SUPPORTING STATEMENT
FOR
REPORTING AND RECORDKEEPING REQUIREMENTS AND
AVAILABILITY OF SAMPLE ELECTRONIC PRODUCT
FOR MANUFACTURERS AND
DISTRIBUTORS OF ELECTRONIC PRODUCTS
OMB No. 0910-0025

1. Circumstances Making the Collection of Information Necessary

ABSTRACT:

Sections 532 through 542 (21 U.S.C. 360ii through ss) of the Federal Food, Drug, and Cosmetic Act (the Act) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products. Section 532 of the Act directs the Secretary to establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic radiation, and authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) directs the Secretary to review and evaluate industry testing programs on a continuing basis; and Sections 535(e) and (f) direct the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliance with performance standards. The authority for records and reports is contained in Sections in 537(b) – (c) of the Act. Such program shall include the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products.

The regulations promulgated under these authorities are listed in the Code of Federal Regulations (CFR), Title 21, Chapter I, Subchapter J. Specifically, 21 CFR parts 1002 - 1010 specify information to be provided to the Food and Drug Administration (FDA), to users, and/or to be maintained in the event of an investigation of a safety concern or a product recall. Subchapter A regulations, 21 CFR 5.10(a)(3), 5.25(b), 5.35(a)(4), and 5.600 through 5.606 delegate administrative authorities to the FDA and the Center for Devices and Radiological Health (CDRH).

The CDRH also conducts laboratory compliance testing of products covered by regulations for product standards in 21 CFR Parts 1020, 1030, 1040, and 1050.

This information collection is not related to the American Recovery and Reinvestment Act of 2009.

FDA is requesting from the Office of Management and Budget (OMB), approval for the information collection requirements contained in 21 CFR Parts 1002, 1003, 1004, 1005, 1010 1020, 1030, 1040, and 1050.

The specific citations and forms are listed below as follows:

21 CFR 1002.3 - Disclosure – Notification (Reporting):
Requires manufacturers, when directed by the FDA, to provide technical and safety information to users.

21 CFR 1002.10(a)-(k) - Reporting:

Requires manufacturers to report to FDA product identification, product design and operation, product testing, quality control procedures, test results, and product labeling prior to the entry of the product into commerce. **Product Reports;** The following report forms are used to obtain the required information requested in 21 CFR 1002.10 for each specific product, following the applicable performance standard in 21 CFR 1020-1050: **FDA Form 3626** "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components" **FDA Form 3627** "Diagnostic X-Ray CT Products Radiation Safety Report" **FDA Form 3630** "Guide for Preparing Product Reports on Sunlamps and Sunlamp Products" **FDA Form 3632** "Guide for Preparing Product Reports on Lasers and Products Containing Lasers" **FDA Form 3639** "Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40" **FDA Form 3640** "Reporting Guide for Laser Light Shows and Displays" **FDA Form 3644** "Guide for Preparing Product Reports for Ultrasonic Therapy Products" **FDA Form 3646** "Mercury Vapor Lamp Products Radiation Safety Report" **FDA Form 3659** "Reporting and Compliance Guide for Television Products" **FDA Form 3660** "Guidance for Preparing Reports on Radiation Safety of Microwave Ovens" **FDA Form 3801** "Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps"

21 CFR 1002.11(a)-(b) - Reporting:
Requires manufacturers to provide information to FDA on changes in product safety or testing.

21 CFR 1002.12(a)-(e) - Reporting:
Requires manufacturers to report abbreviated information on product safety and testing, instead of 1002.10 reports. The following forms are used to obtain the required information: **Form**

FDA 3629, "Abbreviated Report" **FDA Form 3661** "Guide for the Submission of an Abbreviated Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use" **FDA Form 3662** "Guide for Submission of an Abbreviated Radiation Safety Reports on Cephalometric Devices Intended for Diagnostic Use" **FDA Form 3663** "Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)"

21 CFR 1002.13(a)-(c) - Reporting:
Requires manufacturers to report annually to FDA a summary of manufacturer records maintained in accordance with 1002.30, and provide quarterly updates of models instead of 1002.10 or .11 reports. **Annual Reports;** The following report forms are used to obtain the required information: **FDA Form 3628** "General Annual Report (includes Medical, Analytical, and Industrial X-Ray Products Annual Report)" **FDA Form 3631** "Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products" **FDA Form 3634** "Television Products Annual Report" **FDA Form 3636** "Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products" **FDA Form 3638** "Guide for Filing Annual Reports for X-Ray Components and Systems" **FDA Form 3641** "Cabinet X-Ray Annual Report" **FDA Form 3643** "Microwave Oven Products Annual Report" **FDA Form 3645** "Guide for Preparing Annual Reports for Ultrasonic Therapy Products" **FDA Form 3647** "Guide for preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps"

