

**OMB No. 0910-0025; Exp. May 31, 2010**

**Section: eRadHealth Menu**

Role

What is your role?

[L]

*Note:*

*If you are acting as an agent of the actual manufacturer, please select your role, for example, Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.*

Submission Information

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

**Section: Manufacturer Data**

Introduction

## **Electronic Product Radiation Safety Reporting Form**

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This FDA Electronic Submission (eSub) software is the next version of the application developed to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, when you submit through it you will receive your acknowledgement email message with Accession Number within minutes!

Information about the FDA Electronic Submissions Gateway can be found at [www.fda.gov/escg](http://www.fda.gov/escg). Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

**U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Attn: eSubmitter Team  
Document Mail Center - WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002**

Submissions received in the mail on CD will be processed within a few days of receipt.

You should be familiar with the regulatory requirements for radiological products at [www.fda.gov/cdrh/radhealth/](http://www.fda.gov/cdrh/radhealth/) and medical devices available at [www.fda.gov/cdrh/devadvice/](http://www.fda.gov/cdrh/devadvice/). If you have specific questions about the regulations, please contact us at: [DSMICA@fda.hhs.gov](mailto:DSMICA@fda.hhs.gov).

If you have specific questions regarding this software, please contact the eSub team by email at: [eSubmitter@fda.hhs.gov](mailto:eSubmitter@fda.hhs.gov).

Thank you for using our electronic product reporting software. Please communicate your comments and suggestions to the eSub team as often as you like.

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

General Information

## General Information for Radiological Health Products

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH).

The Radiological Health staff, CDRH developed this software application for the Product and Annual reports. This application will assist manufacturers of electronic products that emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements 1,2,3.

Reports submitted on radiation safety of electronic products must follow the appropriate form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the

accession number that CDRH assigns 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. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database.

**CDRH DOES NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED.**

It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce, 21 CFR 1002 requires the manufacturer to submit the product and Annual Reports and to comply with all applicable importation requirements (21CFR 1005). If there are deficiencies, CDRH may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. CDRH will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21CFR 1003 - 1004) for products already introduced into commerce.

CDRH can now accept and process 'CeSub' electronic submissions at this time, if all attachments are PDF files only, and the cover letter is printed out and included with a real signature. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy (save a copy to your hard drive) of the completed report in your records.

We are providing our new software applications for the old reporting forms upon request during this beta testing period of development in Spring, 2005. Other regulatory information is still available on the Internet under [www.fda.gov/cdrh/radhealth/](http://www.fda.gov/cdrh/radhealth/). No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to [cdrhsub@cdrh.fda.gov](mailto:cdrhsub@cdrh.fda.gov).

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report.

When new models of a product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new 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 may be submitted using the Annual Report software included in this application. [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 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Definitions

# Definitions for Rad Health Products

## Manufacturers

Manufacturer is any person or organization engaged in the business of manufacturing, assembling, or importing of electronic products (21 CFR1000.3(n)). Manufacturers of electronic products subject to 21CFR1000-1050 must:

- Design and manufacture their products to be in compliance with applicable performance standards;
- Test their products to assure compliance;
- Certify compliance of their products;
- Maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- Use the published reporting forms or electronic software application to submit reports to CDRH, including Product reports describing the manner of compliance of the product design and testing program and Annual Reports summarizing their compliance testing;
- Report accidental radiation occurrences (i.e., possible, suspected, or known exposures);
- Report any radiation defects or noncompliances; and
- Recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

## Accidental Radiation Occurrences

An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

## Importers

Importer is any person or organization engaged in the business of importing electronic products. An importer is considered to be a manufacturer. The requirements for Manufacturers given above also apply to importers if the requirements have not been done by the foreign manufacturer.

## United States Agent for Foreign Manufacturers

Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer's agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of the Radiation Control for Health and Safety Act of 1968 (21U.S.C. 360mm(d)) and this section. The agent maybe an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

## From The Federal Food, Drug, and Cosmetic ActSec 536 [21 U.S.C. 360mm](d) Designation of agent for purposes of service

It shall be the duty of every manufacturer offering an electronic product for importation into the United

States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

Sec. 531 [21 U.S.C. 360hh] (1) the term "**electronic product radiation**" means:

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Sec. 531 [21 U.S.C. 360hh](2) the term "**electronic product**" means:

(A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

Burden to Industry

## Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 26 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

