GUIDE FOR PREPARING PRODUCT REPORTS ON SUNLAMPS AND SUNLAMP PRODUCTS (21 CFR 1002)

September 1995

(Address corrections Aug. 2008)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Center for Devices and Radiological Health
Rockville, Maryland 20857

FOREWORD

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with the applicable standard (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. The manufacturer is required to submit the report (21 CFR 1002) and to comply with all applicable importation requirements (21 CFR 1005) prior to the shipment of products in interstate commerce. If there are deficiencies, we may disapprove the firm's quality control and testing program or determine that the product contains a radiation defect or fails to comply with a standard. We will notify the manufacturer if we make such a determination. Then the manufacturer may be required to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

We are making our reporting guides available on the CDRH web site at http://www.fda.gov/cdrh/comp/eprc.html, for downloading and reproduction. They are not copyrighted and may be reproduced as needed.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same address. If you need additional

regulations for electronic products or medical devices, contact the Division of Small Manufacturers Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Lillian J. Gill
Director
Office of Compliance

MAILING ADDRESS:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

PREFACE

Manufacturers of products subject to the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C, are required to furnish various reports to the Center for Devices and Radiological Health (CDRH). This guide is for use by manufacturers of sunlamps, ultraviolet lamps, and products intended to incorporate these lamps.

The reporting and recordkeeping requirements are specified in Part 1002, Title 21 CFR Chapter I, Subchapter J. Section 1002.10 of the Regulations requires the submission of a product report for products listed in Section 1002.1, Table 1. All product reports must be submitted in accordance with Section 1002 prior to the introduction of the product into U.S. commerce. (This includes products imported into the U.S.)

Section 1002.7 requires that reports conform to the organization and item enumeration of the guide to ensure the inclusion of the information requested. This will facilitate review and minimize follow-up correspondence.

I. Paul Leggett, Chief
Electronic Products Branch
Office of Compliance

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INTRODUCTION

Sunlamp Product Reports, Supplemental Reports, and Abbreviated Reports must be submitted to the Center for Devices and Radiological Health (CDRH) at the address below prior to introduction of the products into U.S. commerce. (This includes products imported into the U.S.) In addition, all sunlamp product manufacturers are required to register, list, and submit a 510(k) notification, as described in the Medical Device Requirements below.

RADIOLOGICAL HEALTH REQUIREMENTS

A complete Product Report (formerly called Initial or Model Change Reports) is required for each product model or model family. A model family is a group of two or more sunlamp products or ultraviolet lamps with similar design, performance features and intended function, and that are manufactured using the same or very similar quality control testing procedures. A complete report on one model of a model family should be submitted with a supplemental report for each other model in the family. The supplemental report should respond to the appropriate parts of the report, referencing the number of each item that is different as well as the ones that are the same as the original report.

When changes in a reported model's design or manufacturing procedures have been made that alter the emission or radiation safety characteristics of the product, a supplemental report that describes the changes must be submitted to CDRH. Supplemental reports are also required for new models belonging to a previously reported model family. These reports should also respond to the appropriate parts of the reporting guide. If there is no change from a prior report, this fact must be stated. Report the changes in detail and reference the number of the affected item. A new model family must be reported as a new product report. Your responses may reference earlier reports; however, cross-referencing other reports should be minimized to avoid confusion or errors. Be sure that referenced information is accurate, current, and applicable to reported models.

Some of the information requested in this guide can be given in the space provided. If a question is not applicable to your product, write "N.A." next to the question and indicate why it is not applicable. Where attachments are required, indicate as specified. Attachments should be clearly numbered the same as that specific part of the guide. For example, an attachment responding to part 3.2 should be labeled "Attachment 3.2."

When new models of a lamp are introduced, if the models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is

only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports should be clearly marked as such and be submitted prior to October 1, December 1, March 1, and/or June 1 when required. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.20(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

All reports and correspondence must be addressed to:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

When a report is received at CDRH, an accession number will be assigned to the report. The submitter will be informed of the accession number in a letter acknowledging receipt of the report. The acknowledgement letter is not a technical review of the report. The report will be reviewed by CDRH technical staff as soon as possible and the submitter will be advised of the results. Report supplements should be clearly identified with accession number of the original product report.