21 CFR 1002.20(a)-(c) - Reporting:
Requires manufacturers to report to FDA the circumstances, amount of exposure, and remedial actions taken concerning any accidental radiation occurrence involving their electronic products. If a firm is also required to report the incident under 21 CFR 803, those regulations take precedence. **Form FDA 3649,** "Accidental Radiation Occurrence (ARO)" report is used to obtain the required information requested in 21 CFR 1002.20.

21 CFR 1002.30(a)-(b) - Recordkeeping:
Requires manufacturers to keep records on test data and procedures, correspondence regarding

radiation safety, and distribution records.

21 CFR 1002.31(c) - Reporting:
Requires manufacturers, when requested by FDA, to provide copies of the distribution records required to be maintained by 1002.30(b). [Excluded under 5 CFR 1320.3(c).]

21 CFR 1002.40(a)-(c) - Recordkeeping:
Requires dealers and distributors to retain first purchaser information, to be used by manufacturers when a product recall is instituted to insure the radiation safety of a product.

21 CFR 1002.41(a)-(b) - Recordkeeping:

Specifies that the dealer/distributor records in 1002.40 may be retained by the dealer or forwarded to the manufacturer for retention; also that the manufacturer or dealer shall retain distribution records (1002.30(b) and 1002.40) for five years. The burden is included in those sections.

21 CFR 1002.50(a) - Reporting:
Specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements when there is a low risk of injury.

21 CFR 1002.51 - Reporting:
Specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements if the product is intended for U.S. Government use. The burden is combined with the 1002.50 exemption request, because the processes are essentially identical.

21 CFR 1003.10(a)&(c) - Reporting:
Requires manufacturers to notify FDA when their product has a defect or fails to comply with applicable performance standards. If 21 CFR 803 also applies, that regulation takes precedence. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.10(b) - Disclosure – Notification (Reporting):
Requires manufacturers to notify purchasers, dealers, and distributors of product defects or noncompliances, including a description of hazard, instructions for use pending correction, and a corrective action plan. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.11(a)(3) - Reporting:
Specifies criteria by which manufacturers may refute FDA's notice of defective or noncompliant

product. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.11(b) - Reporting:
Requires manufacturers, when notified by FDA, to provide information on the number of defective products introduced into commerce. Firms provide the information with the 1003.10(a) report. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.20(a)-(h) - Reporting:
Requires manufacturers to provide to FDA the same report as 1003.10(a), under different circumstances of discovery. [Excluded under 5 CFR 1320.3(c).]

12 CFR 1003.21(a)-(d) - Disclosure - Notification:
Specifies the content of the notification required by 1003.10(b). [Excluded under 5 CFR

1320.3(c).]

21 CFR 1003.22(a)-(b) - Reporting:
Requires manufacturers to provide to FDA copies of the 1003.10 disclosure sent to purchasers,

dealers or distributors. Firms provide the information with the 1003.10(a) report. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.30(a)-(b) - Reporting:
Specifies criteria by which manufacturers may request an exemption from the 1003.10 disclosure

and possible product recall. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.31(a)-(b) - Reporting:
Specifies the content of the 1003.30 report. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1005.10 – Reporting:
Requires manufacturers or their agents, when notified by FDA, to provide certain information on the product being introduced into commerce and sample being shipped to FDA for testing. **Form FDA 2767,** "Notice of Availability of Sample Electronic Product," is used to collect the required information requested in 21 CFR 1005.10.

21 CFR 1005.21(a)-(c) - Reporting:
Specifies criteria for manufacturers or importers to request correction of noncompliant products for importation into the United States, including specific corrections, timeframe and location for completion. Such requests are made on Form FDA 766, Application for Authorization to Relabel

or to perform other action of the Federal Food, Drug, and Cosmetic Act and other related Acts. [Excluded under 5 CFR 1320.3(c),]

21 CFR 1005.22(b) - Reporting:
Specifies criteria for manufacturers or importers to request extension of time to bring product into compliance. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1005.25(a)-(b) - Reporting:
Requires importers to report identification information and compliance status of products to FDA. Initial designations are provided in the 1002.10, 1002.11, and 1002.12 reports, so that burden is included in those sections. For each shipment, identification is made on Form 2877. **Form FDA 2877**, “Declaration for Products Subject to Radiation Control Standards,” is used to collect the required information requested in 21 CFR 1005.25.

