



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
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Telephone: 206-486-8788
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May 14, 1997

VIA FEDERAL EXPRESS

In reply please refer to Warning Letter SEA 97-21

WARNING LETTER

Nancy J. Crawford, Owner
Quik Tan, Inc.
15600 NE 8th Street, Suite A-8
Bellevue Washington 98008

Dear Ms. Crawford:

Inspection of your tanning salon on April 29 and May 2, 1997, by FDA Investigator John Hall, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). Our investigator documented significant items of noncompliance with the Federal Performance Standards for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20) in conjunction with the tanning booths in operation at your facility.

Inspection revealed the five (5) tanning booths to be adulterated within the meaning of Section 501(c) of the Act in that they contain UV lamps which are not designed for use in tanning booths. Lamps used in these booths, which are a mixture of lamps made by [REDACTED] are labeled for medical use only. No documentation was provided to show that these lamps are acceptable and compatible for use in these booths.

Inspection also revealed your tanning booths are misbranded within the meaning of Section 502(f) of the Act in that there is, a) no exposure schedule that includes duration and spacing of sequential exposures; b) no label stating "Wear protective eyewear; failure to may result in severe burns or long-term injury to the eyes;" c) no manufacturer's label designating compatible lamp types; d) and no user instruction manuals.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure 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

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Quik Tan, Inc., Bellevue, WA
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these violations may result in regulatory action, including seizure, injunction, and/or civil penalties, without further notice.

You should notify this office in writing, within fifteen (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 Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,


Roger D. Lowell
District Director
Seattle District

Attachments:

21 CFR 1040.20, Sunlamp products and ultraviolet lamps
intended for use in sunlamp products