

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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WARNING LETTER

August 15, 1997

Ramona J. Ivy
Owner
Tropical Tan
1150 West Main Street
Lewisville, TX 75067

Dear Ms. Ivy:

The inspection of your tanning facility, Tropical Tan located at 1150 West Main Street, Lewisville, TX 75067, on June 30, 1997, by investigator Joseph T. Goertz 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, Part 1040.20 (21 CFR 1040.20) in conjunction with tanning beds in operation at your facility. Tanning beds in rooms 1 thru 5 were manufactured by Sun Industries, Inc., Jonesboro, AR. The tanning beds in rooms 6 thru 10 are Wolff brand beds, manufactured by Allisun America, LTD., McHenry, IL.

The inspection revealed that the tanning beds were misbranded within the meaning of Section 502(f) of the Act. The multiple timer settings were not compatible with the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the labeling [21 CFR 1040.20 (c)(2)] for tanning beds in rooms 6, 7, 8, 9 and 10. In addition, the warning labels on tanning beds located in rooms 1, 2, 3, 4 and 5 were either torn, smeared or illegible [21 CFR 1040.20 (d)(1)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding sunlamp products at your firm. It is your responsibility to assure that electronic sunlamp products are maintained so that they continue to comply with the provisions of the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

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

Your reply should be directed to Deborah M. McGee, Radiation Specialist, U.S. Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, telephone (214) 655-8100, ext. 138.

Sincerely,

A handwritten signature in cursive script, appearing to read "B. Belinda Collins".

B. Belinda Collins
Regional Radiological Health Representative
Southwest Region

DM:dm