



**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  
FACSIMILE: 214-655-8130

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

00-SWR-WL-83/0

October 6, 2000

Gregory Henson  
President  
Heartland Tanning Supplies  
4251 N. E. Port Drive  
Lee's Summit, MO 64064

Dear Mr. Henson:

The inspection of your manufacturing facility, Heartland Tanning Supplies, Inc. located at 4251 N. E. Port Drive, Lee's Summit, MO 64064, on September 12, 2000, 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 manufactured at your facility. The inspection indicated noncompliances for Heartland model 154 Ovation suntanning beds.

As required in Section 537(b) of the Act, annual reports were not generated annually for your sunlamp products [21 CFR 1002.13]. In addition, quality control procedures and records of results of tests [21 CFR 1002.30(a)(1)&(2)] were not provided to ensure function of the emission control device [21 CFR 1040.20(c)(2)&(3)].

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 ensure 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.

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

Page 2  
October 6, 2000

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,

*Daryl E Brown*  
Gary L. Pierce *for*  
Regional Food and Drug Director  
Southwest Region

Cc: Randal Russell  
Technical Manager  
Heartland Tanning Supplies, Inc.  
4251 N. E. Port Drive  
Lee's Summit, MO 64064