<b>Manufacturer and Report Information</b>
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<i>Information:</i>	<p><i>This general report requests names, addresses, phone numbers, etc. for your firm, various officials of your firm, consultants who may assist in preparing the report, parent firm (if any), importer and designated agent (for foreign firms). Some of this information is mandatory and its absence will prevent you from completing the report submission. You can check for missing data using the "Missing Data" report from the "Output" menu.</i></p> <p><i>If you are acting as an agent or consultant for another firm who is certifying the product (or laser light show), please enter the certifying manufacturer and list yourself as the report submitter, below.</i></p>
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<i>Information:</i>	<p><i>Attention: Variance Applicants</i></p> <p><i>If you are acting as an agent or consultant for, or on behalf of, or filing for, a company that will be manufacturing or producing a Class IIIb or IV projector or laser light show or both which require an approved variance, the following explanations may provide further clarification.</i></p> <p><i>Manufacturer: This is the firm or company who is requesting the variance, will certify the product or show, and will be the holder and owner of the variance. This is not the agent or consultant who may be filing this report or Variance request for the manufacturer; that agent may be the submitter, identified in a later screen.</i></p> <p><i>Responsible Individual: This person works for the Manufacturer and is responsible for compliance of the projector and/or show. In the case of laser light shows, he or she may be the company president, CEO, or the laser light show head operator or a manager who oversees the shows.</i></p> <p><i>Reporting Official: This person works for the Manufacturer and is responsible for reports, recordkeeping, and submitting FDA required documents and correspondence.</i></p>
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<b>Manufacturer Responsible for Product Compliance</b>
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<i>Note:</i>	<p><i>This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.</i></p>
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Select the Manufacturer's address from the Establishment Address book:	
<i>Establishment Information:</i>	
Establishment Name	
Division Name	
Home Page	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	
Address	

<b>Responsible Individual</b>
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<i>Note:</i>	<p><i>The responsible individual is the highest level and most responsible individual affiliated with this establishment.</i></p>
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Select the Responsible Individual from the Contact Address book:

<i>Contact Information:</i>	
Contact Name	
Occupation Title	
Email Address	
<i>Establishment Information:</i>	
Establishment Name	
Division Name	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	
Address	

<b>Manufacturer's Reporting Official</b>
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<i>Note:</i>	<i>This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes in testing and quality control procedures submitted to FDA must be signed by this individual.</i>
Select the Reporting Official from Contact Address book:	
<i>Contact Information:</i>	
Contact Name	
Occupation Title	
Email Address	
<i>Establishment Information:</i>	
Establishment Name	
Division Name	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	
Address	

<b>Report Submitter</b>
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<i>Note:</i>	<i>The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. All documents prepared by the submitter must have the manufacturer's reporting official signature for authenticity of submitted</i>
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documentation.	
Select the Submitter from the Contact Address book:	
<i>Contact Information:</i>	
Contact Name	
Occupation Title	
Email Address	
<i>Establishment Information:</i>	
Establishment Name	
Division Name	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	
Address	
<i>Comments:</i>	
Internal Reference Number:	

<b>Parent Establishment</b>
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Is there a parent establishment?	[L]
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Select the Parent Establishment and Contact from the Contact Address book:	
<i>Contact Information:</i>	
Contact Name	
Occupation Title	
Email Address	
<i>Establishment Information:</i>	
Establishment Name	
Division Name	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	



Address	
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Manufacturer Designated United States Agent
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<i>Note:</i>	<i>Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.</i>
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Is there a United States agent that has been designated by the manufacturer?	[L]
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Written Agreement
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<b>Item: 1 (could contain up to 10 items with none required)</b>
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<i>Note:</i>	<i>If any of the required responses below do not apply to your designated agent, enter 'NOT APPLICABLE' or 'NA.'</i>
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Select the Designated Agent from the Contact Address book:

*Contact Information:*

Contact Name	
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Occupation Title	
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Email Address	
---------------	--

*Address*

Establishment Name	
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Division Name	
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Address	
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Telephone Number	
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Fax Number	
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Attach a copy of written agreement with the designated U.S. agent:

[Multi-Line Plain Text]

File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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Importer
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<b>Item: 1 (could contain up to 10 items with none required)</b>
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Select the Importer from the Contact Address book:

*Contact Information:*

Contact Name	
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Occupation Title	
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Email Address	
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<i>Establishment Information:</i>	
Establishment Name	
Division Name	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	
Address	

