



**WARNING LETTER**

**VIA FEDERAL EXPRESS**

October 9, 2001

Svetlana A. Helm  
Owner  
Ultra Tan, Inc.  
3585 S. Durango Dr., #103  
Las Vegas, NV 89146

Dear Ms. Helm:

An inspection of your tanning facility located at 3585 S. Durango Dr., #103, Las Vegas, NV 89146, on August 16, 2001, investigator Anthony E. Keller, R.Ph., revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). Investigator Keller observed 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).

The inspection revealed that three sunlamp products (two [REDACTED] models and one [REDACTED] model) inspected at your facility are misbranded with the meaning of Section 502(f) of the Act, in that they do not incorporate a control on the product to enable the person being exposed to terminate manually radiation emission from the product at any time without disconnecting the electric plug or removing the ultraviolet lamp, as required by 21 CFR 1040.20(c)(3).

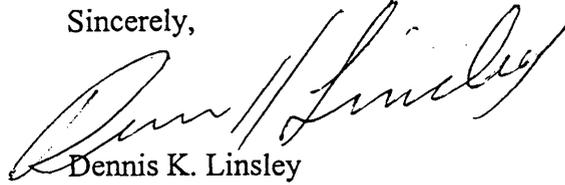
The above violations are not intended to be an all-inclusive list of deficiencies regarding sunlamp products in use by facilities operated by your firm. It is your responsibility to ensure that sunlamp products in use at your facilities meet applicable performance standards and are in compliance with the provisions of the Act. You should take prompt action to correct the violations. 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 violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We acknowledge receipt of your "To whom it may concern" letter dated August 17, 2001 sent to investigator Keller, but do not find that response adequate. You state that, "A large number if not the majority of tanning beds in use in salons incorporate computer control with a timer (start, stop) system mounted on

the wall located within the tanning room to be accessed by the customer.” Wall-mounted switches must be reachable by the customer without getting out of position, which is not the case with these units, according to Investigator Keller’s description.

Your response should be directed to Paul A. Peterson, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions, contact Mr. Peterson at (510) 337-6856.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dennis K. Linsley".

Dennis K. Linsley  
District Director  
San Francisco District