Compliance Program Guidance Manual: Field Implementation of the Sunlamp and Sunlamp Product Performance Standard, as amended;

Final Guidance for Industry and FDA

Document issued on: October 6, 2001

This document supersedes "Compliance Program Guidance Manual: Field Implementation of the Sunlamp and Sunlamp Products Performance, as amended," dated May 15, 1990**.**

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Electronics Products Devices Branch
Division of Enforcement III
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Norman L. Timberlake or Manuel G. Karos at (301) 594-4654 or email at NLT@cdrh.fda.gov or MGK@CDRH.fda.gov.

Additional Copies

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Compliance Program Guidance Manual: Field Implementation of the Sunlamp and Sunlamp Product Performance Standard, as amended;

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Compliance Program Guidance Manual 7386.002

SUBJECT:	IMPLEMENTATION DATE
FIELD IMPLEMENTATION OF THE SUNLAMP AND SUNLAMP PRODUCTS PERFORMANCE STANDARD AS AMENDED.	Upon Receipt of Final Document
Attachments A-H	COMPLETION DATE September 30, 2005

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
95 US-11 95 UN-11	86002

FIELD REPORTING REQUIREMENTS:

A. GENERAL

Copies of the following documents should be sent to:

Electronic Products Branch (HFZ-342)
Office of Compliance
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

- All regulatory or administrative recommendations.
- The EIR (violative) including the attached checklist (Attachment B/B.1).
- All complaint/injury reports and any follow-up information.
- Sample Collection Reports associated with or resulting from the inspection.
- Warning Letters sent by the district to the firm.
- Any corrective action plan or response from the firm indicating correction or a willingness to correct a problem.
- Corrective Action Plan approval letters.
- Letters Granting exemption or accepting refutation.

B. FACTS REPORTING

NOTE: A FIELD TEST OF A SUNLAMP PRODUCT SHOULD BE REPORTED AS A DOMESTIC FIELD TEST/EXAM IN FACTS. FOR GUIDANCE ON REPORTING, REFER TO THE ORA DATA CODES.

All FACTS data should be entered by the accomplishing district where the operation was performed.

C. SPECIAL

If it is determined that a sunlamp product (or ultraviolet lamp) does not comply with the Federal standard, special reporting procedures are necessary and are detailed under Part III, A., "Operations."

PART I - BACKGROUND

A sunlamp product is an electronic product designed to use one or more ultraviolet lamp(s) and is intended for irradiation of any part of the living human body by ultraviolet radiation within a specified range of wavelengths to induce skin tanning. The ultraviolet lamps, subject to the performance standard, produce radiation within a prescribed range of wavelengths and are intended for use in sunlamp products.

Sunlamp products include portable home units, table top models, tanning beds and tanning booths. These units may incorporate different types of fluorescent lamps, reflector spot (RS) or High Intensity Discharge (HID) with different levels of energy output and radiation at different wavelengths. These products are recognized as hazardous and produce an estimated 3,000 hospital emergency room cases a year.

Since sunlamp products are radiation emitting electronic products as defined by Section 531 of Subchapter C- Electronic Product Radiation Control (EPRC) formerly the Radiation Control for Health and Safety Act (RCHSA) and medical devices as defined by Section 201(h)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), they are regulated under both laws.

Under authority of Section 534 of the (EPRC), a performance standard for sunlamp products and ultraviolet lamps intended for use in these products was promulgated effective May 7, 1980 (21 CFR 1040.20). The standard was intended to reduce sunlamp related injuries by reducing unnecessary exposure and overexposure to sunlamp radiation by: (1) limiting shorter wavelength emissions that are not necessary and pose unreasonable risk, (2) providing for adequate warning label and user instructions containing safety information, and (3) requiring special lamp bases, protective eyewear, timers, and controls to help users limit the duration and amount of exposure.

This performance standard was promulgated when the common sunlamp product was a table-top, home portable unit incorporating one or two RS lamps having a large part of their radiation output in the wavelength range of 260 to 320 nanometers (UVB). In 1979-80, a new-wave of sunlamp products came onto the market. These products, commonly referred to as Tanning Booths, usually measured 3'x3'x7' and contained one or two fluorescent ultraviolet lamps in each corner. These products also had relatively high UVB output.

Around early 1983, another product in the shape of a bed and/or canopy entered the market with fluorescent lamps that emit radiation mainly in the 320-400 nanometer range (UVA), with usually less than 5% in-the UVB range. This type of product requires longer exposure times to achieve its intended purpose and the risk of chronic sunburn is reduced relative to the older type of products. Most manufacturers requested variance under 21 CFR 1010.4 to equip the products with timers which would allow exposure in excess of ten minutes. Since the products usually required 30 minutes to achieve their intended result, the variances were granted with two conditions: (1) the maximum timer interval shall not exceed the maximum recommended exposure time specified in the required product label, and (2) the UVB to UVA ratio shall not exceed .05 (no more than 5% UVB). The manufacturers are required to specify the variance number and effective date on the product).

Some of these products incorporate High Intensity Discharge (HID) lamps. These lamps are usually used for facial tanning, although some whole body exposure systems use such lamps exclusively. In most cases, however, these lamps are used in conjunction with ultraviolet fluorescent lamps. The HID lamps are much smaller than fluorescent lamps, (usually about 1/2" in diameter by 3" in length) and they usually incorporate an outer, clear, glass envelope.

On September 6, 1985, amendments to the performance standard were published and became effective in September 8, 1986. The purpose of the amendments is to accommodate new products employing design concepts significantly different from those for which the original standard was developed. Also, FDA experience in applying the original standard indicated that some requirements were either inappropriate for or not applicable to some products. The amendments are intended to establish a standard that is appropriate for the present technology of suntanning and new sunlamp product designs. This revised program offers guidance for testing products against the original standard or revised standard, as appropriate.

The District Offices have the authority (delegated under 21 CFR 5.37 and 5.89) to make declarations of noncompliance and/or defect. The field also has the authority to approve corrective action plans under 21 CFR 1004 and to grant exemptions (from notification and product repair) in accordance with 21 CFR 1003.31.

PART II - PROGRAM

A. OBJECTIVES

This is a continuing non-statistical compliance program intended for field personnel to:

1. Identify and inspect importers and manufacturers of sunlamp products and UV lamps intended to be used in them and take appropriate administrative or enforcement actions, if necessary, to prevent introduction of violative products into commerce.

2. Identify and test products subject to the sunlamp products performance standard to determine compliance with the standard.

3. Identify and test sunlamp products manufactured prior to the effective date of the sunlamp products performance standard to assure that they are not defective.

4. Assure corrections are made to identified violative products.

This circular is primarily intended as additional instruction to be followed during establishment inspections of medical device manufacturers whose devices include sunlamp products, as defined in 21 CFR 1040.20. However, the technical information in this circular should also be used as guidance for field testing of sunlamp products at user sites, investigation of consumer complaint/injury reports and accidental radiation occurrence reports, and inspection of importers and manufacturers for compliance with the FFDCA.

B. PROGRAM MANAGEMENT INSTRUCTION

1. Field Test Priorities

Facilities to be investigated for product testing are prioritized in the following order.

- suspected violative facilities (commercial tanning salons, distributors, etc.);
- importers
- newly identified facilities;

2. Inspection Priorities

- manufacturers having compliance problems;
- newly identified manufacturers;

3. Planning Instructions

- The District OEI should be used to determine those firms to be inspected. District import personnel may provide information on consignees of products subject to the standard.
- CDRH will send a copy of each letter (e.g., response to inquiry concerning future establishment of import business) to the manufacturer/importer to the district offices.
- Search phone books and monitor newspaper ads and any other available sources to identify health spas, beauty salons, and other locations of commercial tanning facilities within the district.

- There will be no routine physical sample collections under this program.