21 CFR 1010.2(d) - Reporting:
Specifies criteria for manufacturers to request alternate means of certification to a standard.

21 CFR 1010.3(a)-(c) - Reporting:
Requires manufacturers to provide to FDA the coding systems if information on labels is coded and to identify each brand name, and the name and address of the individual or company for whom each product so branded is manufactured. Firms provide such information in the 1002.10,

1002.11, and 1002.12 reports, therefore the burden is included in those sections.

21 CFR 1010.4(b) - Reporting:
Specifies criteria for manufacturers to petition FDA for a variance from a performance standard

including alternate means of safety, or suitable means of safety along with reasons why the standard is inappropriate. **Form FDA 3633,** "General Variance Request," applicable to products other than Laser Light Shows and related products and is used to obtain the required information requested in 21 CFR 1010.4. **Form FDA 3147**, "Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device," is used only by manufacturers of laser light show products to submit the required information in order to justify a variance approval. **Form FDA 3635,** "Laser Light Show Notification" is used to obtain certain required information specified in Form FDA 3147.

21 CFR 1010.5(c)-(d) - Reporting:
Specifies criteria by which manufacturers or U.S. government agencies may request an exemption (or amendment or extension) from performance standards when a product is to be used exclusively by a part of the U.S. Government and has adequate radiation emission specifications.

21 CFR 1010.13 - Reporting:
Specifies criteria for manufacturers to request alternate test procedures from those specified in a performance standard. The burden is combined with 1010.5(c)-(d) because the processes are essentially identical.

1020.20(c) (4) -Disclosure - Notification (Reporting):
Requires manufacturers of cold cathode tubes to provide safety instructions and specifications to users.

1020.30(d) (1)&(2) - Reporting:
Requires individuals or companies who install certified diagnostic x-ray components to submit a

report of assembly to FDA as certification that the final product meets safety regulations (Form FDA 2579). Section 21 CFR 1020.30(d)(2) of the regulation was amended to omit some requirements which had resulted in a burden reduction. In this section, reports of assembly need not be submitted for replacement tube housing assemblies that are reinstalled in or newly assembled into existing x-ray systems; Certified accessory components under 21 CFR 1002.10; repaired components; or temporarily installed components into an x-ray system. **Form FDA 2579**, "Report of Assembly of a Diagnostic X-ray System," is used to obtain the required information requested in 21 CFR 1020.30(d).

1020.30(g) -Disclosure - Notification (Reporting):
Requires manufacturers of diagnostic x-ray systems and their major components to provide assembly, installation, compatibility, and testing information to assemblers of such products, and others upon request.

1020.30(g) (2) -Recordkeeping:
Requires manufacturers of diagnostic x-ray systems and their major components to provide assemblers a statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator.

1020.30(h) (1)-(4) - Disclosure - Notification (Reporting):
Requires manufacturers of diagnostic x-ray systems and their major components to provide safety and technical information and instructions to the purchasers and users of such products, and others upon request.

1020.30(h) (5)-(6) - Disclosure - Notification (Reporting):
Requires manufacturers of fluoroscopic x-ray systems to provide safety and technical information

and instructions to the purchasers and users of such products, and others upon request.

1020.32(j)(4) -Disclosure – Notification (Reporting):
Requires the manufacturers of fluoroscopic x-ray equipment to provide technical information to

users. It is to be included in the same information required by 1020.30(h).

1020.32 (a) (1) -Disclosure - Notification (Reporting):
Requires manufacturers of fluoroscopic x-ray equipment to provide precautions and safety

information to assemblers and users. It is provided in the same manual as the information required in 1020.30(g) and (h).

1020.32 (g) -Disclosure - Notification (Reporting):
Requires manufacturers of radiographic systems that contain Positive Beam Limitation (PBL) to provide precautions and safety information to users. It is provided in the same manual as the information required in 1020.30(h).

1020.33(c) -Disclosure - Notification (Reporting):
Requires manufacturers of Computed Tomography (CT) x-ray systems to provide technical and safety information to users. It is provided in the same manual as the information required in 1020.30(h), or in a separate manual devoted entirely to this information.

1020.33(d) -Disclosure - Notification (Reporting):
Requires manufacturers of CT systems to provide quality assurance information to users. It is provided in a separate section in the same manual as the information required in 1020.30(h).

