



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

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Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
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WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

98-SWR-WL-13

August 3, 1998

Scott A. Ortega
President
Mirage Spas and Tanning Salon
1909 St. Michael's Drive
Santa Fe, NM 87505

Dear Mr. Ortega:

The inspection of your tanning facility, Mirage Spas and Tanning Salon located at 1909 St. Michael's Drive, Santa Fe, NM 87505, on June 26, 1998, by Investigator Robert G. Antonsen 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. The inspection indicated noncompliances for the Sonnen Braune and Sunvision Pro 26 LX tanning beds.

The inspection revealed that the tanning beds were misbranded within the meaning of Section 502(f) of the Act. There were no user termination controls on the Sonnen Braune tanning units to enable the person being exposed to terminate manually radiation emission from the product [21 CFR 1040.20(c)(3)]. The Sunvision Pro 26 LX tanning beds lacked all required labeling for warning, danger, certification and identification [21 CFR 1040.20(d)]. In addition, the tanning beds containing Radiance 9000-F71-CE lamps required documentation of lamp compatibility with product [21 CFR 1040.20(d)].

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,



Edward R. Esparza
Regional Food and Drug Director
Southwest Region

DM:dm

bcc: HFA-224