4. Program Interactions

a. QS/GMP Inspections

The field will make QS/GMP inspections under the Federal Food, Drug and Cosmetic Act (FFDCA) for all sunlamp product manufacturers. Concurrent inspection of sunlamp product manufacturers for compliance with both the device and radiation control portions of the FFDCA and the device QS/GMP is encouraged. QS/GMP inspections should be performed in accordance with C.P. 7382.845 and scheduled for inspection in accordance with instructions in that program.

b. WEAC Testing

C.P. 7386.006E delineates the UV lamp and sunlamp product testing to be conducted by WEAC.

c. Import Program

Since 1983, new types of sunlamp products (tanning beds and facial units) incorporating high and medium pressure high intensity discharge lamps were introduced into the United States from Europe. These types of lamps are intended to decrease the time needed for tanning and/or to increase the tanning effect for those areas of the body that are reportedly harder to tan.

According to data obtained from manufacturers' reports and promotional literature, this type of lamp emits short wave UV-B and UV-C, which is harmful to human eyes and skin. Also, since the lamps operate at an over-pressure, the possibility of an explosion cannot be entirely excluded. Some of these lamps may not have adequate filters, and may not meet the irradiance ratio limits for UV lamps prescribed by the standard (21 CFR 1040.20). They may also be considered defective because they emit radiation unnecessary for the accomplishment of the primary purpose and consequently create a risk of injury to any person.

Import Alert 95-01, Sunlamps and Sunlamp Products, directs increased surveillance and detention of these hazardous products and other noncompliant sunlamp products. See C.P. 7386.007 for additional instruction.

Importers are "manufacturers," as defined by Section 531 of the EPRC [and further defined by 21 CFR 1000.3(n)]. Unreported and/or noncompliant products should be detained. The detained products may be brought into compliance if the importer complies with the reporting requirement under 21 CFR 1002, and the products are corrected, tested, and certified as required by the standard (21 CFR 1040.20).

Foreign manufacturers are required to designate an agent, as specified by 21 CFR 1005.25. These agents are for communication purposes, and usually help to solve any problems with the foreign manufacturers.

5. Resource Instructions

- CDRH may be contacted to assist in supplying information, providing materials and technical assistance, and coordinating inspections (See Attachment A).

PART III - INSPECTIONAL

A. OPERATIONS

1. Inspections

a. LEVEL 1, 2, & 3 Inspections (See 82845-Part III for detailed guidance)

Where possible, make concurrent inspections to include both device QS/GMP coverage and this program. Inspections will be conducted for manufacturers of UV lamps and sunlamp products (including booths, couches, beds and facial units) to determine compliance with both the device and radiation control portions of the FFDCA. Verify that product specifications and quality control procedures, including instrumentation, are adequate to assure compliance with the standard. Check that records are maintained and reports submitted as required by 21 CFR 1002. CDRH personnel may request participation in these inspections.

b. For Cause Inspections

Follow-up as requested by the CDRH, ORA headquarters, Regional or District directive. These inspections are but not limited to: reports of accidental radiation occurrences, consumer complaints of injuries, and manufacturers in your district who have had deficiencies or defective products, etc., reported by other districts. CDRH personnel may request participation in these inspections.

2. Field Tests

Perform field testing of commercial tanning units at user locations and at manufacturing sites if appropriate. If violative products are found, provide results on Form FDA-483 to the owner and the operator of the equipment (or to the manufacturer). Use the checklist (Attachment B) to document all field tests. (The checklist and field test guidance included as Attachment B.1 should be used for those products manufactured before September 8, 1986). Use the following procedures when violative products are found:

a. Class A Deficiencies (SEE ATTACHMENT C)

(1) Discuss with the owner and the operator the health hazards and regulatory considerations, and request the owner/operator to remove the product from use until corrections are made. Advise that the product manufacturer will be notified of the problem (if the deviation is the manufacturer's responsibility).

(2) Contact your supervisor to determine if State or local authorities can prevent continued use if the owner/operator refuses to voluntarily discontinue usage. Coordinate with Compliance Branch Director for immediate issuance of Declaration of Noncompliance (and/or defect) to the most responsible individual for the product noncompliance and/or defect (the letter may be hand delivered). [The responsible party is usually the manufacturer, however, in cases when the product is modified and/or labels removed or altered, the person performing that act is responsible.] Give primary considerations to administrative detention/seizure if immediate local assistance is not available to remove the products from service and if responsible individual continues refusal. (See Part V B.5.e. of this program for detention/seizure criteria).

(3) Notify Manuel Karos, CSO in CDRH (HFZ-342) at (301) 594-4654 at ext. 149 and local health authorities (through RRHR) immediately. Submit Attachment B and appropriate documentation within 48 hours to your supervisor for distribution.

(4) Follow-up as necessary if the product is voluntarily removed from usage to assure that the product is not returned to service until corrected by the manufacturer or owner. Class A noncompliances and defects require 100% follow-up to assure correction.

(5) If a follow-up field test determines that the product has been returned to service without correction, document non-compliances or defects for regulatory consideration.

b. Class B and C Deficiencies (SEE ATTACHMENT C)

(1) Advise the owner and the operator of the equipment that the product(s) is noncompliant with the standard, recommend corrections before further use, and advise that the manufacturer will be notified of the problem if the deviation is the manufacturer's responsibility. If the product is pre-standard, request voluntary correction of deficiencies.

(2) Distribute field test report with summary sheet (Attachment B and/or B.1) to your supervisor within five (5) days.

(3) On follow-up assignment, field test to determine correction of the noncompliances and document any continuing violation.

3. Sample Collections

Collect documentary samples as necessary to document violations. No physical samples will routinely be collected. (Refer to IOM 405.2). The date of manufacture or assembly and interstate commerce must be well documented. If no date of manufacture is shown on the product, determine and document the date the establishment first used the device or started business.

4. Imports

Note: Refer to C.P. 7386.007, Imported Electronic Products and CPG 7133.24 regarding Noncompliant Defective Sunlamp Products.

B. REPORTING

1. Field Tests

Use Attachment B. Section 1. Distribute the field test report and summary as follows:

a. Manufacturer's home district

b. Testing district

c. HFZ-342

d. Investigator copy

For Class A deficiencies, submit test reports within 48 hours; for Class B and C deficiencies, submit within 5 days.

PART IV - ANALYTICAL

No laboratory testing will be conducted under this program. See C.P. 7386.006E

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

A. REGULATORY PHILOSOPHY AND STRATEGY

Sunlamp products and UV lamps are regulated under Subchapter C - Electronic Product Radiation Control (EPRC)(formerly the Radiation Control for Health and Safety Act of 1968) and Subchapter A - Drug and Devices of Chapter V of the FFDCA. The type of violation involved (radiation vs. non-radiation), and whether the responsible manufacturer can be identified will determine which of the two authorities should be applied. Enforcement of the EPRC provisions (Subchapter C) is preferred where the manufacturer can be identified and radiation related violations are encountered. The FFDCA, Subchapter A, provisions relating to devices may be invoked when it provides a more appropriate or effective remedy; **for additional guidance refer to Part V of CP 7382.845.**

It is intended that districts use the authorities delegated to them under 21 CFR 5.37 and 5.89 to declare products noncompliant or defective. Such declarations are issued to the manufacturer or importers of sunlamp products and/or UV lamps intended to be used in sunlamp products, by means of a Warning Letter, but not to the commercial tanning establishments unless the establishment is the manufacturer or importer and/or responsible for the violation. Districts have also been delegated authority and responsibility to approve corrective action plans submitted by manufacturers in accordance with 21 CFR 1004.6, or grant exemption from user notification and product correction in accordance with 21 CFR 1003.31. If, after the expiration of the period specified in the Warning Letter, the manufacturer has not applied for an exemption, the District Director shall direct the manufacturer, to furnish within 15 days the notification to the persons specified in 1003.10(b) in the manner specified in 1003.21.

For multiple product defects or noncompliances, the primary enforcement approach is a recall. Under Subchapter C of the FFDCA, the manufacturer is required to identify and correct all noncompliant products. See 21 CFR 1003 and 1004, and RPM Chapter 7, Attachment F, for procedures. More stringent legal action is appropriate for failure to recall, for failure to correct serious health hazards, and for intentional violations. Civil penalties may be sought under Section 303(f), which provides for more severe penalties, or Section 539(b)(1).