1020.33(g) (4) -Disclosure - Notification (Reporting):
Requires manufacturers of certain CT systems to provide alignment instructions to users. It is provided in the same manual as the information required in 1020.30(h).

1020.33(j) (1)&(2) - Disclosure - Notification (Reporting):
Requires manufacturers of CT x-ray systems to provide specific, technical instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation to users. The information provided according to 21 CFR 1020.30(h) should be in the same manual as the information required in 1020.30(h).

1020.40(c) (9) (i)&(ii) -Disclosure - Notification (Reporting):
Requires manufacturers of cabinet x-ray systems to provide technical, safety, maintenance, and assembly information to purchasers.

1030.10(c) (4) -Disclosure - Notification (Reporting):
Requires manufacturers of microwave ovens to provide legible radiation safety instructions to users. This information should be contained in a separate section and should be an integral part of requirements supplied in an enclosed cookbook or users manual.

1030.10(c) (5) (i-iv) -Disclosure - Notification (Reporting):
Requires manufacturers of microwave ovens to provide safety information and adequate

instructions to service dealers and distributors and others upon request.

1030.10(c) (6) (iii) -(Reporting):
Describes warning labels on Microwave Ovens. In the history of this performance standard, the Director for the Center for Devices and Radiological Health has never determined that a specific warning is required for a microwave oven manufacturer. Therefore, this citation has been added to the burden chart with a minimal burden.

1030.10(c) (6) (iv) -(Reporting):
Specifies the information to be provided to FDA when a manufacturer of microwave ovens

requests an exemption from required user warning labels.

1040.10 (a) (3) (i) -(Reporting):
Requires manufacturers of laser products sold for use as a component or replacement to register

with FDA and provide a listing by type of product in lieu of the reporting required by 1002.10.

Form FDA 3637, "Laser Original Equipment Manufacturer (OEM) Report," is used to obtain the required information requested in 21 CFR 1040.10(a)(3)(i).

1040.10 (a) (3) (ii) - (Recordkeeping):
Requires manufacturers of laser products sold for use as a component or replacement to maintain distribution records in accordance with 1002.31

1040.10(h) (1) (i)-(vi) - Disclosure - Notification (Reporting):
Requires manufacturers of laser products to provide assembly, operation and maintenance instructions, technical information, legible reproductions of all label and hazard warnings, and a listing of all controls, adjustments, and procedures for operations and maintenance to users- The FDA is considering an amendment to simplify the information and harmonize with the international standards.

1040.10(h) (2) (i)-(ii) -Disclosure - Notification (Reporting):
Requires manufacturers of laser products to provide service information to dealers and distributors and to others upon request. It is provided in the same manual, as information required

in 1040.10(h)(1).

1040.10(i) - (Reporting):
Requires manufacturers who modify certified laser products to recertify and reidentify the product in accordance with 1010.2 and 1010.3. Thus, the firm is required to report compliance information to FDA as required by 1002.10 (burden documented in 0MB 0910-0025).

1040.11 (a) (2) -Disclosure - Notification (Reporting):
Requires manufacturers of certain medical laser products to provide instructions and a schedule

for calibration with each product. It may be provided in the same manual as information to purchasers required in 1040.10(h)(1).

l040.30 (c) (1) (ii) -Disclosure - Notification (Reporting):
Describes the general regulations for high intensity, mercury vapor discharge lamps, specifically the labeling of these lamps. Burden in this area is considered negligible, as the imprinting of the lamps has become industry standard. Industry also has said that if this requirement were eliminated, they would continue the practice because of the cost implications of retooling all manufacturing of mercury vapor lamps.

l040.30 (c) (2) Disclosure – Notification (Reporting):
Describes labeling of mercury vapor discharge lamps in lieu of permanently affixing or inscribing tabs or labels on the product as required by 1010.2(b) and 1010.3(a). The manufacturer of any high intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

1050.10(d) (1)-(4) - Disclosure - Notification (Reporting):
Requires manufacturers of ultrasonic therapy products to provide informational labels on the components.

1050.10(f) (1) -Disclosure - Notification (Reporting):
Requires manufacturers of ultrasonic therapy products to provide service information to dealers and distributors and others upon request. Also provides user instructions concerning safety and precaution, adequate description of the spatial distance of the ultrasonic radiation field, and adequate description of the uncertainties of magnitude.

1050.10(f) (2) -Disclosure - Notification (Reporting):
Requires manufacturers of ultrasonic therapy products to provide safety and technical information to users. It is provided in the same manual as information required in 1050.10(f) (1).