**Additional Manufacturing Locations**

**Item: 1 (could contain up to 100 items with none required)**

<i>Note:</i>	<i>If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsible for Product Compliance section, then the names, addresses, and FDA registration numbers should be provided. In addition any codes used on labels to identify a manufacturing location must be provided. Each factory location must assure all production procedures are followed identically step by step as provided in this report. If the procedures are not the same then separate reports should be filed.</i>
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Select the Manufacturer Address from the Establishment Address book:

<i>Establishment Information:</i>	
Establishment Name	
Division Name	
Home Page	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	
<i>Mailing Location:</i>	
Address	
<i>Comments:</i>	
Code used on identification labels:	

**Section: Product Data**

**Product and Model Identification**

Note:

At this time we are only accepting electronic versions of reporting guides contained within this software. Other reporting guides that are not yet electronic are available for downloading from <http://www.fda.gov/cdrh/comp/eprc.html>.

Product Type Reported

Report Information

Is this submission a supplement to an Annual Report submitted previously for the same reporting year?

[L]

Provide the Accession Number of the original report for which this is a supplement:  
(Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc.)

**Please verify that your accession number matches the report type that is being filed. The third character of your accession number must correspond with its associated report type as shown in the table below:**

Report Type Description:	Third Character:
Initial Product Report	1
Model Change Product Report	2
Annual Report	3
Abbreviated Report	8
Variance Request	A
Laser OEM Registration and Listing Report	R

Are you requesting a new variance, a renewal, extension or amendment to a previous variance?

[L]

If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.

Stop:

*If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request, Other" as your Type of Submission in the Submission Information Screen. If you select "Variance Request, Other" you must select the product for which you are requesting a variance at the end of the screen.*

Special Considerations

Note:

Check all items in this section that may apply to this submission.

Noncompliances or Defects

Does this document or any of its attachments contain:

A self-declaration or notification of noncompliance or defect?

[L]

Provide an explanation:

[Multi-Line Plain Text]

**Responses to Noncompliances or Defects**

<b>Does this document or any of its attachments contain any of these responses concerning noncompliances?</b>	
A refutation of noncompliances?	[L]
A request for an exemption from notification?	[L]
Corrective action plans you may be conducting?	[L]
A description of any design changes that correct noncompliances for future production?	[L]
Provide an explanation:	
[Multi-Line Plain Text]	

**Exemption Requests**

<b>Does this document or any of its attachments contain:</b>	
Exemption of a product for government use from a standard (1010.5)?	[L]
Exemption for products for government use from reporting and recordkeeping (1002.51)?	[L]
Special exemption of products from reporting and/or recordkeeping (1002.50)?	[L]
Request for approval of alternate labeling?	[L]
Application for alternate test procedures (1010.13)?	[L]
Provide an explanation:	
[Multi-Line Plain Text]	
Attach any necessary files.	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

**Variance Requests**

<b>Message:</b>	<i>Click the plus sign to list the requirements from which you are requesting a variance.</i>
This submission includes an application for a variance from certain requirements.	
Item 1	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	[HTML Text]

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Stop:	<p><i>For all Variance requests, two submissions must be made to the FDA.</i></p> <p><i>The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD &amp; submittal letter, please mail to:</i></p> <p><i>U.S. Food and Drug Administration Center for Devices and Radiological Health Attn: eSubmitter Team Document Mail Center - WO66-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002</i></p> <p><i>Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:</i></p> <p><i>Food and Drug Administration Division of Dockets Management (HFA-305) 5630 Fishers Lane, Room 1061 Rockville, MD 20857</i></p>

### Responses to Communications from FDA

<b>Does this document or any of its attachments contain:</b>	
A response to an inspection?	[L]
What was the date of the inspection?	[Date]
A response to a warning letter from the Food and Drug Administration (FDA)?	[L]
What was the date of the Warning Letter?	[Date]
A response to a report review inquiry from the Center for Devices and Radiological Health (CDRH) (the inquiry may have been in the form of a letter, email, or phone call)?	[L]
What was the date of the inquiry?	[Date]
A response to any other communication from FDA?	[L]
What was the date of the communication?	[Date]
Provide an explanation:	
[Multi-Line Plain Text]	

### Additional Information

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

### Private Labeling

Is the product sold by other companies under different brand names?	[L]
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## Private Labeling-Table

Item: 1 (could contain up to 20 items with 1 required)

Give the name and address of the manufacturer:

*Establishment Information:*

Establishment Name

Division Name

Email Address

*Address*

Address

Telephone Number

Fax Number

Give the firm establishment registration number of the manufacturer listed above (if known):

Enter brand names and/or model designations in the following table by clicking on the Add button. If you prefer to attach a file, please click on the Add button and enter the text "See File Attachment" as the first table entry.

