Electronic Products

0910-0025

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss) 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 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) through (c) of the FD&C Act. The program includes the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products.

FDA's regulations regarding Radiological Health (Electronic Products) are codified at 21 CFR, Chapter I, Subpart J (parts 1000 through 1050).

FDA is requesting extension of approval from the Office of Management and Budget (OMB), for the information collections associated with the Electronic Products.

The following 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)-(c), 1003.11(a)(3) and (b), 1003.20(a)-(h), 1003.21(a)-(d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a)-(i), 1004.3(a)-(i), 1004.4(a)-(h), 1005.21(a)-(c), and 1005.22(b). These requirements apply to the collection of information during the conduct of investigations or audits (5 CFR 1320.4).

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 1030.10(c)(6), 1040.10(g), and 1040.30(c)(1).

The following are descriptions of each information collection (IC) in this ICR:

Technical and safety information for users (21 CFR 1002.3)—*Third-party disclosure*
Requires manufacturers, when directed by the FDA, to provide technical and safety information to users.

Product reports (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. 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 parts 1020 through 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"

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

Abbreviated reports (21 CFR 1002.12)—*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)"

Annual reports (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 1002.11 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"

Accidental radiation occurrence reports (21 CFR 1002.20)—*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 part 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.

Manufacturers records (21 CFR 1002.30 and 1002.31(a))—*Recordkeeping*
Requires manufacturers to keep records on test data and procedures, correspondence regarding radiation safety, and distribution records.

Distribution records (21 CFR 1002.31(c))—*Excluded under 5 CFR 1320.4*
Requires manufacturers, when requested by FDA, to provide copies of the distribution records required to be maintained by 1002.30(b).

Dealer/distributor records (21 CFR 1002.40 and 1002.41)—*Recordkeeping and Third-party disclosure*
Section 1002.40 requires dealers and distributors to retain first purchaser information, to be used by manufacturers when a product recall is instituted to ensure the radiation safety of a product. Section 1002.41 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 for five years.

Exemption requests (21 CFR 1002.50(a) and 1002.51)—*Reporting*
Section 1002.50(a) specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements when there is a low risk of injury. Section 1002.51 specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements if the product is intended for U.S. Government use. The burdens are combined because the processes are essentially identical.

- **FDA Form 3642** "General Correspondence"

Discovery of defect or failure to comply, notification, and exemption from notification (21 CFR 1003.10, 1003.11(a)(3) and (b), 1003.20(a)-(h), 1003.21(a)-(d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a)-(i), 1004.3(a)-(i), 1004.4(a)-(h), 1005.21(a)-(c), and 1005.22(b))—*Excluded under 5 CFR 1320.4*
Section 1003.10(a) and (c) 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. Section 1003.10(b) requires manufacturers to notify purchasers, dealers, and distributors of product defects or noncompliance, including a description of hazard, instructions for use pending correction, and a corrective action plan. Section 1003.11(a)(3) specifies criteria by which manufacturers may refute FDA's notice of defective or noncompliant product. Section 1003.11(b) 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. Section 1003.20(a)-(h) requires manufacturers to provide to FDA the same report as 1003.10(a), under different circumstances of discovery. Section 1003.21(a)-(d) specifies the content of the notification required by 1003.10(b). Section 1003.22(a) and (b) 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. Section 1003.30(a) and (b) specifies criteria by which manufacturers may request an exemption from the 1003.10 disclosure and possible product recall. Section 1003.31(a) and (b) specifies the content of the 1003.30 report. Section 1005.21(a)-(c) 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. Section 1005.22(b) specifies criteria for manufacturers or importers to request extension of time to bring product into compliance.

Product and sample information (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.

Identification information and compliance status (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.

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

Coding system information (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.

Variance (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" is 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.

Exemption from performance standards (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.

Alternate test procedures (21 CFR 1010.13)—*Reporting*
Specifies criteria for manufacturers to request alternate test procedures from those specified in a performance standard.

Television receiver critical component warning (1020.10(c)(4))—*Third-party disclosure*
Requires manufacturers of television receivers to permanently affix or inscribe a warning label that includes the specification of operating high voltage and an instruction for adjusting the high voltage to the specified value.