OMB approval is also requested for the following forms:

FDA Form 2579 “Report of Assembly of a Diagnostic X-ray System”
FDA Form 2767 “Notice of Availability of Sample Electronic Product”
FDA Form 2877 “Declaration for Imported Electronic Products Subject To Radiation Control Standards”
FDA Form 3649 “Accidental Radiation Occurrence”

FDA Form 3626 “A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components”
FDA Form 3627 “Diagnostic X-Ray CT Products Radiation Safety Report”
FDA Form 3628 “General Annual Report (includes Medical, Analytical, and Industrial X-Ray Products Annual Report)”
FDA Form 3629 “Abbreviated Report”
FDA Form 3630 “Guide for Preparing Product Reports on Sunlamps and Sunlamp Products”
FDA Form 3631 “Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products”
FDA Form 3632 “Guide for Preparing Product Reports on Lasers and Products Containing Lasers”
FDA Form 3633 “General Variance Request”
FDA Form 3634 “Television Products Annual Report”
FDA Form 3635 “Laser Light Show Notification”
FDA Form 3636 “Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products”
FDA Form 3637 “Laser Original Equipment Manufacturer (OEM) Report”
FDA Form 3638 “Guide for Filing Annual Reports for X-Ray Components and Systems”
FDA Form 3639 “Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40”
FDA Form 3640 “Reporting Guide for Laser Light Shows and Displays”
FDA Form 3147 “Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device”
FDA Form 3641 “Cabinet X-Ray Annual Report”
FDA Form 3642 “General Correspondence”
FDA Form 3643 “Microwave Oven Products Annual Report”
FDA Form 3644 “Guide for Preparing Product Reports for Ultrasonic Therapy Products”
FDA Form 3645 “Guide for Preparing Annual Reports for Ultrasonic Therapy Products”
FDA Form 3646 “Mercury Vapor Lamp Products Radiation Safety Report”
FDA Form 3647 “Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps”
FDA Form 3659 “Reporting and Compliance Guide for Television Products”
FDA Form 3660 “Guidance for Preparing Reports on Radiation Safety of Microwave Ovens”
FDA Form 3661 “Guide for the Submission of an Abbreviated Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use”
FDA Form 3662 “Guide for Submission of an Abbreviated Radiation Safety Reports on Cephalometric Devices Intended for Diagnostic Use”
FDA Form 3663 “Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)”

2. Purpose and Use of the Information

The respondents to this information are from the private sector; businesses for profit. The information collections are either specifically called for in the Act or were developed to aid the Agency in performing its obligations under the Act. These requirements are placed upon manufacturers, importers, and assemblers of electronic products. The data reported to FDA and the records that are maintained allow FDA and the industry to make decisions and take actions, which protect the public from radiation hazards presented by electronic products. This information refers to the identification, location, operational characteristics, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

The reports are reviewed by FDA staff to determine product safety, conformance with performance standards, and adequacy of quality control testing. Potential and actual problems are resolved with the individual firm. The information supplied can be used by the FDA to locate and select sample products for conformance with regulations.

Forms were designed to aid respondents in the submission of this information. In the event this information was not collected by FDA on forms, each manufacturer would have to respond in letter format with all the data now on FDA forms, requiring more time and expense on their part. FDA would also then require written notification from FDA's Winchester Engineering and Analytical Center (WEAC), detailing all products received, from whom, returned to whom, model and chassis numbers, etc. to assure that the Agency's information coincided with their products. These extra steps to obtain information now on a form would significantly increase the cost in man-hours and duplications to both federal and industry organizations. Testing an appropriate percentage of these products to protect the public would also be hindered by any slower progress in FDA's receipt of the information.

The consequence of not obtaining the required information is that the public may unknowingly be exposed to unnecessary radiation hazards presented by electronic products. Without this information, FDA could not adequately make rational decisions and take appropriate actions to protect the public from these hazards as called for in the Act.

3. Use of Information Technology and Burden Reduction

The FDA has implemented several improved information technologies and methods to reduce the burden placed on manufacturers and assemblers, such as electronic transfer and optical storage of documents. This collection's forms have been designed to provide the minimum needed information in order to evaluate the product.

Well-designed forms can eventually lead to automated reviews of the submissions by software, identifying potential compliance problems and potential radiation hazards within days of receipt, reducing current time-consuming FDA processing and review times by an order of magnitude, and utilizing modern communication techniques to pass the information back to the manufacturer

almost immediately.

