UNITED STATES FOOD & DRUG ADMINISTRATION

Electronic Products Requirements

OMB Control No. 0910-0025 – Revision

RIN-0910-AH65

SUPPORTING STATEMENT

Part A – Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) rulemaking. In the final rule, "*Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products,*" FDA is amending and repealing parts of the radiological health regulations it administers. FDA is issuing this final rule under the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 351, 352, 360, 360e-360j, 360hh-360ss, 371, 374, and 381). Many of the requirements in our radiological health regulations are over 30 years old. As described in the proposed rule (84 FR 12147, April 1, 2019), the final rule amends and repeals certain radiological health regulations to reduce regulatory requirements that are outdated and duplicative. Specifically, the final rule amends parts of the radiological health regulations covering recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, applications for variances, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products while still assuring the public health and safety is protected against harmful exposure to radiation emitting electronic products and medical devices.

FDA is responsible for protecting and promoting public health regarding electronic product radiation from medical devices (such as x-rays and mammograms) and electronic products (such as baggage x-rays for security, laser pointers, Ultraviolet tanning, and cell phones). Voluntary consensus standards regarding safety and essential performance have been developed and continually improved to increase the safety of these devices (sections 514(c) and 531-542 of the FD&C Act). We believe radiation emitting medical devices and electronic products that comply with Federal standards provide a reasonable assurance of safety and effectiveness when properly used by trained personnel, and concern has shifted to minimizing improper uses.

We therefore request approval for the information collection provisions associated with our electronic products regulations, included in the applicable forms, as amended by the final rule, and as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents to the information collection are from the private sector; businesses for profit. We use the information collection to determine compliance with statutory and regulatory requirements and adherence to performance standards. Information including records and reports are reviewed by FDA to determine product safety, conformance with performance standards, and adequacy of quality control testing. Potential and actual problems are resolved with individual firms through follow-up information collection. We discuss these activities on our website at Radiation Emitting Electronic Products.

3. Use of Improved Information Technology and Burden Reduction

The information collection is supported by the use of the following forms:

Table 1. OMB Control No. 0910-0025: Index of Forms

AGENCY FORM NUMBER	TITLE
FDA 2579[1]	Report of Assembly of Diagnostic X-ray System
FDA 2767	Notice of Availability of Sample Electronic Product
FDA 2877	Declaration for Imported Electronic Products Subject to Radiation Control Standards
FDA 3147	Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device
FDA 3628	Reports on Radiation Safety Testing of Electronic Products (General)
FDA 3629	Abbreviated Report
FDA 3630	Product Reports on Sunlamps and Sunlamp Products
FDA 3631	Annual Reports on Radiation Safety Testing of Sunlamp Products
FDA 3632	Product Reports for Lasers and Products Containing Lasers
FDA 3633	General Variance Request
FDA 3634	TV Annual Report
FDA 3635	Laser Light Show Notification
FDA 3636	Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products
FDA 3637	Laser Original Equipment Manufacture Report
FDA 3639	Cabinet X-ray System Reporting
FDA 3640	Laser Light Shows and Displays
FDA 3641	Cabinet X-Ray Annual Report
FDA 3642	General Correspondence Report for CDRH Electronic Submissions
FDA 3643	Microwave Oven Products Annual Report
FDA 3646[2]	Mercury Vapor Lamp Products Radiation Safety Report
FDA 3649	Accidental Radiation Occurrence Report
FDA 3659	TV Product Report
FDA 3660	Reports on Radiation Safety of Microwave Ovens
FDA 3663	Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)

[1] Form revised consistent with final rule.
[2] Form revised consistent with final rule.

AGENCY FORM NUMBER	TITLE
FDA 3759	Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products
FDA 3760	Product Reports for Medical Ultrasound Products
FDA 3801	Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps
FDA 4004	Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use

The forms are developed in portable document format (pdf) intended to facilitate the uniform submission of information by respondents. Although certain submissions continue to be accepted in a paper-based format, most forms are completed and submitted electronically through established FDA IT systems, including systems administered by our Center for Devices and Radiological Health (CDRH) specifically maintained to support information collection associated with electronic products requirements. We encourage electronic filing using FDA's Electronic Submissions Gateway (FDA ESG), which allows manufacturers to create accounts and submit files using the CDRH eSubmitter software application. Additionally, CDRH has developed and maintains a voluntary electronic submission (eSubmitter) mechanism to automatically edit-check for errors in online submissions, ensure data integrity, and allow FDA staff to review information with greater efficiency. We believe the software reduces the number of supplements needed, and provides data often missing from paper-based submissions. The forms are also supported by instructional information and recommendations found in submission guides and applicable guidance documents.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. We estimate 22 percent of respondents are small businesses (manufacturers, importers, and assemblers of electronic products).