Cold cathode tubes (1020.20(c)(4))—*Third-party disclosure*
Requires manufacturers of cold cathode tubes to provide safety instructions and specifications to users.

Report of assembly of diagnostic x-ray components (1020.30(d)(1)-(d)(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). 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).

Information on diagnostic x-ray systems (1020.30(g))—*Recordkeeping and Third-party disclosure*
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. Section 1020.30(g)(2) 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.

Diagnostic x-ray system safety and technical information (1020.30(h)(1)-(h)(4))—*Third-party disclosure*
Section 1020.30(h)(1)-(h)(4) 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.

Fluoroscopic x-ray system safety and technical information (1020.30(h)(5)-(h)(6) and 1020.32(a)(1), (g), and (j)(4))—*Third-party disclosure*
Section 1020.30(h)(5) and (h)(6) requires manufacturers of fluoroscopic x-ray systems to provide safety information and instructions to the purchasers and users of such products, and others upon request. Section 1020.32(a)(1) requires manufacturers to provide to users precautions concerning the importance of remote control operation. Section 1020.32(g) requires manufacturers of radiographic systems that contain Positive Beam Limitation to provide precautions and safety information to users. Section 1020.32(j)(4) requires the manufacturers of fluoroscopic x-ray equipment to provide technical information to users.

Computed tomography (CT) equipment (1020.33(c)-(d), (g)(4), and (j))—*Third-party disclosure*

Section 1020.33(c) requires manufacturers of 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. Section 1020.33(d) requires manufacturers of CT systems to provide quality assurance information to users. Section 1020.33(g)(4) requires manufacturers of certain CT systems to provide alignment instructions to users. Section 1020.33(j) 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.

Cabinet x-ray systems information (1020.40(c)(9)(i)-(c)(9)(ii))—*Third-party disclosure*

Requires manufacturers of cabinet x-ray systems to provide technical, safety, maintenance, and assembly information to purchasers.

Microwave oven radiation safety instructions (1030.10(c)(4))—*Third-party disclosure*

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 user manual.

Microwave oven safety information and instructions (1030.10(c)(5)(i)-(c)(5)(iv))—*Third-party disclosure*

Requires manufacturers of microwave ovens to provide safety information and adequate instructions to service dealers and distributors and others upon request.

Microwave oven warning labels (1030.10(c)(6)(iii))—*Third-party disclosure*

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.

Microwave oven exemption from warning labels (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.

Laser products registration (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).

Laser products distribution records (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.

Laser products information (1040.10(h)(1)(i)-(h)(1)(vi))—*Third-party disclosure*
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.

Laser product service information (1040.10(h)(2)(i)-(h)(2)(ii))—*Third-party disclosure*
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).

Laser products recertification (1040.10(i))—*Reporting*
The reporting burden for laser products recertification is included in the burden estimate for Product Reports—1002.10. Section 1040.10(i) 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. Manufacturers report this information on Form FDA 3632.

Medical laser product instructions (1040.11(a)(2))—*Third-party disclosure*
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).

Sunlamp products (1040.20)—*Third-party disclosure*
Describes the labeling requirements for sunlamp products and ultraviolet lamps intended for use in sunlamp products. As described above, the labeling requirements in 1040.20(d)(1)(i), (d)(2)(i), and (d)(2)(iii) are 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)).

Mercury vapor lamp labeling (l040.30(c)(1)(ii))—*Third-party disclosure*
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.

Mercury vapor lamp permanently affixed labels (l040.30(c)(2))—*Third-party disclosure*
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.

Ultrasonic therapy products (1050.10(d) and (f))—*Third-party disclosure*
Section 1050.10(d) requires manufacturers of ultrasonic therapy products to provide informational labels on the components. Section 1050.10(f)(1) 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. Section 1050.10(f)(2) 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).

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

2. Purpose and Use of the Information Collection

The respondents to this information collection are from the private sector; businesses for profit. The information collections are either specifically called for in the FD&C Act or were developed to aid FDA in performing its obligations under the FD&C 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 that 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 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 FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

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 form FDA 2579 is printed from the 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 them via Internet through the FDA Gateway, significantly reducing the time 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 information technology tools to automatically edit-check for errors in online submissions, ensure data integrity, and allow FDA staff to perform reviews, trending, and sampling analyses with greater ease. 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.