The Product Reporting Guides and Annual Reporting Guides are available from the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) in Rockville, Maryland at 1-800-638-2041. DSMICA should be contacted for requests of any current documents and reporting guides. If you have specific questions regarding regulations or filling out these reports, call the Electronic Products Branch, Office of Communication, Education, and Radiation Programs at 240-276-3332.

Manufacturers who do not manufacture the ultraviolet lamps for their products need not respond to Part 3 of the guide. Those who manufacture only the ultraviolet lamps need not respond to Part 2.

MEDICAL DEVICE REQUIREMENTS

Sections 510(b), (c), and (d) of the Federal Food, Drug, and Cosmetic Act (the Act) requires the owner/operator of an establishment to register with the FDA within 30 days after the beginning of manufacture, initial distribution, or processing of a device intended for human use. Initial registration is made on the "Initial Registration Form" (FDA 2891), and annually thereafter on the "Annual Registration Form" (FDA 2891a).

Section 510(j) of the Act requires devices to be listed on the "Device Listing Form" (FDA 2892) to FDA. Unlike registration, listing is only updated when a significant change occurs in the product(s). FDA forms 2891, 2891a, and 2892 may be obtained from, and completed and returned to the Information Processing Branch (HFZ-307), CDRH, FDA, 9200 Corporate Blvd., Rockville, MD 20850, (301) 594-4699.

Section 510(k) of the Act requires device manufacturers to notify FDA, at least 90 days in advance, of their intent to market a device. This is known as "Premarket Notification." There is no printed form for 510(k) submissions; however, a format to be followed can be found in 21 CFR 807.87.

The DATE(S) OF SUBMISSION(S) and REPORT RECEIPT AND IDENTIFICATION NUMBERS for registration, listing, and 510(k) submissions are to be supplied in Part 1 of this reporting guide.

DEFINITIONS

NOTE: These definitions have been revised.

PRODUCT REPORT (21 CFR 1002.10) - A Product Report is a report submitted by a manufacturer of a regulated product, e.g., sunlamps, laser products, Tvs. The Product Report describes the product, details how the product complies with the standard, and explains the quality control program to assure compliance. A Product Report can be used for families of products as well as for individual products.

SUPPLEMENTAL REPORT (21 CFR 1002.11) - A Supplemental Report provides information supplementary to a previously submitted Product Report. It is used to report a new model in a previously reported model family, a modification of a previously reported model, or other changes to a previous report (e.g., changes in testing programs, additions or changes in user or service manuals, responses to CDRH report review letters).

Supplemental Reports are also required for changes that:

a. affect actual or potential radiation emission,

b. affect the manner of compliance with a standard or affect the manner of testing for radiation safety.

Supplemental Reports should clearly reference the CDRH accession number of the Product Report and the appropriate sections of this guide.

ANNUAL REPORT (21 CFR 1002.13) - An Annual Report summarizing the required records must be submitted by September 1 for the 12 months ending on June 30 of the same year. In addition, the Annual Report is the appropriate vehicle for identifying new models for which Supplemental Reports are not required. If the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need only identify them in their annual report, or in quarterly updates to the annual report. Copies of the annual report form to be followed are available from DSMA by calling 1-800-638-2041.

NOTE: Before preparing this report, the submitter should become familiar with the Federal Performance Standard (which has been retyped as Appendix A) and the "Quality Control Guide for Sunlamp Products" (HEW Publication FDA 84-8234). Reviewing and understanding these documents will make preparation of the product report easier. However, because Appendix A has been excerpted from the Federal Register, it should not be used for citing the regulation. Persons who wish to cite the regulation should consult the Federal Register directly.

PART 1: MANUFACTURER AND MODEL IDENTIFICATION

1.1 Manufacturer:

Manufacturing Firm:

Address:

Corresponding Official (person preparing this report):

Signature:

Name & title:

Telephone number:

Firm's prime contact or responsible person if different from above:

Name & title:

Telephone number:

1.2Designated Agent (for firms exporting to U.S., 21 CFR 1005.25):

Signature:
(or attach written agreement with agent)
Name & title:

Address:

Telephone number:

1.3 Importer(s) (List all importers and addresses if applicable):

1.4 Date of this Report:

1.5 Report Type: ( ) Sunlamp Product Report, or

( ) Supplement to CDRH Accession No.:

submitted on (date):

1.6 Product Identification:

List the model designation (name and model number) of the product being reported. If model is a member of a model series or family, also provide a series or family designation.

