



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2771

**Warning Letter**

WL-CIN-8150-01

June 15, 2001

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Loretta B. Moss, Owner  
Electric Beach  
610F West Main Street  
Campbellsville, KY 42718

Dear Ms. Moss,

An inspection of your tanning salon was conducted on May 16-17, 2001 by FDA Investigator Jerry Corwin. The inspection found 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). These are serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

The following items of noncompliance with the Federal Performance Standard for Sunlamp Products were noted:

Your tanning units do not comply with 21 CFR 1040.20(c)(2)(ii) in that the maximum timer interval exceeds the manufacturer's recommended maximum exposure times as indicated on the labeling.

- a. For the [REDACTED] Bed, the maximum exposure time should only be twelve minutes. You allow thirty minutes.
- b. For the [REDACTED] Beds, the maximum exposure time should be twenty minutes. You allow thirty minutes.
- c. For the [REDACTED] beds, you were unaware of the maximum exposure time. You allow thirty minutes.

All [REDACTED] beds lacked warning labels specified in 21CFR 1040.20(d)(1)(i). The [REDACTED] beds also lacked labels for: recommended exposure positions, directions, recommended exposure schedules, statement of time for expected results to appear and designation of the ultraviolet lamp type to be used. These requirements are found in 21CFR 1040.20(d)(1)(ii-vi).

Inspection also documented that you do not always offer protective eyewear as required by 21CFR 1040.20(c)(4). The investigation found that while you are not present at the firm, [REDACTED] makes people purchase protective eyewear, bring their own or go without.

All twenty-one beds lack a control to enable the person being exposed to manually terminate the tanning session without leaving the exposure position as required by 21CFR 1040.20(c)(3).

You do not have users manuals that contain adequate directions for use, and technical and safety information for the twenty-one beds in operation at your facility as required in 21CFR 1040.20(e).

You were unable to demonstrate the compatibility of the sunlamp bulbs for use in any of the beds at your facility.

The [REDACTED] and [REDACTED] beds are also adulterated within the meaning of Section 501 (c) and misbranded within the meaning of Section 502(a) of the Act in that the units are labeled as complying with 21CFR 1040.20 when in fact they do not comply with the standard. The beds are further misbranded within the meaning of Section 502(f)(1) because they lack adequate directions for use and under Section 502(f)(2) because they lack adequate warnings.

Due to the serious hazards involved in the deficiencies noted above, it is requested that you do not use the products until appropriate corrections have been made.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar 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. Please include copies of any available documentation demonstrating that corrections have been made. When responding, you have the following options:

- A. Refutation - You may submit your views and evidence to establish that the alleged noncompliance or defect does not exist. NOTE: Should your refutation not be accepted, you may request a Regulatory Hearing to state your views in accordance with 21CFR 1003.11(a)(3).
- B. If you determine that the noncompliance or defect is caused by the factory-based manufacturer, you must notify him of the noncompliance and send documentation of such notification to this office.
- C. If you can establish that the system is compliant, and that the alleged noncompliance or defect does not exist or does not relate to the safety of the product, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 days of the receipt of this letter.
- D. Make the necessary corrections, and provide a written description of your corrective action to this office.

Failure to promptly correct these violations can result in regulatory action being taken by the Food and Drug Administration without further notice. These actions include but are not limited to seizure, injunction and/or civil penalties as provided for in Sections 303 and 539 of the Act.