The administrative detention/seizure would be used only when the product presents a serious health hazard (i.e., has one or more Class A defects) and the Agency has exhausted other means to remove the products from service. (Part III A.2.a. describes actions to be taken by Investigations Branch when Class A deficiencies are found, including State/local involvement to halt use of the product.) Before detention/seizure action, a Warning Letter such as a Declaration of Noncompliance (or Defect) or other written notification must be given to the owner/operator providing in detail the violations, health hazards and FDA's and the manufacturer's rights and options under the laws.

CDRH will, upon request by the district offices, review and evaluate proposed corrective action plans (CAPs) submitted in response to Declarations of Noncompliance or Defect. The district office must wait for CDRH evaluation and comments before responding to a refutation, and/or exemption request. The district office should also wait for CDRH's evaluation of a CAP (if submitted to CDRH for evaluation).

For violations involving prestandard products, issue a Warning Letter to the manufacturer or importer to achieve voluntary correction of deficiencies in all products. Where the manufacturer cannot be identified (or located), request the owner/operator to voluntarily bring the product(s) into compliance. Corrections by the manufacturer or owner/operator under Subchapter C of the FFDCA are handled on an individual case by case basis. Consider declarations of defect and detention/seizure only for serious health hazards (Class A violations).

B. CASE GUIDANCE

1. Regulatory Actions

a. Warning Letters

(1) Recordkeeping, Reporting, and Certification Requirements under Subchapter C of the FFDCA.

Issue Warning Letters for violations of Subchapter C of the FFDCA, such as: *

(a) failure to maintain required quality control and testing records.

(b) failure to maintain required sales (distribution) records (see CPG 7133.18 for guidance).

(c) failure to submit required product, supplemental and annual reports. (Note: Manufacturers of less than 10 products for use in their own commercial suntanning facilities are exempted from reporting, if the Director, Office of Compliance, CDRH, is notified of the number and location of products. See CDRH Director's Letter of September 16, 1981, Attachment G.)

(d) failure to submit accidental radiation occurrence reports or comply with the Medical Device Reporting regulation.

(e) failure to certify sunlamp products (however, products comply with all other parts of the standard).

(2) Declaration of Defect or Noncompliance

Current law and regulations require the Agency to declare noncompliance with a standard when it is found. Every declaration of noncompliance should result in a mandatory recall unless the manufacturer can refute the allegations or is granted an exemption. The exemption can be granted upon request by the manufacturer or by the Agency at its own initiative.

(3) Declaration of Noncompliance (or Defect) and mandatory corrective action (repair, replace or refund)

This is the action of choice for violative products when:

- Multiple products, entire model lines, or a series of products are known to be defective or noncompliant, and not a one-of-a-kind product, or

- There are multiple products of suspected similar design but actual noncompliance has been documented for only a few (e.g., one franchise operation).

This action requires the manufacturer to identify and correct all products of similar noncompliant/defective design.

(a) Issue a declaration of defect Warning Letter for Class A radiation hazards listed in Attachment C if:

- The responsible manufacturer is known, and

- The product was introduced into commerce prior to May 7, 1980.

(b) Issue a declaration of noncompliance Warning Letter to the responsible manufacturer for any Class A or B violation of the Sunlamp Products Performance Standard if: *

- The product was manufactured and introduced into commerce on or after May 7, 1980.

Note: See CPG Sec. 390.100 for the definition of "Commerce", 21 CFR 1003.11, CPG Sec. 390.200 and RPM Chapter 7, Attachment F concerning procedures and policy for declaration of noncompliance/defect.

Strict adherence to the recommended text for a declaration of noncompliance or defect letter (Attachment D) is necessary to satisfy all the Agency notification requirements of

21 CFR 1003.11. A copy of all declarations of noncompliance or defect must be forwarded to HFZ-342.

(4) Time Frames for Action

(a) Immediately notify CDRH and State and local health authorities (through RRHR) for any Class A hazard.

(b) Issue declaration of noncompliance/defect Warning Letter for:

- Class A hazards within five (5) working days.
- Class B hazards within 15 working days.

(c) Issue follow-up assignments to determine if the hazard has been corrected:

- For Class A violations, 15 days after initial inspection.
- For Class B violations, at the district's discretion, or on request of CDRH.

(5) Minor Declaration of Noncompliance

A minor declaration of noncompliance is a declaration of noncompliance where the violation of the standard does not justify further regulatory action (Class C violations) at this time. The Agency notifies the manufacturer of the items of noncompliance and at the same time, on the Agency's own initiative, exempts the manufacturer from the requirements of purchasers notification and product repair. However, the manufacturer is still obligated to change his design before further production. Factors to be considered in your decision to use this action are:

(a) The nature of the violation and its potential public health significance.

(b) The number of products involved.

b. Refutation or Exemption from Notification and Correction

Within 15 days after notification of the noncompliance/defect by FDA, a manufacturer may refute the alleged noncompliance under 21 CFR 1003.11(a)(3) or request an exemption from purchaser notification and correction as specified under 21 CFR 1003.30. If a manufacturer refutes the alleged noncompliance/defect, or requests an exemption, the district office will review the evidence presented by the manufacturer and obtain an evaluation from HFZ-342 before granting or denying the request for exemption or responding to the refutation. A copy of the response issued to the manufacturer must be sent to HFZ-342. Districts should refer to RPM Chapter 7, Attachment F.

NOTE: If the firm disagrees with Agency action, it may request a hearing under 21 CFR 16. If the district receives such a request, it should notify HFZ-300 to designate a hearing officer in accordance with 21 CFR 5.30(d).

c. Approval of Corrective Action Plans

Issue a letter to the manufacturer granting conditional or final approval to implement the corrective action plan (CAP) (after review and approval by CDRH if review was requested) and submit a recall recommendation to HFZ-342 for classification. Refer to RPM Chapter 7, Attachment F for approval of manufacturer's corrective action plans. See Attachment F for sample CAP approval letter.

d. Civil Penalties

Civil penalties should be recommended for violations of Subchapter C of the FFDCA after all other actions have failed to achieve compliance, or for knowing and willful violations. More severe civil penalty assessments may be sought under Section 303(f). See CPG Sec. 390.300 and RPM Chapter 6, Civil Penalties - Electronic Product Radiation Control. Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged in order to facilitate timely implementation of the action; contact the Chief, Ultraviolet Products Section, HFZ-342, (301) 594-4654 or Manuel G. Karos, CSO at the same number.

All necessary samples and other supporting documentation must be tabbed and their location cross-referenced in the recommendation in order to assist in a timely review.

e. Detention/Seizure

Use administrative detention and recommend seizure of a defective or noncompliant sunlamp product if:

- There is a Class A health hazard, and;
- The owner/operator refuses to remove the sunlamp product from service or returns the product to use before the Class A hazard is corrected, and
- The Electronic Product Radiation Control (Subchapter C) provisions are ineffective in achieving timely correction by the manufacturer.

A Declaration of Noncompliance/Defect should be issued as soon as possible to the individual most responsible for the violations, with a copy of other written notification to the owner/operator explaining the health hazards involved, prior to initiation of detention/seizure procedures.

See CPG Sec. 396.300 for specific guidance on detention/seizure of sunlamp products.

Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged; contact Norman L. Timberlake, Chief, Ultraviolet Products Section, HFZ-342, (301) 594-4654 or Manuel G. Karos, CSO at the same number. All necessary samples and other supporting documentation must be tabbed and their location cross-referenced in the recommendation in order to assist in a timely review. It is recommended that you provide a table which cross-references the violation with the FDA-483 item number, the inspection report page number and the exhibit. Direct reference authority is provided for seizure actions when an administrative action has been previously approved (see current CPG).

Note: Imports Detention

If detained as an imported electronic product, the violative charge will read:

> "The article appears to be in violation of Section 534(h) of the FFDCA (formerly the Radiation Control for Health and Safety Act of 1968) in that it does not comply with the Federal Performance Standard (21 CFR 1040.20) and refusal for admission is authorized under section 536(a) of the FFDCA.

f. Injunction

Recommend an injunction for continuing flagrant violations that present a significant risk of injury. You may recommend civil penalties and injunctions concurrently.