1.7 Product Type:

( ) Sunlamp Product ( ) Ultraviolet Lamp

( ) Booth ( ) HID

( ) Bed ( ) Reflector Spot

( ) Portable ( ) Other:

( ) Tabletop

( ) Other:

1.8 Private Label Identification:

Supply the following information if the reported product is sold to other manufacturers or suppliers for sale under a different name or as a component of another product. (YOU MUST PROVIDE A COPY OF EACH PRODUCT LABEL AND USER'S INSTRUCTIONS.)

BRAND NAME	MODEL NUMBER	NAME & ADDRESS OF FIRM UNDER WHOSE NAME PRODUCT IS SOLD

1.9Other reporting requirements under the Act (as described in the Introduction):

	SUBMISSION DATE	REPORT/IDENTIFICATION NO.
510(k)		
Reg & Listing		

PART 2: SUNLAMP PRODUCT DESCRIPTION

2.1 Attach a description of the sunlamp product. The description MUST include:

a. exterior and interior structures of the assembled product;

b. description and manufacturer's specification for the reflector, timer, filters, ultraviolet lamps, ballasts, etc.;

c. photographs and diagrams including parts identification;

d. electrical circuit diagram.

Is information submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

2.2 Identify all ultraviolet lamps that are to be used in the sunlamp product.

LAMP MANUFACTURER	BRAND NAME	FULL MODEL NUMBER

Number of lamps used in sunlamp product:

Type of base or socket used for each ultraviolet lamp in the product (mogul screwbase, medium bipin, etc.):

2.3 Timer [21 CFR 1040.20(c)(2)]:

a. Timer type

( ) Mechanical ( ) Solid State/Digital

( ) Token ( ) Electric

( ) Credit card ( ) Remote

b. Maximum timer interval (minutes):

Minimum timer interval (minutes):

c. Can the timer be reset before the end of the preset time interval?

( ) Yes ( ) No

d. What is the maximum timer interval error as a percent of that interval?

± %

e. What is the maximum recommended exposure time indicated on the label as required by 21 CFR 1040.20(d)(1)(iv)?

f. If the timer is operated using a token or credit card, what mechanism assures that: (1) the maximum recommended exposure time is not exceeded, and (2) the recommended multiple exposure time intervals are included?

g. When radiation emission from a sunlamp product has been terminated for any reason, including termination by a timer, is resumption of such emission possible without manual activation by the user?

( ) Yes ( ) No If "No," explain why:

h. Describe the control on the sunlamp product that enables the user to manually terminate radiation emission at any time without disconnecting the electrical plug or removing the lamp [21 CFR 1040.20(c)(3)].

Its location on the product:

2.4 Protective eyewear [21 CFR 1040.20(c)(4)]:

a. Manufacturer's name:

Address:

Model designation:

b. Number of sets of protective eyewear supplied with the sunlamp product:

c. Provide the spectral transmittance in the wavelength ranges:

200-320 nm %

320-400 nm %

more than 400 nm %

d. Spectral transmittance measurements attached?

( ) Yes ( ) No If "No," explain why:

e. Can the user see clearly enough while wearing the protective eyewear to reset the timer?

( ) Yes ( ) No If "No," explain why:

2.5 Labeling:

Submit copies or accurate reproduction of the following labels along with a photograph or drawing showing their location on the product.

a. Certification label (21 CFR 1010.2)
b. Identification label (21 CFR 1010.3)
c. Warning label [21 CFR 1040.20(d)(1)]

d. Provide the data and calculations used to determine the maximum recommended exposure time and exposure schedule in accordance with the "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products" dated August 21, 1986. See Appendix C.

Labeling and other material submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

2.6 Ultraviolet lamp labels:

Are the ultraviolet lamps incorporated in your product labeled as required by 21 CFR 1040.20(d)(2)?

( ) Yes ( ) No If "No," explain why:

Submit copies or accurate reproduction of the following labels along with a photograph or drawing showing the location (on the product) of the required labels.

a.Certification label (21 CFR 1010.2)
b.Identification label (21 CFR 1010.3)
c.Warning label [21 CFR 1040.20(d)(2)]

Are labels submitted as attachment?

( ) Yes ( ) No If "No," explain why:

2.7 User instructions [21 CFR 1040.20(e)(1)]:

Submit copies of all instructions that you provide to the users.

