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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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

98-SWR-WL-04/0

January 21, 1998

Jeff Everett
Owner
Sun Splash Tanning
114 Rear Main Street
Festus, MO 63028

Dear Mr. Everett:

The inspection of your tanning facility, Sun Splash Tanning located at 114 Rear Main Street, Festus, MO 63028, on December 3 & 4, 1997, by Investigator Dennis Butcher 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 two SunQuest Pro 24 XL tanning beds distributed by European Tanning Systems, Inc. (SN 0066499 and SN 0066500).

The inspection revealed that the tanning beds located in rooms 1 and 4 were misbranded within the meaning of Section 502(f) of the Act. There were no user instruction manuals available for these tanning beds to provide adequate directions for use in such manner as necessary for the protection of users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(e)(1)]. The maximum timer interval for these tanning beds exceeded the manufacturer's recommended maximum exposure time [21 CFR 1040.20(c)(2)]. In addition, 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 the tanning beds.

During this inspection, it was acknowledged that other items of noncompliance were immediately addressed by your facility. 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.

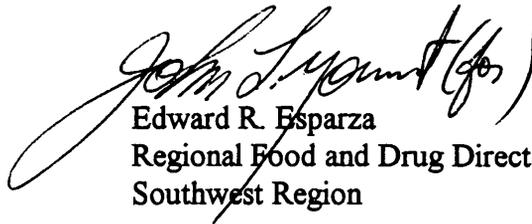
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You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

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