C. FEDERAL/STATE RELATIONS

Some states have adopted the Federal Performance Standard as their guidelines for minimum safety of sunlamp products.

It is, therefore, recommended that the districts coordinate regulatory activity with appropriate state representatives through the RRHR, especially where local authority is needed to remove a hazardous product from the market.

Districts should use all reasonable means available to encourage voluntary conformance of products with the performance standard regardless of the date of manufacture. Warning Letters can be used as a means to encourage voluntary correction by owner/operators. Voluntary corrections made by an owner/operator will not be considered as an act of manufacture.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

A. REFERENCES

1. Federal Food, Drug, and Cosmetic Act Subchapter -C- Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968, Public Law 90-602, October 18, 1968.)

2. Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968, 21 CFR, Subchapter J, Radiological Health.

3. Sunlamp Products, Performance Standard - 21 CFR 1040.20.

4. Quality Control Guide for Sunlamp Products. (Publication; FDA 84-8234)

5. Sunlamp Notices to Manufacturers.

   A. Policy on Warning Label Required on Sunlamp Products (6/25/85).

   B. Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products (8/21/86).

   C. Policy on Lamp Compatibility (9/2/86).

6. Sunlamp Products Reporting Guide, (dated September, 1995).

7. CP 7382.845 - Inspection of Medical Device Manufacturers.

8. CP 7386.007 - Imported Electronic Products.

9. CP 7386.006E - Medical Device Laboratory Testing.

10. Regulatory Procedures Manual, Chapter 7, Attachment F, "Recalls of Radiation Emitting Electronic Products under the Radiation Control for Health and Safety Act."

11. Regulatory Procedures Manual Chapter 6, Civil Penalties.

12. CPG 7133.02 - Definition of Commerce - 21 CFR 1000.3 (g).

13. CPG 7133.05 - Determination... that Product Fails to comply or has defects, 21 CFR 1003.11.

14. CPG 7133.06 - Early Correction of Defect.

15. CPG 7133.16 - Applicability of the Sunlamp Performance Standard to UVA Tanning Products.

16. CPG 7133.18 - Exemption for Certain Sunlamp Product Purchaser Records.

17. CPG 7133.23 - Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products.

18. CPG 7133.24 - Defective Suntanning Booths and Beds.

19. CPG 7133.29 - Policy on Warning Label Required on Sunlamp Products.

20. Import Alert 95.01, Sunlamps and Sunlamp Products.

21. Directed Multidistrict Inspection Request, Control Number 950137, dated March 10, 1995.

22. Investigations Operations Manual - Chapter 5, Subchapter 550.

23. Guide to Inspections of Quality Systems

B. ATTACHMENTS

Attachment A - General and Technical Assistance Communications List.

Attachment B - Inspectional Checklist for Sunlamp Products, Including Pertinent Parts of the Regulation.

Attachment B.1 - Inspectional Checklist for Sunlamp Products Manufactured Prior to September 8, 1986, Including Pertinent Parts of the Regulation.

Attachment C - Ratings for Anticipated Noncompliances, Defects/Deficiencies.

Attachment D - Sample Declaration of Noncompliance or Defect/Warning Letter.

Attachment E - Sample Letter Directive to Notify and Recall.

Attachment F - Sample Letter Corrective Action Plan (CAP) Approval.

Attachment G - Center Director's Letter-Exemption from Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers, dated September 16, 1981.

Attachment H - Import Alert 95.01, Sunlamps and Sunlamp Products

Attachment I - Post Inspection Letters

C. PROGRAM CONTACTS

CDRH Program Contact:	Collin L. Figueroa, Electronic Products Branch Chief, Division of Enforcement III (HFZ-342) 301-594-4654 ext. 142
ORA Contact:	CDR James M. Simpson, Division of Emergency & Investigational Operations, (HFC-13O) (301) 827-1124

Additional contact may be made with individuals listed on Attachment A.

PART VII - CENTER RESPONSIBILITIES

- On an as needed basis, CDRH personnel may conduct on site plant visits to resolve difficult reporting and/or non-routine compliance problems with a particular manufacturer/importer. District participation will be invited for such visits. CDRH personnel may also request to participate in any comprehensive or directed inspection. HFZ-306 will coordinate scheduling with the Director, Investigations Branch.

- Within three (3) months after receipt of all documentation for the fiscal year, an informal evaluation will be conducted to review the results of the program and any needed improvements to increase program effectiveness. No formal written evaluation report will be prepared unless requested by the Director, Office of Compliance.

- Accidents and Incidents: In most instances the CDRH becomes aware of accidents or incidents through ORA's surveillance activities, manufacturer's reports, and Medical Device Reporting (MDR). If reports are received from other sources, the CDRH will notify the field (through DEIO - Division of Emergency & Investigational Operations) so that the necessary follow-up may be initiated.

GENERAL COMMUNICATION LIST

ORA Contact: CDR James M. Simpson, Division of Emergency & Investigational Operations, (HFC-13O)
(301) 827-1124

Regional Radiological Health Representatives/District Device Monitors (See IOM - ORA Field Directory for listing)

Collin L. Figueroa, Electronic Products Branch Chief, Division of Enforcement III, CDRH
(301) 594-4654 ext. 142

TECHNICAL COMMUNICATION LIST

Manuel G. Karos
(301) 594-4654 ext. 149
FAX (301) 594-4672
E-mail MGK@CDRH.fda.gov

Norman L. Timberlake
(301) 594-4654 ext. 154
FAX (301) 594-4672
E-mail NLT@CDRH.fda.gov

INSPECTIONAL FIELD TEST CHECKLIST REPORT FOR SUNLAMP PRODUCTS MANUFACTURED AFTER SEPTEMBER 8, 1986
(Including Pertinent Parts of the Regulation)

FACILITY NAME:_____ PERSON INTERVIEWED:_____

ADDRESS:_____ TELEPHONE NUMBER:_____

_____ FIELD TEST DATE:_____

WARNING LABEL [21 CFR 1040.20(d)(1)]
Accessible To View: Yes / No Legible From One Meter: Yes / No Exposure Position: Yes / No "DANGER" Statement:: Yes / No

If "NO" to any of the above, Explain:_____

Exposure Schedule times: Minimum _____min. / Maximum _____min. Warning Label Location:_____

List All Lamp Types Designated On Unit Labeling:_____

CERTIFICATION LABEL [21 CFR 1040.20(d) & 21 CFR 1010.2]
Adequate Certification: Yes / No Written In English: Yes / No Legible: Yes / No

If "NO" to any of the above, Explain:_____

IDENTIFICATION LABEL [21 CFR 1040.20(d) & 21 CFR 1010.3] (AS APPEARS ON LABEL)

Name & Address of Manufacturer:_____

Model #:_____ Serial #:_____ Date of Manufacture:_____

PROTECTIVE EYEWEAR [21 CFR 1040.20(C) (4)]
Maximum Number of Users for Sunlamp Product:_____

Number of pairs:_____ Model Type:_____ Manufacture:_____
Number of pairs:_____ Model Type:_____ Manufacture:_____

LAMPS IN UNIT [21 CFR 1040.20(d) (1) & (d) (2)] & LAMP COMPATIBLITY [21 CFR 1040.20 (e) 2 (iii)]
Total Number of Lamps in Unit:_____ Lamp Compatibility Information : YES / NO / N/A

Lamp Model Designation:_____ Number of Lamps: _____ Manufacture:_____

Lamp Model Designation:_____ Number of Lamps: _____ Manufacture:_____

Facilities Lamp Supplier(s) (name, address, fax & phone #):_____

TIMER [21 CFR 1040.20 (C)(2)]
Type of Timer: Digital / Electro-mechanical / Spring Wound / Token / Other:_____

Timer Capabilities:_____(Minimum Time) _____(Maximum Time) Timer Interval (i.e. 1min increments): _____

Timer Interval Compatible with Exposure Schedule: YES / NO, If "NO", Explain:_____

Timer Manufacturer Name and Address:_____

Timer Accuracy: 10%: _____min _____sec, 50%: _____min _____sec, 100%:_____min _____sec
(Note: Record Timer Accuracy in minutes and seconds for 10%, 50% and 100% of Maximum Timer Capability for the Sunlamp Product. Remote timers are acceptable provided all other requirements of (C)(2)/(3) are maintained.)