We have been consistently receiving approximately 50 percent of submissions using eSubmitter. FDA staff continues to encourage usage and provide individual assistance to industry.

4. Efforts to Identify Duplication and Use of Similar Information

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 FD&C 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 Businesses or Other Small Entities

We estimate that approximately 22 percent of respondents are small businesses (manufacturers, importers and assemblers of electronic products).

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 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 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 Center for Devices and Radiological Health (CDRH), Division of International and Consumer Education (DICE), provides technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the Act. DICE 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 DICE 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 informed 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.

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 the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of 01/23/2020 (85 FR 3925). No comments were received.

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 FD&C 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 Respondents

In preparing this Supporting Statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

This ICR collects personally identifiable information (PII). The PII collected is for business contact purposes only. The PII submitted via each FDA form is: Form FDA 3636 (Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products); Form FDA 3639 (Cabinet X-ray System Reporting Form); Form FDA 3640 (Reporting Guide for Laser Light Shows and Displays); Form FDA 3643 (Microwave Oven Products Annual Report); Form FDA 3645 (Guide for Preparing Annual Reports for Ultrasonic Therapy Products); Form FDA 3646 (Mercury Vapor Lamp Products Radiation Safety Report); Form FDA 3647 (Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps); Form FDA 3663 (Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)); Form FDA 3759 (Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products); Form FDA 3801 (Guide for Preparing Initial Reports and

Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps); Form FDA 4004 (Guidance for the Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use); Form FDA 3147 (Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device); Form FDA 3628 (Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General); Form FDA 3630 (Guide for Preparing Product Reports on Sunlamps and Sunlamp Products); Form FDA (Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamp Products); and Form FDA 3632 (Guide for Preparing Product Reports for Lasers and Products Containing Lasers) collect name, title, work address, work telephone number, and work email address. Form FDA 3661 (A Guide for the Submission of an Abbreviated Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use); and Form FDA 3662 (A Guide for the Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic Use) collect name, work address, work telephone number, and work email address. Form FDA 3637 (Laser Original Equipment Manufacture Report); Form FDA 3642 (General Correspondence Report for CDRH Electronic Submissions); Form FDA 3649 (Accidental Radiation Occurrence Report); Form FDA 3659 (TV Product Report); Form FDA 3760 (Guide for Preparing Product Reports for Medical Ultrasound Products); Form FDA 3629 (Abbreviated Report); Form FDA 3633 (General Variance Request); Form FDA 3634 (TV Annual Report); Form FDA 3635 (Laser Light Show Notification); Form FDA 3638 (Guide for Filing Annual Reports for X-Ray Components and Systems); and Form FDA 3641 (Cabinet X-Ray Annual Report) collect name, title, work address, work telephone number, work fax number, and work email address. Form FDA 3644 (Guide for Preparing Product Reports for Ultrasonic Therapy Products) collects name, title, work address, and work email address. Form FDA 3660 (Guidance for Preparing Reports on Radiation Safety of Microwave Ovens); and Form FDA 2767 (Notice of Availability of Sample Electronic Product) collect name, title, work address and work telephone number. Form FDA 2877 (Declaration for Imported Electronic Products Subject to Radiation Control Standards collects name, title, and work address. Form FDA 2579 (Report of Assembly of a Diagnostic X-Ray System); Form FDA 3626 (A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components); and Form FDA 3627 (A Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems) collect name.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

Section 537 of the FD&C 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 collection does not include questions about sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Respondents to this collection of information are 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, including recent product report submissions. An evaluation of the type and scope of information requested was also used to derive some time estimates.

Table 1.--Estimated Annual Reporting Burden

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Product reports—1002.10(a)-(k)	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 3801—UV lamps	1,400	2.2	3,080	24	73,920
Product safety or testing changes—1002.11(a)-(b)		480	2.5	1,200	0.5	600
Abbreviated reports—1002.12	3629—General abbreviated report 3661—X-ray tables, etc. 3662—Cephalometric device 3663—Microwave products (non-oven)	60	1.8	108	5	540
Annual reports—1002.13(a)-(b)	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	1,660	1.3	2,158	18	38,844

