



Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
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May 17, 1999

WARNING LETTER
CIN-WL-99-246

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Catherine L. Smith, President
Sit Inc.
dba Southern Island Tan, Inc.
5905 New Cut Road
Louisville, KY 40214

Dear Ms. Smith:

The inspection of your tanning salon located at 5905 New Cut Road, Louisville, Kentucky, on April 21, 1999 by the Food and Drug Administration revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations (CFR) Section 1040.20 with tanning beds and booths in operation at your facility. The nonconformance causes the tanning beds and booths to be misbranded within the meaning of Section 502(f) of the Act and fail to meet the Performance Standard for Sunlamp Products.

The following nonconformance was documented:

1. There were no user termination controls on the tanning beds or booths to enable the person being exposed to manually terminate radiation emission from the product.
2. The tanning beds and seven of the eight tanning booths lack required labeling such as recommended exposure position and directions for achieving it; recommended exposure schedule and designation of the ultraviolet lamp type to be in the product. One of the booths (OAHU) did not have the "DANGER Ultraviolet Radiation" statement.
3. The firm had removed the 100W lamps and old ballast and replaced them with 160W lamps and new ballast in all beds. There was no documentation of lamp compatibility.
4. Labels are not permanently affixed on the exterior surface of the beds. They are affixed to the wall in the room where each bed is located.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure injunction and/or civil penalties.

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Please notify this office with 15 days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,


Henry L. Fielden
District Director