TERMINATION CONTROL [21 CFR 1040.20 (C)(3)]
Presence: YES / NO Description: Toggle / Push Pull / Push Button / Other:_____

How is exposure re-initiated:_____

USER INSTRUCTIONS [21 CFR 1040.20 (e) (1)] (i.e. owner manual / operator manual)

Provided by the Manufacturer: YES /NO, Available to Patrons: YES / NO, Contains Instructions To Determine Exposure Schedule and Skin Types: YES / NO, Contains Reproduction of "WARNING LABEL" :YES / NO, Contains Instructions for Obtaining Replacement

Parts and Repairs: YES / NO, If "NO" to any, Explain:_____

_____ INSPECTING DISTRICT

_____ NAME OF PERSON AND TITLE

(2) Timer system. (i) Each sunlamp product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label required by paragraph (d) of this section.

(ii) The maximum timer interval(s) may not exceed the manufacturer's recommended maximum exposure time(s) that is indicated on the label required by paragraph (d)(1)(iv) of this section.

(iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the product.

(iv) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the sunlamp product has been terminated.

(v) The timer requirements do not preclude a product from allowing a user to reset the timer before the end or the preset time interval.

(3) Control for termination of radiation emission. Each sunlamp product shall 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 electrical plug or removing the ultraviolet lamp.

(4) Protective eyewear. (i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of the protective eyewear required by paragraph (C)(4)(i) of this section shall not exceed a value of 0.001 over the wavelength range of greater than 200 nanometers 320 nanometers and an value of 0.01 over the wavelength range of greater than 320 nanometers through 400 nanometers, and shall be sufficient over the wavelength greater than 400 nanometers to enable the user to see clearly enough to reset the timer.

(5) Compatibility of lamps. An ultraviolet lamp may not be capable of insertion and operation in either the "single-contact medium screw" or the "double-contact medium screw" lampholders described in American National Standard C81.10-1976, Specifications for Electric Lamp Bases and Holders--Screw-Shell Types, which is incorporated by reference. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or available for inspection at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(d) Label requirements. In addition to the labeling requirements in Part 801 and the certification and identification requirements of 21 CFR 1010.2 and 1010.3, each sunlamp product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1)Labels for sunlamp products. Each sunlamp product shall have a label(s) which contains:

(i)A warning statement with the words "DANGER--Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product."

(ii) Recommended exposure position(s). Any exposure position may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) A recommended exposure schedule including duration end spacing of sequential exposures and maximum exposure time(s) in minutes.

(v) A statement of the time it may take before the expected results appear.

(vi) Designation of the ultraviolet lamp type to be used in the product.

(2) Labels for ultraviolet lamps. Each ultraviolet lamp shall have a label which contains:

(i) The words "Sunlamp-DANGER-Ultraviolet radiation. Follow Instructions."

(ii) The model identification.

(iii) The words "Use ONLY in fixture equipped with a timer."

(3) Label specifications. (i) Any label prescribed in this paragraph for sunlamp products shall be permanently affixed or inscribed on an exterior surface of the product when fully assembled for use so as to be legible and readily accessible to view by the person being exposed immediately before the use of the product.

(e) Instructions to be provided to users. Each manufacturer of a sunlamp product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to avoid or to minimize potential injury to the user, including the following technical and safety information as applicable:

(1) Sunlamp products. The users' instructions for a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the product including the function, use, and setting of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for determining the correct exposure time and schedule for persons according to skin type.

(v) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, and which will, if installed or used as instructed, result in continued compliance with the standard.

(2) Ultraviolet lamps. The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraph (d)(1)(i) and (2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

(iii) A clear identification by brand and model designation of all lamp models for which replacement lamps are promoted, if applicable. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0195).

INSPECTIONAL CHECKLIST REPORT

FOR SUNLAMP PRODUCTS MANUFACTURED PRIOR TO SEPTEMBER 8, 1986
(Including Pertinent Parts of the Regulation)

Facility Name:_____Person Interviewed_____

Address:_____Telephone ( )_____

_____Field Test Date _____

Mfr. Name _____Address:_____

Home District_____CFN/FEI_____Product Type:_____

Model_____Serial Number_____Date Manufactured _____/_____/_____

Lamps: UV-A_____UV-B_____HID_____Properly labeled_____Mfr/Model:_____

Max Timer Setting_____Gradations_____Consistent w/exposure schedule:_____

Timer Exceed Max. Recom. Exp._____Accuracy @ 10% _____ 50%_____ 100%_____

Type of Timer_____(e.g. Token) Mfr. of Timer_____How can user terminate exposure?_____

How is exposure re-initiated?_____Eyewear_____Sufficient #_____

Labeling visible w/eyewear_____Eyewear Mfr. and Model_____

Certification Label:_____(Va_____)Permanently affixed_____Viewable_____

Location_____Properly Worded_____Mfr. I.D. Label_____ Viewable_____

Full Name/Address_____Date Mfrd._____Place Mfrd._____

Warning Label: Readily Viewable_____Location_____Danger Statement_____

Lamp Type_____Min. exposure distance_____How measured_____Warning: Min. exposure distance_____

Warning: Protective Eyewear_____Warning: Max. exposure time_____Exposure Schedule_____

Time before results can be expected_____Any misleading statements?_____

User's Instructions: Provided by the Mfr._____Available to patrons_____

Contains copy of warning label_____Instructions for replacement parts _____ Statement of # of people/eyewear_____

Equipment Recommendations: User position indicated_____Timer error less than 10%_____Temperature Control_____

Electrical Safety_____Mechanical Safety_____Protection from Lamps_____Access and Support_____

_____ _____
Name and Title Inspecting District

(c) Performance requirements—(1) Irradiance ratio limits. For each

(2) Timer, (i) Each sunlamp product shall incorporate a timer with multiple timer settings adequate for the recommended exposure time intervals for different exposure distances and expected results of the product as specified in the label required by paragraph (d) of this section.

(ii) The maximum timer interval shall not exceed the recommended maximum exposure time as indicated on the label required by paragraph (d)(1)(vii) of this section, or 10 minutes, whichever is less. This requirement does not preclude a product from allowing a user to reset the timer before the end of the preset time interval. No timer interval shall have an error greater than ± 10 percent of the maximum timer interval of the product.

(3) Control for termination of radiation emission Each sunlamp product &hall incorporate a control on the product to enable the user manually to terminate radiation emission from the product at any time without a disconnecting the electrical plug or removing the ultraviolet lamp.

(4) Resumption of radiation emission. When radiation emission from a Sunlamp product has been terminated for any reason Including by a timer, resumption of such emission I shall not be possible until the product is reactivated manually by the user.

(5) Protective eyewear. (i) Each Sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximmum number of persons that the instructions provided under paragraph (f)(1)(iii) of this section recommend to be exposed simultaneously to radiation from such product

(6) Compatibility of lamps, An ultraviolet lamp shall not be capable of insertion and operation in any of the following lampholders:

(i) "Single-contact medium screw," described in American National Standard C81.10-1976.

(ii) –"Double-contact medium screw." described in American National Standard C81.10-1976.

(d) Label requirements. In addition to the labeling requirements in part 501 of this chapter and the certification and identification requirements of 21 CFR 1010.2 and 1020.3 of this chapter, each sunlamp Product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (f) of this section All labels prescribed in this paragraph shall be permanently affixed or inscribed on an exterior surface of the product so as to be legible and readily accessible to view when the Product is fully assembled for use.

(1) Each sunlamp product shall have a label which contains:

(i) The words "DANGER-Ultraviolet radiation. Follow instructions. As with natural sunlight overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

(ii) Designation of the ultraviolet lamp type -which is to be used in the product.

(iii) A recommended minimum use distance specified both in meters and in feet (or in inches).

