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FORM FDA 3801 (6/14)

Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps

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This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/ .

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

HHS Publication FDA 89-8275

Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps

(21 CFR 1002.10 and 1002.12)

Compiled by
Office of Compliance and Surveillance

April 1989

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, Maryland 20993

FOREWORD

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

Also, CDRH technical reports in radiological health are made available to the World Health Organization (WHO) under a memorandum of agreement between WHO and the Department of Health and Human Services. Three WHO Collaborating Centers, established under the Bureau of Radiological Health, continue to function under CDRH:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

We welcome your comments and requests for further information.

John C. Villforth
Director
Center for Devices and
Radiological Health

PREFACE

Manufacturers of products subject to the Radiation Control for Health and Safety Act of 1968 are required to furnish various reports to the Center for Devices and Radiological Health. This guide is for use by manufacturers of medical 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 an initial and model change report for products listed in Section 1002.61(a)(4). All initial and model change reports must be submitted in accordance with Section 1002.10 and 1002.12, 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 followup correspondence.

Ann B. Holt
Acting Director
Office of Compliance and Surveillance

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GUIDE FOR PREPARING INITIAL REPORTS AND MODEL CHANGE REPORTS ON MEDICAL ULTRAVIOLET LAMPS AND PRODUCTS CONTAINING SUCH LAMPS (21 CFR 1002.10 and 1002.12)

INTRODUCTION

This guide has been prepared to assist manufacturers of medical ultraviolet lamps and products intended to incorporate these lamps in the preparation of initial and model change reports. These reports are required if such products are intended for the irradiation of any part of the living human body by light of wavelength in air less than 320 nanometers to perform a diagnostic or therapeutic function. The intended use of the product for the functions mentioned above is determined by the labeling statements (including advertisements and product description) by the manufacturer, and from an analysis of the design and use of the product.

An initial report is required for each model bearing a separate model number. If there is a model series and the different models in that series have minor differences which do not in any way alter the radiation safety characteristics, a complete report on one of the models followed by supplemental reports on the others will be adequate. Supplemental reports should respond to the appropriate parts of the guideline. Where there is no change from a prior report this fact may be so stated. Report the changes in detail and reference the number of the affected item. However, the supplement must clearly indicate the items of the part which have not been changed.

Manufacturers who do not manufacture the ultraviolet lamps for their products need not respond to Part 4 of the guide.

Many of the responses solicited by this guide can be made in the space provided. Where attachments are required, so indicate in the space provided in the body of the guide. Attachments should be numbered the same as the specific item of this guide to which they are addressed. For example, an attachment responding to Item 2.2 should be labeled Attachment 2.2.

Your reports and report supplements are to be submitted to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

If you have any questions, please contact the Ultraviolet Products Section, at 1-800-638-2041.

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PART 1

MANUFACTURER, REPORT TYPE, AND MODEL IDENTIFICATION

1.1 Manufacturer:

_____
(Name)

_____
(Address)

_____

Corresponding Official (person preparing this report):

_____
(Signature)

_____
(Name)

_____
(Title)

_____ _____
(Telephone Number) *(Email)*

_____
(Date of Report)

1.2 Designated Agent (for foreign manufacturers importing to the U.S., see 21 CFR 1005.25):

_____
(Signature, or attach written agreement with agent)

_____
(Name)

_____
(Title)

_____
(Telephone Number)

1.3 Importer(s) (list all importers if applicable):

_____
(Name)

_____
(Address)

_____

1.4 Report Type:

(☐) Initial (☐) Model Change

(☐) Supplement to CDRH Accession No. _____ submitted on _____
(Date)

1.5 Product Identification:

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

1.6 Product Type: (☐) Booth (☐) Portable (☐) Other _____
(☐) Bed (☐) Tabletop

1.7 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. (Provide a copy of each product label and user's instructions.)

Brand name	Model number	Name & address of company under whose name product is sold

1.8 Intended Use:

Specify the intended function of the reported product (e.g., diagnostic or therapeutic).

1.9 Other reporting requirements under FD&C Act:

	Submission date	Report receipt accession number
510(k)		
PMA		
Registration and Listing		

PART 2

MEDICAL ULTRAVIOLET PRODUCT DESCRIPTION

2.1 Attach a description of the ultraviolet product. The description must include:

a. exterior and interior structures of the assembled product;
b. description and specification for the reflector, timer, filters, ultraviolet lamps, etc.;
c. photographs and diagrams which include parts identification;
d. electrical circuit diagram.

Information submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

_____

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

Ultraviolet lamp brand name Model number

_____

_____

_____

Number of lamps used in the product _____

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

2.3 Timer:

a. Timer type

(☐) Mechanical (☐) Solid State/Digital
(☐) Electric (☐) Remote

b. Maximum timer interval (minutes) _____

Minimum timer interval (minutes) _____

c. What is the maximum timer interval error as a percent of that interval?
± _____ %

d. Can the product be operated if the timer is removed?
(☐) Yes (☐) No (If "Yes," explain why)

_____

e. Can the product be operated if the timer fails or is defective?
(☐) Yes (☐) No (If "Yes," explain why)

_____

2.4 Protective eyewear:

a. _____
(Manufacturer's Name)

_____
(Address)

_____
(Address)

_____
(Model Designation)

b. Number of sets of protective eyewear supplied with the product _____

c. Provide the spectral transmittance in the following wavelength ranges:

_____ %
(200-320 nm)

_____ %
(320-400 nm)

_____ %
(more than 400 nm)

d. Spectral transmittance measurements submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

_____

e. If protective eyewear is not provided, please explain why:

_____

_____

2.5 Labeling:

a. Submit copies of the label which is used to determine the place of manufacture. If this information is provided in code, please provide the key to the code:

_____

_____

b. For each model of medical ultraviolet lamp and/or product, submit copies of all warning signs, labels and instructions for installation, operation and use which relate to electronic radiation safety, along with a photograph or drawing showing the location of these labels.