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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

Requiring respondents to report information to the agency more often than quarterly is necessary in instances of accidental radiation occurrences that are associated with a death or serious injury (21 CFR 1002.20). 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 might not be located quickly when a particular product or system is suspected of causing harm. These records are needed to protect the public from immediate health hazards,

and therefore are considered records pertaining to health which are not subject to the quarterly limit (5 CFR 1320.5(d)(2)(i)).

Over the past several years, recordkeeping requirements have been significantly reduced, but the timeframe for maintaining these records (5 years) remains the same. 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. Without this information, FDA's protection of the public from significant health risks might be compromised. 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)).

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

In the *Federal Register* of April 1, 2019 (84 FR 12147), FDA published a notice of proposed rulemaking, including an analysis of the proposed information collection. Our responses to comments are included in section V of the final rule, *Comments on the Proposed Rule and FDA Response*. We have made no changes to the burden estimates found in our proposed rule as a result of public comments received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. Although the ICR collects personally identifiable information (PII) through the utilization of agency forms, as listed in Q-3 above, the data elements are collected for business contact purposes only. We have determined that the PII submitted through each of the respective forms is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimizes the PII to be collected to protect the privacy of the individuals.

Freedom of Information Act (FOIA)

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 collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Respondents to this collection of information are electronic product manufacturers, importers, and assemblers.

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

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Product reports—1002.10(a)-(k)	3639—Cabinet x-ray 3632—Laser 3640—Laser light show 3630—Sunlamp 3659—TV 3660—Microwave oven 3801—UV lamps	1,149	2.2	2,529	24	60,685
Supplemental reports—1002.11(a)-(b)		440	2.5	1,100	0.5 (30 minutes)	550
Abbreviated reports—1002.12	3629—General abbreviated report 3646—Mercury vapor lamp products radiation safety report 3663—Microwave products (non-oven)	54	1.8	97	5	485
Annual reports—1002.13(a)-(b)	3628—General 3634—TV 3641—Cabinet x-ray 3643—Microwave oven 3636—Laser 3631—Sunlamp	1,410	1.3	1,833	18	32,994

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

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Accidental radiation occurrence reports —1002.20	3649—ARO	75	4	300	2	600
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 (6 minutes)	1
Identification information and compliance status —1005.25	2877—Imports declaration	12,620	2.5	31,550	0.2 (12 minutes)	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
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		0		0		102,744

[1] Numbers have been rounded.

Table 3.--Estimated Annual Recordkeeping Burden[1]

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Manufacturer test and distribution records—1002.30 and 1002.31(a)	1,409	1,650	2,324,850	0.12 (7 minutes)	278,982
Dealer/distributor records—1002.40 and 1002.41	2,909	50	145,450	0.05 (3 minutes)	7,273
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5 (30 minutes)	25
Laser products distribution records—1040.10(a)(3)(ii)	70	1	70	1	70
Total	0		0		286,350

[1] Numbers have been rounded.

Table 4.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	FDA Form	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
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2)	FDA 2579—Assembler report	1,230	34	41,820	0.30 (18 minutes)	12,546
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

Table 4.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Microwave oven radiation safety instructions—1030.10(c)(4)		1	1	1	20	20
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)		2	1	2	20	40
Laser product service information—1040.10(h)(2)(i)-(h)(2)(ii)		2	1	2	20	40
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
Total		0		0		15,508

[1] Total hours have been rounded.

Our burden estimates are based on our continued experience with the information collection and informal communications with industry, as well as 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 time estimates associated with the respective activities. We do not account for burden that may be attributable to requirements found in 21 CFR parts 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). Because these requirements apply to the collection of information during the conduct of investigations or audits (5 CFR 1320.4), we do not believe they otherwise constitute a collection of information as defined by the PRA. Similarly, we do not account for burden that may be attributable to requirements in 21 CFR parts 1030.10(c)(6), 1040.10(g), and 1040.30(c)(1). Because the information collection includes 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)), we believe these elements are not subject to OMB review and approval under the PRA.