Are user instructions submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

PART 3: ULTRAVIOLET LAMPS

3.1 Describe the ultraviolet lamp, including design specifications and a picture or diagram.

Description submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

3.2 Type of base on lamp:

3.3 List sunlamp product(s) that is (are) designed to be used with the lamp.

MANUFACTURER AND BRAND NAME	MODEL NUMBER

3.4 Replacement lamps:

a. Identify the brand name and model designation of all lamps for which this lamp is promoted as a replacement. [This must also be in the lamp user instructions per 21 CFR 1040.20(e)(2)(iii).]

MANUFACTURER & BRAND NAME	MODEL NUMBER	PRIVATE LABEL MODEL NUMBER(S)

b. Provide the data and calculations used to determine lamp compatibility (equivalency). See Appendix D, "Policy on Lamp Compatibility," dated September 2, 1986.

Material submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

c. Provide specifications which document equivalency (identical lamp) between manufacturer's brand and private label(s).

Material submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

3.5 Labeling:

Submit a copy or facsimile of the following labels required by the performance standard.

Certification label (21 CFR 1010.2)
Identification label (21 CFR 1010.3)
Warning label [21 CFR 1040.20(d)(2)]

Labels submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

3.6 Identify the location of each required label on the product and packaging.

	LOCATION ON PRODUCT	LOCATION ON PACKAGING
Certification label		
Identification label		
Warning label		

3.7 User instructions [21 CFR 1040.20(e)(2)]:

Submit a copy of the user instructions that you provide to the users.

User instructions submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

PART 4: EMISSION CHARACTERISTICS

4.1 Spectral characteristics:

Description of procedures for spectroradiometric measurement:

a. At what distance from the product were the spectral irradiance measurements made?

meters

b. What spectral irradiance standards were used?

1. Source of standard

2. When last calibrated

3. Uncertainty

c. At what wavelengths was the spectral irradiance of the product measured?

4.2 Attach a graphical plot of the spectral irradiance from the product in the 200-710 nm wavelength range. Plot should be on a semilog graph with the spectral irradiance on the logarithmic scale.

Graphical plot submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

4.3 Provide the irradiance values per nanometer (Watt/cm^2/nm) over the wavelength range of 200 to 400 nm.

See Appendix B for Spectroradiometric Measurement and Testing Procedures.

See Appendix C for Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products. This document provides the formula and weighting factors to determine the exposure schedule and maximum recommended exposure time.

4.4 Irradiance ratio [21 CFR 1040.20(c)(1)]:

Watts/cm^2 (200-260 nm) ÷ Watts/cm^2 (260-320 nm):

Watts/cm^2 (260-320 nm) ÷ Watts/cm^2 (320-400 nm):

4.5 Describe the equipment and procedures used for spectral irradiance measurements. Include diagrams of light path, position, make, model, and type of various optical equipment and electronics used.

Description submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

4.6 Provide the uncertainties for the spectroradiometric measurements in the wavelength range of 200 to 400 nm.

Material submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

4.7 Describe how you estimated the uncertainties within the specified wavelength range.

Description submitted as an attachment?

( ) Yes ( ) No If "No," explain why:

PART 5: QUALITY CONTROL TESTING

5.1 Preproduction and incoming parts test:

a. Describe all design and engineering tests conducted on the product.

( ) Description attached

b. Describe all tests and/or checks made on incoming parts, including filters, reflectors, timers, ballasts, and lamps, prior to their acceptance to ensure that the final product complies with the performance standard for sunlamp products (21 CFR 1040.20).

( ) Description attached

5.2 Quality control tests or checks made during and after manufacture:

Describe the tests or checks conducted during or after manufacture that ensure compliance with the standard for the following:

a. timer functioning and accuracy (at multiple intervals, including maximum);
b. irradiance ratio;
c. protective eyewear transmittance;
d. means to terminate exposure;
e. warning label;
f. identification label;
g. certification label;
h. user instructions - adequacy and presence;
i. presence and quantity of protective eyewear;
j. other:

Include detailed descriptions of all sampling plans, instrumentation (including calibration), test procedures (including in-process and finished product quality control inspections), and rejection criteria used.

( ) Description attached

5.3 Submit copies of all written quality control test procedures and check sheets (demonstrating actual test results) used for incoming component tests, manufacturing tests, and final acceptance tests.