(iv) Directions for measuring the minimum use distance.

(v) A warning that exposure at distances less than the mimimum use distance is not recommended.

(vi) A warning to use protective eyewear whenever the product is energized.

(vii) A recommended maximum exposure time m minutes.

(viii) A recommendation for duration. Frequency, and spacing of sequential exposures.

(ix) A statement of the time it may take before the expected results appear

(2) Each ultraviolet lamp shall have a label which contains:

(i) The words "Sunlamp-DANGER Ultraviolet radiation. Follow instructions.

(ii) The model identification.

(iii) The words – "Use ONLY In fixture equipped with a timer."

(3) in lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by 21 CFR 1010.2(b) and 1010.3(a) of this chapter, the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tap or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed an the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. When the tags or labels required by 21 CFR 1010.2(b) and 21 CFR 1010.3(a) of this chapter are affixed or inscribed an the ultraviolet lamp packaging, the name of the manufacture and mouth and year of manufacture required to be permanently affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Bureau of Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp.

(f) Instructions to be provided to users. Each manufacturer of a sunlamp product and ultraviolet lamp shell provide or cause to be provided to purchasers and upon request to others at a cost not to exceed the cost of publication and distribution. instructions for safe use, including the following technical and safety information as applicable:

(1) Sunlamp products. The users' instructions for a sunlamp product shall contain.

(i) A reproduction (color optional) of the label required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A prominently displayed statement containing the words "DANGER--Utraviolet radiation Follow instructions. As with natural Sunlight, overexposure can cause eye injury and sunburn repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

(iii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided

(iv) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product. including compatible protective eyewear, ultraviolet lamps, timers, reflectors and filters, and which will if installed or used as instructed result in continued compliance with the standard.

(2) Ultraviolet lamps. The users' instructions for in ultraviolet lamp not accompanying a sunlamp product shall contain;

(i) A reproduction (color optional) of the label required in paragraph (d)(2) of this section prominently displayed at the beginning of the instructions.

(ii) A statement prominently displayed containing the words "DANGER-Ultraviolet radiation. Follow instructions. As with natural Sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

(iii) A warning that the Instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

RATINGS FOR ANTICIPATED NONCOMPLIANCES/DEFECTS DEFICIENCIES

This listing classifies anticipated problems of noncompliance in terms of relative hazard:

1. Class A - These are clear noncompliances, defects and deficiencies that pose a serious and immediate health hazard.

    1.1. No timer at all or defective timer that fails to shut off.

    1.2. Lack of any protective eyewear.

    1.3. Serious electrical shock hazard.

    1.4. Any other serious radiation or nonradiation health hazard.

    1.5. Use of medical therapy lamps, germicidal lamps, or industrial lamps in the suntanning product.

    1.6. Any other radiation or non-radiation health hazard. (i.e. lack of filter systems)

2. Class B - These are clear noncompliances without an immediate health hazard.

    2.1. A UVB product with a timer which has a maximum timer setting of greater than 10 minutes or the maximum exposure time as recommended by the manufacturer.

    Note: A timer which has a maximum setting of greater than 10 minutes but which has been modified with a mechanical stop at 10 minutes and is within the ± 10% accuracy requirement is considered compliant. However, if the timer can be turned in the opposite direction, this may allow the timer to stick on the stop and the product will operate indefinitely. This is not an acceptable modification and constitutes a Class A noncompliance/defect (1.1 above).

    2.2. Lack of multiple timer settings when specified by the exposure schedule on the product label.

    2.3. Timer error requirement of ± 10% of maximum timer interval is exceeded. (If it exceeds 10% by insignificant amount, it may be treated as a Class C).

    2.4. Lack of any control for the termination of radiation emission by the person being irradiated (user).

    2.5. No exposure schedule.

    2.6. Products which automatically recycle and restart following termination of emission.

    2.7. No protective or noncompliant eyewear provided for UVA products.

    2.8. Noncompliant protective eyewear for UVB products such as cotton balls, "Silver Shades" or other opaque goggles, or use of sunglasses which allow UV to reach the eyes around the sides.

    2.9. Lamps in the product are not the type specified in the product label (or equivalent/compatible and so stated in the replacement lamp user instructions)

    Label Requirements

    2.10. No labels as required by 21 CFR 1040.20(d)(1)(i-ix) or (i-vi)).

    - No "Danger..." warning label as required by 21CFR 1040.20 (d)(1)(i-vi).

- No warning to use protective eyewear.

- No label on the product with designation of the lamp type.

User Instructions

2.11. Lack of users' instructions or other warning to users.

Note: In the case of commercial tanning facilities both the person who operates the booth and the patron are considered users. Warnings are to be supplied to both, but instructions for operation and repair of the booth need only be given to the operator.

3. Class C - These noncompliances are primarily administrative problems with little or no health hazard involved.

3.1. No certification label.

3.2. No identification label.

3.3. No recommended minimum use distance labeled on the product.

3.4. No directions for measuring minimum use distance labeled on the product.

3.5. No recommended maximum exposure time where user is expected to set timer labeled on the product.

3.6. No label on the product warning that exposure at distances less than the minimum use distance is not recommended.

3.7. No label on the product with recommendation for duration, frequency, and spacing of sequential exposures.

3.8. No label on the product stating of the time it may take for expected results to appear.

3.9. Recommended minimum use distance not given in both meters and feet (or inches) when applicable.

3.10 A UVA product with a timer which has a maximum setting of greater than 10 minutes and for which no variance has been granted by CDRH.

Note: A variance may be granted (21 CFR 1010.4) for a longer timer interval in some UVA type products.

SAMPLE LETTERS

Application:

A. General

For products manufactured on or after May 7, 1980, with Performance Standard Deficiencies

B. Specific

1. Declaration of Noncompliance (Warning Letters)

a. For manufacturers of products having Class A or A and B, or A and B and C deficiencies, use paragraphs l, 2, 3, 4, 5, 6, 11, and 12.

b. For manufacturers of products having Class B or B and C deficiencies, use paragraphs l, 2, 3, 4, 6, 11 and 12.

2. Other Warning Letters

a. For owners/operators of products having Class A or A and B, or A and B and C deficiencies, use paragraphs 1, 2, 5, 9, 10, and 12.

b. For owner/operators of products having Class B or B and C deficiencies, use paragraphs, 1, 2, 9, and 12.

3. "Minor Declaration of Noncompliance" (One with exemption). For manufacturers of products having only Class C deficiencies use paragraphs l, 2, 3, 7, 8, 11 and 12. A copy of referenced CFR shall accompany each letter.

Paragraph 1:

CERTIFIED MAIL - RETURN RECEIPT REQUESTED
WARNING LETTER

Paragraph 2: Dear _____:

During an (inspection, field test, etc.) of (identify products, firm name, and address, date of inspection), the following noncompliances with the Federal Performance Standard for Sunlamp Products (21 CFR 1040.20) were noted:

List CFR reference and itemize noncompliances

Paragraph 3: Section 538(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce sunlamp products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be in violation of paragraph 538(a)(4) of the FFDCA. These violations may result in the Food and Drug Administration (FDA) taking regulatory action. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the FFDCA are subject to a civil penalty of up to $1,000.00 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

Paragraph 4: You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged noncompliance<s> does<do> not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

   a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

   b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Paragraph 5: Due to the serious health hazards involved in the deficiencies noted above, it is requested that the product(s) not be used until appropriate corrections have been made.

Paragraph 6: When you have completed all production changes necessary to assure compliance of future units, and have submitted to the Center for Devices and Radiological Health (with a copy to the District Office identified below) a supplement to your initial report describing these changes and any other information required to assure that your products comply with the performance standard, you may then resume introduction of the referenced sunlamp products into commerce.

Paragraph 7: (Company Name) is not being requested to submit a formal corrective action plan at this time. However, you may wish to voluntarily correct those products already in commerce.

Paragraph 8: You may not resume introduction of the referenced sunlamp products into commerce until you have completed all production changes necessary to assure compliance of future units, and have submitted to the Center for Devices and Radiological Health (with a copy to the District office identified below) documentation describing these changes and any other information required to assure that your products comply with the performance standard.

