed that the suntan beds located in your facility did not contain required warnings and labels as follows:

- There were no certification or manufacturing identification labels for the suntan bed in Room #1.

Diamond Tanning (WL 98-NWJ-01)
October 7, 1997
Page 2

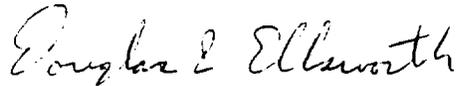
- There were no user manuals available to the patrons for Room #1 and the facial tanning unit.
- The "DANGER..." labeling for the facial tanning unit was incomplete.
- There was no protective eyewear warning for the facial tanning unit.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that suntan products in use at your facility meet applicable performance standards and are in compliance with the provisions of the Act. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure, injunction and/or civil penalties.

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 the noted 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 sent to the U.S. Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., Parsippany, New Jersey 07054, Attn: Rosa Brown, Compliance Technician.

Very truly yours,



DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

RLB/