( ) Copies attached

NOTE: Section 21 CFR 1010.2(c) requires that certification be based on tests in accordance with the standard or on a testing program in accordance

with good manufacturing practices (21 CFR 820). Failure to maintain an adequate testing program will result in disapproval of the program by CDRH.

PART 6: LIFE AND RELIABILITY TESTING

6.1 Attach information for all life and reliability tests on the product and its components, as required by 21 CFR 1002.30(a)(3). If any life tests are done on an accelerated aging basis, so indicate and provide details of the procedures and the formula or factors used in the accelerated tests. Provide this information (including results, data and/or condition of component at each inspection or test interval) for the following tests:

a. timer;
b. irradiance ratio;
c. protective eyewear;
d. means to terminate emission control;
e. warning label;
f. certification label;
g. identification label;
h. mechanical durability;
i. electrical durability;
j. filters;
k. reflectors;
l. others:

Is description attached?

( ) Yes ( ) No If "No," explain why:

APPENDIX A - Federal Regulations - Sunlamp Product Performance Standard

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

(a) Applicability.

(1) The provisions of this section, as amended are applicable as specified herein to the following products manufactured on or after September 8, 1986.

(i) Any sunlamp product.

(ii) Any ultraviolet lamp intended for use in any sunlamp product.

(2) Sunlamp products and ultraviolet lamps manufactured on or after May 7, 1980, but before September 8, 1986, are subject to the provisions of this section as published in the FEDERAL REGISTER of November 9, 1979 (44 FR 65357).

(b) Definitions. As used in this section the following definitions apply:

(1)"Exposure position" means any position, distance, orientation, or location relative to the radiating surfaces of the sunlamp product at which the user is intended to be exposed to ultraviolet radiation from the product, as recommended by the manufacturer.

(2)"Intended" means the same as "intended uses" in §801.4.

(3)"Irradiance" means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm^2).

(4)"Maximum exposure time" means the greatest continuous exposure time interval recommended by the manufacturer of the product.

(5)"Maximum timer interval" means the greatest time interval setting on the timer of a product.

(6)"Protective eyewear" means any device designed to be worn by users of a product to reduce exposure of the eyes to radiation emitted by the product.

(7)"Spectral irradiance" means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2/nm)$).

(8)"Spectral transmittance" means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.

(9)"Sunlamp product" means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

(10)"Timer" means any device incorporated into a product that terminates radiation emission after a preset time interval.

(11)"Ultraviolet lamp" means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any sunlamp product.

(c) Performance requirements.

(1) Irradiance ratio limits. For each sunlamp product and ultraviolet lamp, the ratio of the irradiance within the wavelength range of greater than 200 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers may not exceed 0.003 at any distance and direction from the product or lamp.

(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 of 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 §§ 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 and 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.

(ii) Any label prescribed in this paragraph for ultraviolet lamps shall be permanently affixed or inscribed on the product so as to be legible and readily accessible to view.

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Compliance and Surveillance, (HFZ-352), Center for Devices and Radiological Health, on the Center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a), the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags 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 on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture 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, Office of Compliance and Surveillance, (HFZ-352), Center for Devices and Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular; e.g., if they do not diminish the impact of the required statements; and are not prohibited by this chapter. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0195.)

(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.)

(f) Test for determination of compliance. Tests on which certification pursuant to § 1010.2 is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument.

Dated: August 12, 1985

Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

APPENDIX B

SPECTRORADIOMETRIC MEASUREMENT AND TESTING PROCEDURES

There are several ways to determine radiometric values which, when correctly executed, yield the same physical values. CDRH does NOT insist that any one method be used. We offer the following suggestions only to help in establishing the important parameters. Physically valid alternatives are, of course, acceptable.

Measurements whose results are reported should be performed using generally-accepted radiometric principles and techniques. The information should be reported in spectral irradiance values (Watts/($cm^{-2}nm^{-1}$)). For sunlamp products, all measurements should be made on the entire device consisting of the light source and any related housing or attachments manufactured or assembled for sale in the configuration in which they are intended to be used. However, if the product has components such as a stand or some other component which does not in any way alter the optical performance of the device, then these may be removed before the device is measured. If the ultraviolet lamp must be mounted in some other housing in order to facilitate the measurements, this should be done in such a manner that the optical performance of the lamp is unchanged.