Item 1

Item 2

Item 3

## List of Brand Names and/or Model Designations

File Attachment

[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Details

[HTML Text]

The Original Equipment Manufacturer (OEM) accession number (if known):

Explain how the brand names and model designations correspond with your own brand names and model designations:

[Multi-Line Plain Text]

## Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.

[Multi-Line Plain Text]

If it has not been assigned yet, provide an explanation and submit it as soon as you receive such a filing number.

[Multi-Line Plain Text]

*Note:* See [www.fda.gov/cdrh](http://www.fda.gov/cdrh) for more information on medical device premarket clearance procedures.

Document Key: Specialized Response content is defined within straight brackets [ ]; Special code: [L] List of Values.

**Section: Sunlamp Product**

*Part 1 Product Type and Identification*

Is this a report on products that incorporate sunlamps/ultraviolet lamps?	[L]
Is the product type a:	[L]
If "Other" has been selected, please specify further.	
Is this a report on an ultraviolet lamp?	[L]
Is the product type a:	[L]
If "Other" has been selected, please specify further.	

*Part 2 Sunlamp Product Description*

Attach a description of the sunlamp product. The description must include the following:

- (1) exterior and interior structures of the assembled product;
- (2) description and manufacturer's specification for the reflector, timer, filters, ultraviolet lamps, ballasts, etc.;
- (3) photographs and diagrams which include parts identification;
- (4) electrical circuit diagram

Click on the Add... button below to attach the files.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

*Ultraviolet Lamps Part I*

**Item: 1 (could contain up to 500 items with 1 required)**

Lamp Manufacturer: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]			
Model Designation (Name and/or Number):			
Item			
Item 1		Item 2	
Type of base or socket used for each ultraviolet lamp in the product (no single contact medium screw, or double contact medium screw lamp holders):			[L]
If "Other" has been selected, please specify further.			

*Timer*

Timer [21 CFR 1040.20(c)(2)]:	
Select the timer type:	[L]
Maximum timer interval (in minutes):	



## OMB No. 0910-0025; Exp. May 31, 2010

Minimum timer interval (in minutes):	
Can the timer be reset before the end of the preset time interval?	[L]
If "No" has been selected, please explain further.	
[HTML Text]	
What is the maximum timer interval error as a percent of that interval?	
What is the maximum recommended exposure time indicated on the label required by 21 CFR 1040.20(d)(1)(iv) (in minutes)?	
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?	
[HTML Text]	
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?	[L]
Please explain further:	
[HTML Text]	
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)].	
[HTML Text]	
Where is the location on the sunlamp product of the control described above?	

### Protective Eyewear

Protective eyewear [21 CFR 1040.20(c)(4)]:	
Manufacturer of protective eyewear: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	
Model Designation Number:	
Number of sets of protective eyewear supplied with the sunlamp product:	
Message:	Provide the spectral transmittance in the following wavelength ranges:
200-320 nm (as a percent):	
320-400 nm (as a percent):	
More than 400 nm (as a percent):	
Please attach spectral transmittance measurements:	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Can the user see clearly enough while wearing the protective eyewear to reset the timer?	[L]

## OMB No. 0910-0025; Exp. May 31, 2010

If "No" has been selected, explain why.

[HTML Text]

### Sunlamp Product Labeling

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.

- Certification label (21 CFR 1010.2)
- Identification label (21 CFR 1010.3)
- Warning label (21 CFR 1040.20(d)(I))

See <http://www.fda.gov/cdrh/radhlth/sunlamp.html> (see Notices to Industry)

Note: Click on the plus sign below to select the file(s) to attach to this question.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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Details	[HTML Text]
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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 <http://www.fda.gov/cdrh/radhlth/sunlamp.html> (see Notices to Industry).

Note: Click on the plus sign below to select the file(s) to attach to this question.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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Details	[HTML Text]
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### Ultraviolet Lamp Labeling

Are the ultraviolet lamps incorporated in your product labeled as required by 21 CFR 1040.20(d)(2)?	[L]
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If "No" has been selected, explain why.

[HTML Text]

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.

- Certification label (21 CFR 1010.2)
- Identification label (21 CFR 1010.3)
- Warning label (21 CFR 1040.20(d)(2)).