The forms included here are portable document format (pdf) files, all except forms FDA 2579, 2767, 2877, and 3801 printed from the new electronic submission system FDA has developed and provided for respondent use. The FDA encourages electronic filing via the FDA Electronic Submissions Gateway (FDA ESG) allowing manufacturers to create files using the CDRH eSubmitter software application, then send it via Internet through the FDA Gateway, significantly reducing the burden of time delay and marketing restrictions placed on manufacturers and importers from 1 month to 5 minutes.

The FDA's voluntary electronic submission (eSubmitter) program utilizes IT tools to automatically edit-check for errors in on-line submissions, insure data integrity, and allow FDA staff to more easily perform reviews, trending and sampling analyses. The eSubmitter software reduces the number of supplements needed, and provides data often missing from paper submissions. Additionally, as each form has been developed, the subject matter experts have streamlined the data collection and information requirements to a critical minimum, thereby reducing further the reporting burden on manufacturers.

These methods will be incorporated when CDRH satisfies technical and legal requirements such as data integrity for a regulated industry and comparability of data. The use of the FDA's optical scanning and document retrieval system, IMAGE, has been modified to accommodate the eSubmitter applications for the radiological health area.

Currently, less than 15% of submissions are submitted using the eSubmitter software, but the users continue to increase. FDA staff continues to encourage usage and provide individual assistance to industry.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only authorized Agency to regulate the radiation from electronic products. Therefore, these activities are not duplicated anywhere else. Those electronic products that are also medical devices may be subject to additional (and different) FDA regulations under a separate section of the Act. In rare cases there has been minor duplication of information and where there has been, exemptions have been granted and the requirements changed so that the medical device reporting has precedence over electronic product reporting. Often, the documentation submitted to describe how radiation safety is assured through compliance with mandatory performance standards satisfies both medical device and electronic product reporting requirements. There is no similar information collected that can be used to carry out the enforcement of these regulations.

5. Impact on Small Business or Other Small Entities

All entities subject to these information collections affect businesses (manufacturers, importers and assemblers of electronic products. Currently, there are 4100 firms submitting required product information.

Efforts have been made to require the minimum amount of information possible for the Agency to make decisions and take actions to protect the public from radiation hazards presented by

electronic products. Many of the FDA's recordkeeping requirements are part of normal records necessary for any business practice, and the disclosure information is typically included in the manuals that are provided to purchasers with any manufactured product.

FDA has acted to minimize the burden to any firm whose product undergoes additional government testing by requiring the manufacturer or importer to ship tested products directly to Winchester Engineering and Analytical Center (WEAC) in Winchester, Massachusetts. The government often purchases the product, and/or pays all shipping and insurance charges.

FDA also maintains a CDRH website which provides firms with information pertaining to medical devices and radiological health. The Radiological Health homepage (http://www.fda.gov/Radiation-EmittingProducts/default.htm) provides all the paper-based report forms as well as the opportunity to download and install the new eSubmitter application and User Guide for electronic submission of required information. Furthermore, there is a subscription service which allows subscribers to be automatically be notified by email whenever there are updates and new postings to the homepage. This helps provide answers to questions and problems with Radiological Health and electronic products to all firms, regardless of size.

FDA's Division of Small Manufacturer's, International, and Consumer's Assistance (DSMICA), required by the 1976 Amendments to the Act, provides technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the Act. DSMICA participates in and presents conferences, workshops, and seminars on the application and interpretation of relevant regulations. They also consult with individual firms, and develop and disseminate educational materials. Staff is available to respond to questions and a toll free telephone number was established to facilitate this communication link. Additional information on DSMICA may be obtained by any firm with internet access by logging onto the FDA's web site (http:\\www.fda.gov) and clicking on the Radiological Health Program link.

6. Consequences of Collecting the Information Less Frequently

The frequency of the collection requirements depends on the type of information. There are one-time product reports and annual reports. A firm introducing a new electronic product is required to prepare a one-time product report, for which the burden has been estimated to be 24 hours. Subsequent modifications to that product may require a supplemental report, which take a half hour and are only required when the new model has changes that affect the radiation hazard from the product. Again, this would be a one-time submission. Generally, all manufacturers of electronic products subject to the reporting requirements under this clearance must file an Annual report, which is a production summary report. This burden has been estimated to be 18 hours, an annual burden.

If this information were obtained less frequently, fewer report reviews and evaluations of compliance could be conducted by FDA, which could potentially result in endangering the public health through unnecessary exposure to electronic radiation. In the event that this product information was not provided to FDA in a timely manner, a hazard could go undetected and the risk to the public from unnecessary radiation would be increased significantly. If information was not provided to users, distributors, or assemblers at the time of possession of the product they may be unable to make rational decisions and take actions relating to safety.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.