It is recommended that spectroradiometric measurements on the product be made as follows:

The spectroradiometric measurements on the sunlamp or sunlamp product should be made at the recommended exposure position from the product on an optic axis in the direction of the maximum emission from the product. If more than one such direction exists, choose the one that relates most closely to the intended uses and normal mounting configuration of the product. The measurements on the continuum part of the spectrum should be made at intervals of 1 nanometer (nm) in the ultraviolet wavelength region below 400 nm in which the device emits. In addition, the spectral lines in the emission should be measured with a sufficiently narrow spectral bandpass so as to adequately measure the level of radiation being emitted in those lines.

The measurements should be made with instruments calibrated against standards of spectral irradiance. These standards should have been calibrated either by U.S. National Institutes of Standards and Technology [NIST, previously known as the National Bureau of Standards (NBS)] or by another laboratory against standards calibrated by NIST using NIST-recommended or generally-accepted techniques.

The standards should be used immediately before and after the measurements on the product. Alternatively, if you usually refer to the standard after every reading while scanning the wavelength scale you may use that method. The results should be reported in spectral irradiance values [Watts/($cm^{-2}nm^{-1}$)].

CDRH generally recommends 100 percent testing of products for determination of compliance. For some tests and inspections, a sampling plan may be appropriate, i.e., use of a sampling procedure whereby release of noncomplying products is prevented by testing less than 100 percent of the units produced. Results from acceptable statistical sampling procedures may be used in answering many of the questions in Part 4. Examples of sampling plans are contained in MIL-Std-105D and MIL-Std-414.

APPENDIX C - POLICY on Maximum Timer Interval and Exposure Schedule for Sunlamp Products, dated August 21, 1986

The Center for Devices and Radiological Health (CDRH) will use the following criteria to evaluate the adequacy of the exposure schedule and the recommended maximum exposure time (and therefore the maximum timer interval):

1) The maximum recommended exposure time (and maximum timer interval) must not exceed a value which will result in an exposure of four (4) times the minimal erythema dose (MED) for untanned Type II skin (always burns, then tans slightly). This is based on the CDRH Erythema Action Spectrum [proposed action spectrum of Commission Internationale de L'Eclairage (CIE), modified by CDRH]. See Appendix A for the action spectrum and weighting factors and equations needed to derive it.

The formula for determining the recommended maximum exposure time, "T_e" in seconds is:

$$T_e = \frac{624/M^2}{\sum V_i R_i}$$

where Standard MED = $156 J/M^2$ at 296nm
V_i = weighting factor
R_i = irradiance in W/M^2

2) The recommended maximum exposure time must not exceed a value which will result in an exposure of four (4) times the minimal melanogenic dose (MMD) for untanned Type II skin. This is based on the melanogenic action spectrum developed by Parrish et al. (1982). See Appendix B for this action spectrum.

The formula for determining the recommended maximum exposure time, "T_m" in seconds, is:

$$T_m = \frac{1836 J/M^2}{\sum J_i R_i}$$

where Standard MMD = $459 J/M^2$ at 296nm
J_i = weighting factor
R_i = irradiance in W/M^2

3) The recommended exposure schedule should provide for exposures of no more than 0.75 MED three times the first week, gradually increasing the exposure the following weeks until maximum tanning has occurred (approximately four weeks total) and then provide for maintenance of a tan by biweekly or weekly exposures of up to four (4) MEDs or four (4) MMDs, whichever is less.

CDRH believes that the above criteria balance the need to limit acute (and delayed) damages from unintentionally long exposure and the need to provide for single exposure durations adequate to achieve and maintain a tan.

Walter E. Gundaker, Director
Office of Compliance, CDRH

WEIGHTING FACTORS FOR ERYTHEMA, V_i

[graph available from DSMA]

The equations describing the curve are: $V_i(\lambda) = 1.0$ $(250 < \lambda < 302$ nm)
$V_i(\lambda) = 10^{0.114\,(302 - \lambda)}$ $(302 < \lambda < 325$ nm)
$V_i(\lambda) = 10^{0.0161\,(159 - \lambda)}$ $(325 < \lambda < 405$ nm)

WEIGHTING FACTORS FOR MELANOGENESIS, J_i

[graph available from DSMICA]

The MMD as function of wavelength has been interpolated (using log MMD) from the action spectrum for melanogenesis of Type II skin (Parrish et al. 1982).