Paragraph 9: As required by the FFDCA, the manufacturer of this (these) product(s) is being notified of his obligations under 21 CFR Parts 1003 and 1004 for the noted deficiencies of the product(s). We will appreciate any assistance you can provide to the manufacturer in meeting those obligations.

Paragraph 10: Please advise this office within (30) days of receipt of this letter of any actions you have taken or intend to take.

Paragraph 11: If you do not respond within 15 days, the Agency will consider you to be in violation of Section 538(a)(4) of the FFDCA.

Paragraph 12: If further information is required, please contact (District Contact and address).

Sincerely yours,

SAMPLE LETTERS (Continued)

Application:

A. General - Products with deficiencies, manufactured prior to effective date at Performance Standard (May 7, 1980, and amendment effective September 8, 1986).

B. Specific

Declaration of Defect/Warning Letter

a. For manufacturers of products manufactured prior to May 7, 1980, having Class A and other deficiencies use paragraphs l, 2, 3, 4, 5, 6, 9, and 10.

b. For manufacturers of products manufactured prior to May 7, 1980, having only Class A deficiencies, use paragraphs l, 2, 3, 4, 5, 6, 9, and 10.

a. For owner/operators of products manufactured prior to May 7, 1980, having only Class A or Class A and other deficiencies, use paragraphs 1, 2, 3, 4, 7, 8, and 10.

A copy of referenced CFR shall accompany each letter.

Paragraph l: CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER

Paragraph 2: Dear _____:

This letter is written to advise you of significant adverse findings encountered during (an inspection, field test, etc.) of (identify product) on (date) located at _____.

The following deficiencies were noted:

Paragraph 3: These products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the FFDCA), as amended as well as deviations from the electronic product performance regulations of the FFDCA, Chapter V, Subchapter C – Electronic Product Radiation Control (EPRC, formerly the Radiation Control for Health and Safety Act of 1968) even though they were manufactured prior to May 7, 1980, (and amended September 8, 1986), the effective date of the Performance Standard for Sunlamp Products (21 CFR 1040.20).

Paragraph 4: Due to the serious health hazards involved in the deficiencies noted above, these products have been determined under 21 CFR 1003.11 to be defective electronic products as described in 21 CFR 1003.2(b) and should not be used until appropriate corrections have been made.

Paragraph 5: You must respond in writing within 15 days of receipt of this letter and indicate (l) the number of the referenced products which have been produced; (2) the number of such products that have left the place of manufacture; and (3) your choice of one of the following options:

A. Refutation - You may submit your views and evidence to establish that the alleged noncompliance does not exist.

B. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

C. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must (l) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (2) submit a written corrective action plan (CAP) to fulfill your obligations under 21 CFR 1004.l to repair, replace, or refund the cost of the violative products.

l. Notification Letter - Requirements for preparation of notification letters are prescribed in 2l CFR 1003.2l and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to this office. It is recommended that you submit a draft of this letter to this office for review.

2. Corrective Action Plan - Instructions for preparation of a corrective action plan may be found in 21CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, corrective action plan, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable corrective action plan cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 2l CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Paragraph 6: In addition, other deficiencies were noted as listed below.

Paragraph 7: The manufacturer of this (these) product(s) is being notified of his obligation under 2l CFR Parts 1003 and 1004 for the noted deficiencies of the product(s). We will appreciate any assistance you can provide to the manufacturer in meeting those obligations.

Paragraph 8: You are not being required to correct the noted deficiencies, but the Agency encourages correction to minimize the potential hazards.

Paragraph 9: If you do not respond within 15 days, the Agency will consider you to be in violation of Section 538 (a)(2) of the Federal Food, Drug and Cosmetic Act (formerly known as the Radiation Control for Health and Safety Act of 1968).

Paragraph 10: If further information is required, please contact (District Contact and address) .

Sincerely yours,

CERTIFIED MAIL-RETURNED RECEIPT REQUESTED

John Doe, President
Doe and You Manufacturing Co.
Main Street
Yourtown, ST. 00000

Dear Mr. Doe:

This is to advise you that we have not received any response to our Warning Letter dated April 10, 2000 and received by your firm (according to the returned receipt) on April 25, 2000.

You were given 14 days to respond to one of the three options presented in the letter: A. Refutation, B. Exemption Request, C. Purchaser Notification and corrective action.

Since you have presented no evidence to establish that there is no failure to comply nor requested an exemption, under authority of the Federal Food, Drug and Cosmetic Act (formerly known as the Radiation Control for Health and Safety Act of 1968) and pursuant to 21 Code of Federal Regulations Part 1003.11(c) you are hereby directed to:

1. Within 14 days from receipt of this letter, furnish the notification to the persons specified in 21 CFR 1003.10(b) in the manner specified in 21 CFR 1003.21 and;

2. Within 30 days from receipt of this letter, submit a corrective action plan (CAP) to fulfill your obligations under 21 CFR 1004.1 to repair, replace or refund the cost of the violative products.

You are once more advised that Section 538(a) of the Act prohibits (1) the introduction into commerce of any electronic product (Sunlamp products) which does not comply with the applicable standard, and (2) the failure to furnish any notification or other material or information required by section 537 or 538(a); or to fail to comply with the requirements of section 537(f) of the Act.

If you have any questions, please contact (District Contact and phone number).

Sincerely Yours,

District Director

CERTIFIED MAIL-RETURNED RECEIPT REQUESTED

John Doe, President
Doe & Your Manufacturing Co.
1000 Main Street
Yourtown, ST 00000

Dear Mr. Doe:

This is in response to your letter dated December 31, 1999 submitted as your firm's corrective action plan (CAP) involving 929 Sunlamp products model TWBY and 26 Sunlamp products model YAAB, in response to our declaration of noncompliance letter dated November 21, 1999.

From your letter it is understood that:

1. (state method and details of notification to purchasers as provided by manufacturer)

2. (state actual actions to be taken by manufacturer to correct deficiencies)

3. (state method to be used by manufacturer to verify and document corrections)

Based on the above understanding your CAP is approved and you may proceed with it, subject to the following condition(s):

1. (specify any and all other actions that would be required to assure that all products involved are corrected and that proper documentation is maintained)

The Food and Drug Administration will classify this action as a Class II recall. You will be notified of the recall number assigned. As soon as you have received the recall number you must send a copy of the product location list to this district office. This list must include product model number, product serial number and the name and address of the purchaser and/or product location address. The recall number assigned to this case is to be referenced in the firm's location list and in the monthly status reports. The location list, reports and all future correspondence regarding this case should be sent to:

Food and Drug Administration
Recall and Emergency Coordinator
Your Street
Your City, ST 0000

The reports should describe any difficulties encountered in the implementation and completion of the CAP.

Please note that Doe & Your Manufacturing Co. is responsible for the correction of all noncompliant products . Should the CAP prove ineffective in bringing the noncompliant units into compliance with the applicable regulation, the FDA reserves the right to require the firm to undertake more stringent measures.

You should also be advised that it is an FDA policy to report the facts surrounding all defect and noncompliance cases subject to Section 535(d) of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968). This report is available to the public in the FDA Enforcement Report.

If you have any question, please call (District Contact and address) .

Sincerely yours,

District Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

SEP 16 1981

TO: Manufacturers and Potential Manufacturers of Sunlamp Products (Including Taming Booths)

SUBJECT: Exemption from Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers

BACKGROUND: The regulations in 21 CFR 1002 promulgated under the Radiation Control for Health and Safety Act of 1968 require, among other things, that a manufacturer of an electronic product subject to a performance standard submit an initial report, annual reports, and model change reports, as applicable, to the Director, Bureau of Radiological Health (21 CFR 1002.10, 1002.1.1 and 1002.12). Furthermore, a manufacturer of an electronic product subject to a performance standard is required to maintain certain records including a description of the quality control procedures with respect to the product's radiation safety, results of life testing and copies of written communications between the manufacturer, dealers, distributors and purchasers regarding radiation safety (21 CFR 1002.30(a)) and preserve such records for a period of 5 years from the date of the record (21 CFR 1002.31(a)).