Note: Click on the plus sign below to select the file(s) to attach to this question.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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Details	[HTML Text]
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### User Instructions

Submit copies of all instructions that you provide to the users [21 CFR 1040.20(e)(I)] .

Note: Click on the plus sign below to select the file(s) to attach to this question.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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## OMB No. 0910-0025; Exp. May 31, 2010

	.zip)]
Details	[HTML Text]

### Part 3 Ultraviolet Lamps

Model Designation (Name and/or Number):			
Item			
Item 1		Item 2	
In an attachment, describe the ultraviolet lamp, including design specifications and a picture or diagram. Note: Click on the plus sign below to select the file(s) to attach to this question.			
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
Details	[HTML Text]		
Type of base on the lamp:			
[HTML Text]			

### Ultraviolet Lamps Part II

**Item: 1 (could contain up to 500 items with 1 required)**

Manufacturer:			
Model Designation (Name and/or Number):			
Item			
Item 1		Item 2	

### Replacement Lamps

**Item: 1 (could contain up to 500 items with 1 required)**

Model Designation (Name and/or Number):			
Item			
Item 1		Item 2	

### Lamp Compatibility

Provide the data and calculations used to determine lamp compatibility (equivalency). See <a href="http://www.fda.gov/cdrh/radh1th/sunlamp.html">http://www.fda.gov/cdrh/radh1th/sunlamp.html</a> (see Policy on Lamp Compatibility). Note: Click on the plus sign below to select the file(s) to attach to this question.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

## OMB No. 0910-0025; Exp. May 31, 2010

Provide specifications which document equivalency (identical lamp) between manufacturer's brand and private label(s).	
Note: Click on the plus sign below to select the file(s) to attach to this question.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

### Ultraviolet Lamp Labeling

Submit a copy or facsimile of the following labels required by the performance standard.	
a. Certification label (21 CFR 1010.2)	
b. Identification label (21 CFR 1010.3)	
c. Warning label [21 CFR 1040.20(d)(2)]	
See <a href="http://www.fda.gov/cdrh/radhlth/sunlamp.html">http://www.fda.gov/cdrh/radhlth/sunlamp.html</a> (see Notices to Industry)	
Note: Click on the plus sign below to select the file(s) to attach to this question.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Identify the location of each required label on the product and packaging.	
Certification Label:	
Location on product:	
Location on packaging:	
Identification Label:	
Location on product:	
Location on packaging:	
Warning Label:	
Location on product:	
Location on packaging:	

### User Instructions

User instructions [21 CFR 1040.20(e)(2)]:	
Submit a copy of the user instructions that you provide to the users.	
Note: Click on the plus sign below to select the file(s) to attach to this question.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

### Part 4 Emission Characteristics

## OMB No. 0910-0025; Exp. May 31, 2010

Spectral characteristics:	
Message:	Description of procedures for spectroradiometric measurement.
At what distance from the product were the spectral irradiance measurements made? (in meters)	
Message:	What spectral irradiance standards were used?
-	Source of standard:
-	When last calibrated:
-	Uncertainty:
At what wavelengths was the spectral irradiance of the product measured?	
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.	
Note: Click on the plus sign below to select the file(s) to attach to this question.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

### Irradiance Values

Provide the irradiance values per nanometer (Watt/cm <sup>2</sup> /nm) over the wavelength range of 200 to 400 nm. See <a href="http://www.fda.gov/cdrh/radlth/sunlamp.html">http://www.fda.gov/cdrh/radlth/sunlamp.html</a> for Spectroradiometric Measurement, Testing Procedures, and 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.	
Note: Click on the plus sign below to select the file(s) to attach to this question.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Irradiance ratio [21 CFR 1040.20(c)(1)] :	
Watts per cm <sup>2</sup> (200-260 nm) divided by Watts per cm <sup>2</sup> (260-320 nm):	
Watts per cm <sup>2</sup> (260-320 nm) divided by Watts per cm <sup>2</sup> (320-400 nm):	
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.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Provide the uncertainties for the spectroradiometric measurements in the wavelength range of 200 to 400 nm.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Describe how you estimated the uncertainties within the specified wavelength range.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

**Part 5 Quality Control Testing**

Note:	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.
Preproduction and incoming parts test:	
Describe all design and engineering tests conducted on the product.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
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).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
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.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
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.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

**Part 6 Life and Reliability Testing**

Attach information for all life and reliability tests on the product and its components, as required by 21CFR 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:
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- (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

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Stop:	You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.
Message:	Form FDA 3630 Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (03/06)