The final rule revises the applicability of the recordkeeping and reporting requirements for some products (21 CFR 1002.1). We therefore revised corresponding burden estimates for product reports, supplemental reports, abbreviated reports, annual reports, manufacturer test and distribution records, and dealer and distributor records by reducing the number of respondents/recordkeepers to reflect the revised applicability of the recordkeeping and reporting requirements. We also revised form FDA 3646 "*Mercury Vapor Lamp Products Radiation Safety Report*" (now listed under Abbreviated Reports consistent with the revision of § 1002.1) and removed the following forms:

- Form FDA 3626, "*Initial Reports on Diagnostic X-Ray Systems and Their Major Components*"
- Form FDA 3627, "*Diagnostic X-Ray CT Products Radiation Safety Report*"
- Form FDA 3638, "*Annual Reports for X-Ray Components and Systems*"
- Form FDA 3644, "*Product Reports for Ultrasonic Therapy Products*"
- Form FDA 3645, "*Annual Reports for Ultrasonic Therapy Products*"
- Form FDA 3647, "*Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps*"
- Form FDA 3661, "*Abbreviated Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use*"
- Form FDA 3662, "A*bbreviated Radiation Safety Reports on Cephalometric Devices Intended for Diagnostic Use*"

The amended applicability of the recordkeeping requirements for dealer and distributor records (1002.40 and 1002.41) results in a small decrease in the number of recordkeepers..

We have eliminated requirements for manufacturers to report model numbers of a model family that do not involve changes in radiation emission or requirements of a performance standard in quarterly updates to their annual reporting (21 CFR 1002.13(c)). We have removed the burden estimate associated with 1002.13(c). Generally, other subsections require specified product manufacturers to submit annual reports to FDA which summarize certain manufacturing records (21 CFR 1002.13(a) and (b)); the final rule does not amend these annual report requirements.

We have revised the submission schedule for reporting requirements for AROs that are not associated with a death or serious injury (21 CFR 1002.20).

We have revised the variance applications process (21 CFR 1010.4(b)) to no longer require a manufacturer to submit two additional copies with the original documents. While this amendment would not generate any substantive change to the information collection, respondents may realize a small monetary savings from the usual and customary administrative expenses associated with the preparation of the copies.

We have modified reporting associated with Form FDA 2579.

We have modified reporting requirements for manufacturers that incorporate a certified laser product to reduce reporting that is considered duplicative under certain conditions. Manufacturers that incorporate a certified laser system meeting the conditions of 21 CFR

1010.2(e) are considered distributors of the certified laser and only subject to the applicable distribution recordkeeping requirements under 1002.40 and 1002.41 for the certified products. Accordingly, we have reduced the number of respondents for "*Laser products information—1040.10(h)(1)(i)-(vi*)" and "*Laser product service information—1040.11(h)(2)(i)-(ii)*."

We have repealed, and therefore removed any burden attributable to, performance standards for ultrasonic therapy products in 21 CFR 1050.10.

12b. Annualized Cost Burden Estimate

We estimate that the information collection will be satisfied by regulatory affairs professionals. We use, $71.17, the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm, mean wage rate for a Lawyer (occupation code 23-1011) to calculate the burden for regulatory affairs professionals. To account for benefits and overhead, we double this value to $142.34.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	404,602	$142.34	$57,591,049

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

We estimate the costs to read the rule for all respondents to the initial collection of information. We assume all baseline respondents will need to devote time to reading and understanding the regulation to determine whether this final rule applies to their firm. There are 23,040 initial respondents across all three reporting categories. At an adult average reading speed of 200-250 words per minute, we estimate that each reader will spend about 1 hour reading the rule. We assume one regulatory affairs specialist at each firm will read the rule. Using the adjusted hourly wage rate as calculated in the RIA for the final rule, we value the time spent learning about the rule at a cost of $69.38 per respondent. Multiplying this estimate by the number of total respondents yields a total one-time cost for reading the rule of $1,598,607 ($69.38 x 23,040).

14. Annualized Cost to the Federal Government

Assuming an allocation of 15 full time equivalent (FTE) positions who have responsibilities under the Radiation Control for Health and Safety Act, and that wage costs are) $297,561 (rounded), including employee salary and non-salary costs (based on FDA's fully loaded FTE cost model (domestic) for FY 2021, as provided by agency economists). We estimate that 23.9 percent of the total annual reporting burden hours will be eliminated as a result of the rule (an annual cost savings to FDA of $1,068,244). Therefore, we calculate wage costs to be $3,395,171. In addition to the costs above, the Radiological Health program utilizes a Document Control contractor (DCC) exclusively to support the receipt and processing of these forms, which costs $985,974.78 per year. Cumulatively, we estimate an annualized cost to the Federal government of $4,381,146.

15. Explanation for Program Changes or Adjustments

We have revised the number of respondents to reflect the current number of entities we believe are subject to the requirements in 21 CFR parts 1000 through 1050. This figures corresponds with updated data presented in the analysis of impacts associated with the final rule (FRIA). As a result of these changes and adjustments, the information collection reflects an increase of 2,527,396 responses and a decrease of by 67,392 hours, annually.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

The ICR OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.