Table 1.--Estimated Annual Reporting Burden

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Quarterly updates for new models—1002.13(c)		120	1.4	168	0.5	84
Accidental radiation occurrence reports—1002.20	3649—ARO	30	6.7	201	2	402
Exemption requests—1002.50(a) and 1002.51	3642—General correspondence	4	1.3	5	1	5
Product and sample information—1005.10	2767—Sample product	5	1	5	0.1	1
Identification information and compliance status—1005.25	2877—Imports declaration	12,620	2.5	31,550	0.2	6,310
Alternate means of certification—1010.2(d)		1	2	2	5	10
Variance—1010.4(b)	3633—General variance request 3147—Laser show variance request 3635—Laser show notification	350	1.1	385	1.2	462
Exemption from performance standards—1010.5(c) and (d)		1	1	1	22	22
Alternate test procedures—1010.13		1	1	1	10	10
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2)	2579—Assembler report	1,230	34	41,820	0.30	12,546
Microwave oven exemption from warning labels—1030.10(c)(6)(iv)		1	1	1	1	1
Laser products registration—1040.10(a)(3)(i)	3637—Original equipment manufacturer (OEM) report	70	2.9	203	3	609
Total						134,366

[1] Total hours have been rounded.

Table 2.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[1]
Manufacturers records—1002.30 and 1002.31(a)	1,650	1,650	2,722,500	0.12	326,700
Dealer/distributor records—1002.40 and 1002.41	3,110	50	155,500	0.05	7,775
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5	25
Laser products distribution records—1040.10(a)(3)(ii)	70	1	70	1	70
Total					334,570

[1] Total hours have been rounded.

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Technical and safety information for users—1002.3	1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41	30	3	90	1	90
Television receiver critical component warning—1020.10(c)(4)	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)	1	1	1	1	1
Information on diagnostic x-ray systems—1020.30(g)	6	1	6	55	330
Statement of maximum line current of x-ray systems—1020.30(g)(2)	6	1	6	10	60
Diagnostic x-ray system safety and technical information—1020.30(h)(1)-(h)(4)	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)-(h)(6) and 1020.32(a)(1), (g), and (j)(4)	5	1	5	25	125
CT equipment—1020.33(c)-(d), (g)(4), and (j)	5	1	5	150	750
Cabinet x-ray systems information—1020.40(c)(9)(i)-(c)(9)(ii)	6	1	6	40	240
Microwave oven radiation safety instructions—1030.10(c)(4)	1	1	1	20	20

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Microwave oven safety information and instructions—1030.10(c)(5)(i)-(c)(5)(iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i)-(h)(1)(vi)	3	1	3	20	60
Laser product service information—1040.10(h)(2)(i)-(h)(2)(ii)	3	1	3	20	60
Medical laser product instructions—1040.11(a)(2)	2	1	2	10	20
Sunlamp products instructions—1040.20	1	1	1	10	10
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	1	1	1	1	1
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	1	1	1	1	1
Ultrasonic therapy products—1050.10(d)(1)-(d)(4), (f)(1), and (f)(2)(iii)	1	1	1	56	56
Total					3,058

[1] Total hours have been rounded.

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by regulatory affairs professionals. We have updated the hourly wage rate estimate.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional*	471,994	$30.50	$14,395,817

*The estimated wage rate for a Regulatory Affairs Professional was calculated from the median annual salary ($63,444) listed on Payscale.com (http://www.payscale.com/research/US/Job=Regulatory_Affairs_Specialist/Salary, accessed 01-31-17). The hourly wage rate assumes a 40-hour work week and is rounded to the nearest dollar.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

FDA estimates that 15 full time equivalent (FTE) positions participate in activities under the Radiation Control for Health and Safety Act. An average full time equivalent (FTE) employee is projected to cost FDA's Center for Devices and Radiological Health (CDRH) $213,944 (rounded),* which consists of the employee's salary and any overhead which accompanies that employee. Therefore, the estimated annualized burden to government for this information collection is $3,209,160 per year ($213,944 x 15 FTEs).

* Based on the FY 2017 FDA Budget Request – Executive Summary – All Purpose Table.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments associated with this request for extension.

Note that in the Federal Register of April 1, 2019 (84 FR 12147), FDA proposed to amend and repeal parts of the radiological health regulations covering recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products. As required in 5 CFR part 1320, we requested public comment on proposed revisions to this ICR. At the time of this extension request, the rulemaking has not been finalized.

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 FD&C Act.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.