Parrish Melanogenesis Type II Skin (1982) Normalized to 296 nm

Wavelength (nm)	J_i	Wavelength (nm)	J_i	Wavelength (nm)	J_i
250	.378409	302	.815892	354	.100202E-02
251	.374828	303	.750391	355	.972644E-03
252	.371248	304	.690261	356	.944186E-03
253	.367714	305	.502296	357	.916645E-03
254	.364225	306	.36551	358	.890022E-03
255	.360783	307	.265997	359	.863859E-03
256	.35734	308	.193565	360	.838613E-03
257	.353943	309	.14087	361	.813826E-03
258	.350547	310	.102497	362	.789958E-03
259	.347196	311	.745893E-01	363	.767007E-03
260	.343891	312	.054301	364	.747729E-03
261	.340632	313	.395016E-01	365	.722942E-03
262	.337419	314	.341137E-01	366	.666943E-03
263	.334206	315	.294593E-01	367	.615075E-03
264	.331039	316	.254384E-01	368	.567338E-03
265	.327672	317	.219683E-01	369	.523272E-03
266	.327413	318	.189709E-01	370	.48288E-03
267	.326954	319	.163821E-01	371	.44547E-03
268	.326449	320	.141467E-01	372	.410953E-03
269	.32599	321	.122143E-01	373	.379097E-03
270	.325531	322	.105481E-01	374	.34972E-03
271	.325072	323	.911137E-02	375	.322593E-03
272	.324613	324	.786745E-02	376	.297577E-03
273	.324154	325	.679336E-02	377	.274534E-03
274	.323695	326	.586616E-02	378	.253236E-03
275	.323236	327	.506748E-02	379	.233591E-03
276	.321445	328	.437483E-02	380	.215506E-03
277	.319609	329	.377812E-02	381	.213532E-03
278	.317865	330	.326265E-02	382	.211558E-03
279	.316075	331	.281741E-02	383	.209963E-03
280	.314285	332	.243276E-02	384	.207702E-03
281	.312541	333	.210089E-02	385	.205821E-03
282	.31075	334	.181447E-02	386	.203939E-03
283	.351694	335	.176123E-02	387	.202057E-03
284	.398008	336	.170982E-02	388	.200221E-03
285	.450427	337	.165978E-02	389	.189296E-03
286	.509732	338	.161113E-02	390	.196594E-03
287	.576885	339	.156385E-02	391	.194804E-03
288	.652851	340	.151841E-02	392	.193014E-03
289	.738778	341	.147388E-02	393	.191224E-03
290	.836088	342	.143074E-02	394	.18948E-03
291	.861518	343	.138897E-02	395	.187735E-03
292	.887498	344	.134812E-02	396	.186037E-03
293	.91435	345	.130864E-02	397	.184339E-03
294	.94212	346	.127054E-02	398	.18264E-03
295	.970625	347	.123336E-02	399	.180988E-03
296	1.	348	.11971E-02	400	.179336E-03
297	.990959	349	.116222E-02	401	.177683E-03
298	.982054	350	.112825E-02	402	.176077E-03
299	.973287	351	.10952E-02	403	.17447E-03
300	.96429	352	.106307E-02	404	.172864E-03
301	.886993	353	.103232E-02	405	.171257E-03

APPENDIX D - POLICY ON LAMP COMPATIBILITY, dated September 2, 1986

A replacement lamp will be considered compatible with (or equivalent to) another (original) lamp if:

1) The replacement lamp will not cause any sunlamp product intended to use the original lamp to fail to comply with the standard or to become defective as defined by 21 CFR 1003.2, and;

2) the lamp is as effective, within plus or minus ten percent, as the original lamp, in causing erythema and melanogenesis.

It should be noted that the above criteria apply to sunlamp product exposure schedule and maximum timer interval which must appear on the product's labeling. The manufacturer should use the following procedure to establish conformance with criterion number 2 above:

1) Calculate the recommended maximum exposure time for a single original lamp (Y) using the CDRH August 21, 1986, guidance ("Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products").

2) Calculate the recommended maximum exposure time for a single replacement lamp (X) using the same method.

3) Compare the values; if the value for the replacement lamp (X) is within plus or minus 10% of the value of the original lamp (Y), the lamp would be considered compatible [$Y = X \pm 10\%$].

The distance(s) used for this comparison should represent the typical use distance range in products using the original (Y) lamp.

The CDRH welcomes comments on this policy.

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Radiological Health