A few of the information collection requirements are inconsistent with those outlined in 5 CFR 1320.5 because immediate health hazards require immediate action and reporting must be prompt. If FDA and the affected industry or firm did not have access to this information, equipment could not be located quickly when a particular product or system is suspected of causing harm. If an entire model line is determined to be defective, the firm must be able to locate other installations of the defective units to eliminate additional hazards. For example, one of the collection requirements in this request is inconsistent with that outlined in 5 CFR 1320.5(d)(2)(i) and (ii). Section 1020.30(d) requires the assembler of a diagnostic x-ray system to submit a report of assembly within two weeks of installation. This response time was agreed upon jointly by FDA and the manufacturers because it was felt that the two-week period was sufficient time to fill out and submit the Form FDA 2579 after completion of the assembly.

Over the past several years, recordkeeping requirements have been significantly reduced, but the timeframe for maintaining these records (5 years) remains the same. These records are needed for significant risk products, and therefore are considered records pertaining to health which are not subject to the 3 year limit [5 CFR 1320.5(d)(2)(iv)].

If FDA did not possess this information, equipment could not be located quickly when a particular system is suspected of causing harm, and the protection of the public from significant health risks might be compromised.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

On February 26, 2010 (75 FR 8963), FDA published a notice in the **Federal Register** soliciting comments for 60 days on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d). In response to that notice, no comments were received.

The FDA/CDRH's Office of Communication, Education, and Radiation Programs (OCER) staff meets on a regular basis with consumer groups such as the Consumer Electronics Association to discuss topics relating to the regulation of electronic and radiological health industries.

FDA also routinely consults with members of industry, government, and the public through the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Radiological Devices Panel (RDP). These committees are permanent advisory committees established under Sections 534(f) and 513(b) of the Act. FDA is required to consult with the TEPRSSC before establishment of or changes to standards, and the RDP advises FDA on use of radiation in the healing arts.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondent

Section 537 of the Act states that the Secretary shall not disclose any information which contains or relates to a trade secret or other matter referred to in Section 1905 of Title 18 of the United States Code. Information provided under this collection is handled in a manner to comply with this requirement and the FDA regulations implementing the Freedom of Information Act, 21 CFR Part 20. All information provided will be protected from inappropriate disclosure.

11. Justification for Sensitive Questions

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

FDA estimates the total estimated burden hours for reporting and recordkeeping activities relating to this information collection at 324,112 hours.

12 a. Annualized Hour Burden Estimate

Respondents to this collection of information will be electronic product manufacturers, importers, and assemblers. The burden estimates were derived by consultation with FDA and industry personnel, and are based on actual data collected from industry. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals.

FDA estimates the burden for this information collection as follows:

Table 1 - Estimated Annual Reporting Burden 1

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1002.3	N/A	10	1	10	12	120
1002.10	3626 – Diagnostic X-Ray 3627 – CT X-Ray 3639 – Cabinet X-Ray 3632 – Laser 3640 – Laser Light Show 3630 – Sunlamp 3646 – Mercury Vapor Lamp 3644 – Ultrasonic Therapy 3659 – TV 3660 – Microwave Oven	1000	1.2	1200	24	28,800

	3801 – UV Lamps					
1002.11	N/A	400	0.6	240	0.5	120
1002.12	3629 – General Abbreviated Report 3661 – X-Ray Tables, etc. 3662 – Cephalometric Device 3663 – Microwave Products (non Oven)	50	1	50	5	250
1002.13	3628 – General 3634 – TV 3638 – Diagnostic X-Ray 3641 – Cabinet X-Ray 3643 – Microwave Oven 3636 – Laser 3631 – Sunlamp 3647 – Mercury Vapor Lamp 3645 – Ultrasonic Therapy	1,000	1	1,000	18	18,000
1002.13(c)	N/A	100	2.4	240	0.5	120
1002.20	3649 - ARO	25	1	25	2	50
1002.41(a)	N/A	1	1	1	1	1
1002.50(a) and 1002.51	3642 – General Correspondence	10	0.5	5	1	5
1005.10	2767 – Sample Product	50	1	50	0.1	5
1005.25(b)	N/A	1	1	1	1	1
	2877 – Imports Declaration	600	32	19,200	0.2	3,840
1010.2 and .3	N/A	1	1	1	5	5
1010.4 (b)	3633 – General Variance Request 3147 – Laser Show Variance Request 3635 – Laser Show Notification	160	0.3	48	1.2	58
1010.5(c) and (d)	N/A	4	1	4	22	88
1010.13	N/A	1	1	1	10	10

