



Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Luca Sartini, Partner
Sun Spa Group, LLC
215 West 76th Street
New York, NY 10023

September 21, 1999

Ref: NYK-1999-73

Dear Mr. Sartini:

The inspection of your tanning salon on August 12, 1999 by FDA Investigator Murray L. Kurzman 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, in conjunction with two 2-lamp and one 3-lamp facial tanning units (unidentified as to manufacturer) and seven Vitasun tanning beds in operation at your facility.

The inspection revealed that the tanning beds and facial tanning units were misbranded within the meaning of Sections 502(b), 502(c), and 502(f) of the Act as follows:

Facial tanning units

- There were no labels or tags with the manufacturer's certification and manufacturer's identification [21 CFR 1010.2 and 1010.3].
- There were no labels that contain required "Danger..." warning statements [21 CFR 1040.20(d)(1)(i)], a recommended exposure schedule [21 CFR 1040.20(d)(1)(iv)], and the designation of the ultraviolet lamp type to be used in the product [21 CFR 1040.20(d)(1)(vi)].
- There were no instructions for the units available to be provided to users [21 CFR 1040.20(e)(1)].

Vitasun tanning beds

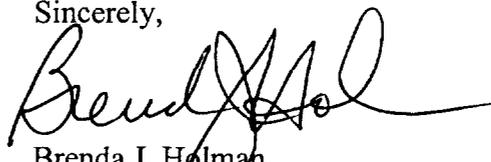
- There were no labels or tags with the manufacturer's identification [21 CFR 1010.3].
- There were no labels that contain a warning statement to avoid overexposure [21 CFR 1040.20(d)(1)(i)] and the designation of the ultraviolet lamp type to be used in the product [21 CFR 1040.20(d)(1)(vi)].
- There were no instructions for the beds available to be provided to users [21 CFR 1040.20(e)(1)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that 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 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, within 15 working days of receipt of this letter, of the 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 the corrections will be completed.

Your response should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attn: Bruce A. Goldwitz, Compliance Officer (telephone 718/340-7000 ext. 5507).

Sincerely,



Brenda J. Holman
District Director

Enclosures: 21 CFR 1040.20, 1010.2, and 1010.3