



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

3/5/98  
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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-05/7

February 18, 1998

Deb Churchill  
Owner  
A Field of Dreams  
138-B W. Church Street  
Lewisville, TX 75057

Dear Ms. Churchill:

The inspection of your tanning facility, A Field of Dreams, located at 138-B W. Church Street, Lewisville, TX 75057, on January 13, 1998, by investigator Joseph T. Goertz revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented a significant item 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 a tanning bed in operation at your facility. The tanning bed is a model E-24H, serial number 3060026, manufactured by Allisun America, LTD., McHenry, IL.

The inspection revealed that the tanning bed was adulterated within the meaning of Section 501(h) of the Act. The timer system on the tanning bed failed to operate during the activation of radiation exposure, as specified in the labeling [21 CFR 1040.20 (c)(2)]. A malfunctioning timer on a sunlamp product is a serious hazard and voluntary removal from service is advisable until repairs are completed.

The above identification of a violation 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 this violation. Failure to correct this violation 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 within 15 working days of receipt of this letter, of specific steps you have taken to correct this violation. If the correction cannot be completed within the allotted time, state the reason for the delay and the time frame within which the correction 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