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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4099

April 17, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Richard Gilbert  
The Sport and Health Company  
1800 Old Meadow Road Unit H  
McLean, Virginia 22102

Dear Mr. Gilbert:

During an inspection of your facility, conducted by the Food and Drug Administration on April 3, 1997, a serious violation of the Federal Food, Drug and Cosmetic Act (the Act) was observed.

The inspection revealed that your tanning beds are adulterated within the meaning of Section 501(c) of the Act, in that the quality of the sunlamp products falls below that which they purport to possess. These tanning beds fail to comply with the Federal Performance Standards for Sunlamp Products, Title 21, Code of Federal Regulations, Section 1040.20, in that:

1. They do not have an "on/off" switch or an emergency shut-off to terminate exposure by the user.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that the electronic sunlamp products in use at your facility meet applicable performance standards and are in compliance with the provisions of the Act. You should take prompt action to correct this deviation. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be

Mr. Richard Gilbert

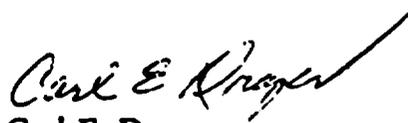
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completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Lori S. Lawless, Acting Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201.

Sincerely,



Carl E. Draper  
Acting District Director

cc: Ms. Lisa Karp, Manager  
Spa Lady  
256 S. VanDorn Street  
Alexandria, Virginia 22207