The Bureau's experience in the enforcement of the performance standard for sunlamp products (21 CFR 1040.20) indicates that the above referenced reporting and recordkeeping requirements seem to be an overburden for an individual or firm who manufactures on a one time or infrequent basis a small number of sunlamp products (usually less than 10) for his own use. Exempting this type of manufacturer from the referenced reporting and recordkeeping requirements under certain conditions would not compromise the spirit or purpose of the Act since FDA can determine compliance through product inspections.

EXEMPTION: Any person who manufactures less than 10 sunlamp products for use in their own commercial suntanning facilities is hereby exempted under the authority of 21 CFR 1002.50 from the requirements of 21 CFR 1002.10, 1002.11, 1002.12, 1002.30 and 1002.31 provided that such person notifies the Director, Division of Compliance, that less than 10 sunlamp products are being manufactured for the use of that person and provides the Director with the name and address of the manufacturing location.

Persons who wish to manufacture more than 10 sunlamp products for use in their own commercial suntanning facilities are not included in this exemption but may make a written application for exemption to the Director, Bureau of Radiological Health, in accordance with 21 CFR 1002.50 stating the number of products they intend to manufacture and over what period of time manufacturing will occur.

John C. Villforth
Director
Bureau of Radiological Health

IA #95-01, REVISED 7/23/93

This revision updates the information and reformats the text of the alert.

TYPE OF ALERT: Automatic Detention

PRODUCT: Sunlamps and Sunlamp Products

PRODUCT CODE: 89------

HARMONIZED
CODE: 8599.40.8040

PROBLEM: Nonconformance with performance standard (DVRS)

PAC FOR
COLLECTION: 82007

COUNTRY: All

MANUFACTURER
OR SHIPPER: All

MANUFACTURER
OR SHIPPER I.D.#: N/A

IMPORTER'S
I.D. #: N/A

CHARGES: If device is noncompliant with applicable standard and/or lacks certification, charge:

"The article is subject to refusal of admission pursuant to Section 536(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) in that it appears to be an electronic product which fails to comply with an applicable standard as prescribed under this subchapter or to which is not affixed a certification in the form of a label or tag in conformity with Section 534(h)."

If no reporting is done, charge:

"The article is subject to refusal of admission pursuant to Section 536(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) in that it appears to be an electronic product that does not comply with an applicable standard as prescribed by Section 534 because no reporting has been provided as required by Section 537(b)."

RECOMMENDING

OFFICE: CDRH, Office of Compliance, Division of Enforcement III, HFZ-312

REASON FOR ALERT: During the past decade, new types of sunlamp products (tanning beds and facial units) incorporating high and medium pressure intensity discharge lamps (HID) were introduced into the United States from Europe. These types of products are intended to decrease the time needed for tanning and/or to increase the tanning effect for those areas of the body, which are reportedly harder to tan.

According to data obtained from manufacturers' reports and promotional literature, the HID lamp emits short wave UV-B and UV-C radiation which is harmful to human eyes and skin. Since these lamps operate at an over-pressure, the possibility of an explosion cannot be entirely excluded. High intensity discharge lamps are identified as being much shorter and smaller in diameter (approximately 2" long x 1/2" in diameter) as compared to the long fluorescent type bulb and are contained in a reflector which may have a transparent blue or clear filter cover.

INSTRUCTIONS:

In accordance with Compliance Program 7382.007, "Imported Electronic Products," districts should continue to review all entries and Declarations (FDA-2877) for sunlamp and sunlamp products to determine if the products have been properly certified. Detention should be issued in accordance with the Compliance Program.

In addition, physical examination should be performed on all sunlamps and sunlamp products that have entered under Affirmation B of the Compliance Program and under circumstances where applicable as follows:

I. SUNLAMP PRODUCTS/Tanning Beds, Facial Units, and Home Use Units, etc.

- CERTIFICATION LABEL: Determine if the certification label is present on the product in accordance with 21 CFR 1010.2.

- LAMP LABEL: Each ultraviolet lamp should have a label which reads: "Sunlamp-DANGER-Ultraviolet Radiation. Follow instructions. Use only in a fixture equipped with a timer", along with model designation.

- SUNLAMP PRODUCT LABEL: Each sunlamp product should have a "DANGER" label which reads: "DANGER-ULTRAVIOLET radiation...sensitive to sunlight."

- GOGGLES: Check for presence of protective goggles.

- USERS INSTRUCTIONS: Check for the presence of an instruction booklet in English.

- HID LAMPS: If HID lamps are used, obtain lamp model identification information and contact CDRH, (301) 427- 1172, to determine if the lamps have been certified.

II. LAMPS- FLUORESCENT & HID LAMPS

- LAMP CERTIFICATION LABEL: Determine if the certification label is present on the label in accordance with CFR 1010.2.

- LAMP LABEL & USERS INSTRUCTIONS: Check for the presence of a lamp label, model designation, and user's instruction pamphlet for each lamp in the shipment.

- FLUORESCENT LAMPS: These lamps are usually shipped as packages of 25 lamps each. The certification label will usually be found on the outside of the box.

- HID LAMPS: These lamps may be shipped in any quantity. Depending on the design, the certification label will be on the lamp packaging, but for large lamp configurations it may be on the lamp housing. Contact CDRH at (301) 427-1172 giving lamp identification information so that CDRH can determine whether the HID lamps are certified.

Automatically detain devices with no certification label or lacking required labeling. Contact CDRH at (301) 427-1172 for information regarding submission of required reports and guidelines for detention.

Refuse entry unless the importer adequately corrects deficiencies or is able to show that the product is properly certified and meets the performance standard (21 CFR1040.20). It may be necessary to field test some products for compliance with the performance standard to establish that the importer has effected correction of a detained product. CDRH may be contacted at (301) 427-1172 for guidance.

Please send copies of all detention notices to HFZ-331 so that appropriate foreign manufacturers and their products maybe added to the Radiation Emitting Products detention list. When field tests are performed, please send copies of the field test record to HFZ-312 (Attention: Manny Karos.)

PRIORITIZATION GUIDANCE: N/A

FOI: No purging is required

KEYWORDS: Sun Lamps, Sunlamp Products, Tanning Beds, HID lamps

PREPARED BY: Linda A. Wisniowski, DIOP, 301-443-6553.

ATTACHMENT I

MODEL NAI POST-INSPECTION NOTIFICATION LETTER

[The following is an example of a letter intended to be issued in situations classified as NAI where no FDA-483 was issued, or only limited less significant violations were reported:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's [description] facility at [address] on [date]. The inspection covered the products described below.

[list of products and their profile classes]

The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address electronic product radiation control/performance standard (EPRC/PS) requirements or quality system/good manufacturing practices (QS/GMPs) in these areas.

Your firm has an ongoing responsibility to ensure you are continuing to maintain compliance with EPRC/PS and conformance with QS/GMPs.

For further information, please contact the following individual at this office:

[name and telephone number]

Sincerely,

ATTACHMENT I

MODEL VAI POST-INSPECTION NOTIFICATION LETTER

[The following is an example of a letter intended to be used in situations classified as VAI where an FDA-483 was issued, but all profile classes were found to be acceptable. This type of letter should be issued only when no regulatory action is contemplated, including issuing a Warning Letter:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's [description] facility at [address] on [date]. The inspection covered the products described below.

[list of products and their profile classes]

While some adverse practices/conditions were observed during the inspection, they do not appear to warrant consideration of regulatory follow-up at this time. These problems were reported to you on the FDA-483 (copy enclosed) issued at the conclusion of the inspection. The problems should be corrected and we encourage you to advise us as to your follow-up actions.

This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address electronic product radiation control/performance standard (EPRC/PS) requirements or quality system/good manufacturing practices (QS/GMPs) in these areas.

Your firm has an ongoing responsibility to ensure you are continuing to maintain compliance with EPRC/PS and conformance with QS/GMPs.

For further information, please contact the following individual at this office:

[name and telephone number]

Sincerely,

Enclosures: FDA-483