1020.20 (c) (4)	N/A	1	1	1	1	1
1020.30(d), (d)(1), and (d)(2)	2579 – Assembler Report	1150	10.7	12,305	0.30	3,692
1020.30 (g)	N/A	200	1.33	266	35	9,310
1020.30 (h) (1) through (h)(4), 1020.32 (a) (1) and (g)	N/A	200	1.33	266	35	9,310
1020.30(h) (5)and (h)(6) and 1020.32(j)(4)	N/A	20	5	100	18	1,800
1020.32(g), 1020.33(c); (d); (g)(4); (j) (3) and (j)(4)	N/A	9	1	9	40	360
1020.40(c)(9) (i) and (c)(9) (ii)	N/A	8	1	8	40	320
1030.10(c)(4)	N/A	41	1.6	66	20	1,320
1030.10(c)(5) (i) through (c) (5)(iv)	N/A	41	1.6	66	20	1,320
1030.10(c)(6) (iii) and (c) (6)(iv)	N/A	1	1	1	1	1
1040.10(a)(3) (i)	3637 – OEM Report	40	1	40	3	120
1040.10(h)(1) (i) through (h)(1)(vi)	N/A	805	1	805	8	6,440
1040.10(h)(2) (i) and (h)(2) (ii)	N/A	100	1	100	8	800
1040.11(a)(2)	N/A	50	1	50	10	500
1040.20 (d) (1)(ii)-(vi), (e)(1), and (e) (2)	N/A	110	1	110	10	1,100

1040.30(c)(1)(ii)	N/A	1	1	1	1	1
1040.30(c)(2)	N/A	7	1	7	1	7
1050.10(d)(1)-(d)(4) and (f)(1)- (f)(2)(iii)	N/A	10	1	10	56	560
TOTAL ANNUAL REPORTING BURDEN						88,435

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	0.12	228,459
1002.40 and 1002.41	2,950	49.2	145,140	0.05	7,257
1020.30(g)	22	1	22	0.5	11
1040.10(a)(3)(ii)	40	1	40	1.0	40
Totals					235,767

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated respondent reporting burden is 88,435 hours. This burden affects 4,100 firms, requiring an average of 21.6 hours per firm annually. The estimated recordkeeping burden is 235,767 hours. This burden affects 4,100 firms, and requires an average of 57.5 hours per firm annually. FDA has reduced the reporting requirements for certain low risk products in recent years, which can be observed in the reporting burden reduction from 26.1 hours in 2007, while the recordkeeping burden remains the same. The remaining records are not considered to be subject to the 3 year limit (5 CFR 1320.6(f)) since they are part of the health risk assessment records for significant risk products.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); 1005.21(a) through (c), and 1005.22(b). These requirements apply to the collection of information during the conduct of general investigations or audits (5 CFR 1320.4(b)).

The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

12 b. Annualized Cost Burden Estimate

The current wage for the reporting and recordkeeping activities of this information collection was estimated from the average salary for regulatory affairs professionals at $75 per hour. FDA estimates, therefore that the total estimated burden cost to industry for reporting and recordkeeping activities relating to this information collection will be $24,315,150, which is the total number of hours expended (324,202) multiplied by the average wage rate of $75 per hour.

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

There is no capital or operating/maintenance cost associated with this regulation.

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal government is $2,586,000. During the CDRH "Center Time Reporting Survey" in 2005, CDRH estimated that 14 employees in the Office of Communications, Education, and Radiation Programs participated in activities under the Radiation Control for Health and Safety Act. The estimated cost was determined by computing the total fully loaded (i.e. with benefits, etc.) full time equivalent (FTE) cost. This cost was determined by taking the 14 staff positions and multiplying by the fully loaded cost of $134,000 per staff year of 2,080 hours. The total cost of $1,876,000 was then increased by the $710,000

contract for data/document management, bringing the total cost to $2,586,000.

15. Explanation for Program Changes or Adjustments

After re-estimating, FDA has reduced the reporting requirements for certain low risk regulated products in recent years, which can be observed in the reporting burden reduction to 21.6 hours in 2010, down from 26.1 hours in 2007. This led to an overall burden reduction of 6,906 annual responses and 18,777 hours

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with Section 533 of the Act.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions. There are no exceptions to the certification statement identified in Item 19 of the OMB Form 83-I.