Information submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

_____

c. Attach any basis, including research or test data that you have, for any warning labels provided.

2.6 Irradiation:

a. Which parts of the living human body are to be irradiated by this product?

_____

b. For the product to fulfill its function, which wavelength ranges are necessary?

1) _____ nm to _____ nm

2) _____ nm to _____ nm

3) _____ nm to _____ nm

c. What radiation emission levels (W/cm^2), for each range, are necessary?

1) _____ nm

2) _____ nm

3) _____ nm

d. Attach justifications for your answers to Item 2.6b & c.
(☐) None Available (☐) Attached

2.7 Product Efficacy:

a. If the product is to be used for a medical or dental function, provide information on how well it achieves the purpose for which it is intended.

_____

_____

_____

b. Are any contraindications for this product indicated?
(☐) None (☐) Contraindications list attached

2.8 Minimum Use Distance:

a. What is the recommended minimum use distance for your product?

_____

Explain why _____

_____

b. Attach any basis, including research or test data that you have, for making or not making this recommendation.

Documentation attached?
(☐) Yes (☐) No (If "No," explain why)

_____

c. Is the recommended minimum use distance listed on the product label?
(☐) Yes (☐) No (If "No," explain why)

_____

2.9 Information to User:

a. Submit a copy of all instructions supplied to purchasers of the product regarding:

1) Duration of single exposure.
(☐) None (☐) Attached

2) Probable latency periods before appearance of any expected effects.
(☐) None (☐) Attached

3) Non-beneficial aspects of excessive exposure to radiation from the product.
(☐) None (☐) Attached

4) Other information regarding the radiation safety of the product.
(☐) None (☐) Attached

b. Which of the information in Item 2.9a is contained:

1) in labels on the product _____

2) on the container _____

3) in literature supplied _____

PART 3

DESCRIPTION OF EMISSION CHARACTERISTICS

(This part should be completed only by manufacturers of products who manufacture the fixtures but not the ultraviolet lamps used therein.)

3.1 Equipment:

a. Describe all spectroradiometric equipment used for the spectral measurement of radiation emitted by your products. Include a description of its capability and accuracy.

Description attached?
(☐) Yes (☐) No (If "No," explain why)

_____

3.2 Spectral irradiance data to be provided under this part should be on a semi-log graphical plot with the spectral irradiance [W/(cm^2 nm)] on the logarithmic scale. Preferably the measurements should be made at 1 meter or at the recommended minimum use distance. Make these measurements both with and without any filter that is used in the product, if the filter is removable or can be displaced by breakage, etc.

a. Attach graphical plots of spectral irradiance as a function of wavelength over the entire optical wavelength region in which the product emits radiation.

Plots Attached?
(☐) Yes (☐) No (If "No," explain why)

_____

b. What are the values of irradiance (W/cm^2) integrated over the following wavelength intervals?

_____ *(200-260 nm)*

_____ *(260-290 nm)*

_____ *(290-320 nm)*

_____ *(320-400 nm)*

3.3 Attach a brief description of the methods and procedures used for measurements reported under Item 3.2.

Description attached?
(☐) Yes (☐) No (If "No," explain why)

_____

NOTE: If the above testing is not performed in-house, please indicate who will be performing the test and equipment being used.

PART 4

LAMP EMISSION CHARACTERISTICS

(This part should be completed by manufacturers of products who also manufacture the ultraviolet lamps used therein. It should also be completed by manufacturers of all other ultraviolet radiation-emitting products, including ultraviolet lamps for which these reports are required.)

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 to 400 nm wavelength range. Plot should be on a semi-log 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 [W/(cm^{2}nm] over the wavelength range of 200 to 400 nm. (See Appendix for Spectroradiometric Measurement and Testing Procedures.)

Values submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

_____

4.4 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)

_____

4.5 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)

_____

4.6 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 submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

---

b. Describe all tests and/or checks made on incoming parts, including filters, reflectors, timers and lamps, prior to their acceptance.

Description submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

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

Describe the tests or checks conducted during or after manufacture that ensure conformance with the specifications for the following:

a. timer functioning and accuracy;
b. reflectors;
c. filters;
d. means to terminate exposure;
e. labeling.

Include a description of any sampling plan, instrumentation, test procedures and rejection criteria used.

Description submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

5.3 Submit copies of all written quality control test procedures and checksheets used for incoming component checks, manufacturing checks and final acceptance checks.

Copies submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

PART 6

LIFE AND RELIABILITY TEST

6.1 Attach information for all life and reliability tests on the product and its components. 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.

Description submitted as an attachment?
(☐) Yes (☐) No (If "No," explain why)

_____

APPENDIX
SPECTRORADIOMETRIC MEASUREMENTS 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 [W/(cm^2 nm)]. 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 product should be made at the recommended minimum use distance 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 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 Bureau of Standards (NBS) or by another laboratory against standards calibrated by NBS using NBS-recommended or generally-accepted techniques.

The standards should be used immediately before and after the measurements on the product. Alternatively, if the standard is usually referred to after every reading while scanning the wavelength scale, that method may be used. The result should be reported in spectral irradiance values [W/(cm^2 nm)].

CDRH generally recommends 100 percent testing of products in determination of compliance. For some tests and inspections, a sampling plan may be appropriate, i.e., use of 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.