4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0618]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0025. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Products--21 CFR Parts 1002 through 1010 (OMB Control Number 0910-0025)--Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in Title 21 of the Code of Federal Regulations, chapter I, subchapter J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of the Department of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act 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) of the FD&C Act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the FD&C Act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliance with performance standards. Section 537(b) of the FD&C Act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall. FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the FD&C Act or were developed to aid the Agency in performing its obligations under the FD&C Act. The data reported to FDA and the records maintained are used by 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 of, location of, operational characteristics of, 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.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

FDA estimates the burden of this collection of information as follows:

- Form FDA 2579 "Report of Assembly of a Diagnostic X-Ray System"
- Form FDA 2767 "Notice of Availability of Sample Electronic Product"
- Form FDA 2877 "Declaration for Imported Electronic Products Subject to Radiation Control Standards"
- Form FDA 3649 "Accidental Radiation Occurrence (ARO)"

- Form FDA 3626 "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"
- Form FDA 3627 "Diagnostic X-Ray CT Products Radiation Safety Report"
- Form FDA 3628 "General Annual Report (Includes Medical, Analytical, and Industrial X-Ray Products Annual Report)"
- Form FDA 3629 "Abbreviated Report"
- Form FDA 3630 "Guide for Preparing Product Reports on Sunlamps and Sunlamp Products"
- Form FDA 3631 "Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamp Products"
- Form FDA 3632 "Guide for Preparing Product Reports on Lasers and Products Containing Lasers"
- Form FDA 3633"General Variance Request"
- Form FDA 3634 "Television Products Annual Report"
- Form FDA 3635 "Laser Light Show Notification"
- Form FDA 3636 "Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products"
- Form FDA 3637 "Laser Original Equipment Manufacturer (OEM) Report"
- Form FDA 3638 "Guide for Filing Annual Reports for X-Ray Components and Systems"
- Form FDA 3639 "Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40"
- Form FDA 3640 "Reporting Guide for Laser Light Shows and Displays"

- Form FDA 3147 "Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device"
- Form FDA 3641 "Cabinet X-Ray Annual Report"
- Form FDA 3642 "General Correspondence"
- Form FDA 3643 "Microwave Oven Products Annual Report"
- Form FDA 3644 "Guide for Preparing Product Reports for Ultrasonic Therapy Products"
- 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 3659 "Reporting and Compliance Guide for Television Products"
- Form FDA 3660 "Guidance for Preparing Reports on Radiation Safety of Microwave Ovens"
- 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"
- Form FDA 3662 "A Guide for the Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic Use"
- Form FDA 3663 "Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)"
- Form FDA 3801 "Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps"

The respondents to this information collection are electronic product and x-ray manufacturers, importers, and assemblers. The burden estimates were derived by consultation with FDA and industry personnel, and are based on 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.

In the Federal Register of June 12, 2013 (78 FR 35279), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--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[2]
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	1,500	1.1	1,650	24	39,600
Product safety or testing changes--1002.11(a)-(b)		1,000	1.5	1,500	0.5	750
Abbreviated reports--1002.12	3629--General abbreviated report 3661--X-ray tables, etc. 3662--Cephalometric device 3663--Microwave products (non-oven)	60	2	120	5	600

Table 1.--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[2]
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	1,500	1	1,500	18	27,000
Quarterly updates for new models--1002.13(c)		3	4	12	0.5	6
Accidental radiation occurrence reports--1002.20	3649--ARO	15	6	90	2	180
Exemption requests--1002.50(a) and 1002.51	3642--General correspondence	10	1	10	1	10
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	1,000	20	20,000	0.2	4,000
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	350	1.2	420
Exemption from performance standards--1010.5(c) and (d)		1	1	1	22	22
Alternate test procedures--1010.13		1	1	1	10	10

Table 1.--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[2]
Report of assembly of diagnostic x-ray components--1020.30(d), (d)(1), and (d)(2)	2579--Assembler report	2,000	14	28,000	0.30	8,400
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	50	3	150	3	450
Total						81,460

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

Table 2.--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[2]
Manufacturers records--1002.30 and 1002.31(a)	1,600	1,650	2,640,000	0.12	316,800
Dealer/distributor records--1002.40 and 1002.41	3,000	50	150,000	0.05	7,500
Information on diagnostic x-ray systems--1020.30(g)	50	1	50	0.5	25
Laser products distribution records--1040.10(a)(3)(ii)	50	1	50	1	50
Total					324,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
Technical and safety information for users--1002.3	1	1	1	12	12
Dealer/distributor records--1002.40 and 1002.41	50	3	150	1	150
Television receiver critical component warning--1020.10(c)(4)	1	1	1	1	1

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
Cold cathode tubes--1020.20(c)(4)	1	1	1	1	1
Information on diagnostic x-ray systems--1020.30(g)	100	2	200	55	11,000
Statement of maximum line current of x-ray systems--1020.30(g)(2)	15	1	15	10	150
Diagnostic x-ray system safety and technical information--1020.30(h)(1)-(h)(4)	100	2	200	200	40,000
Fluoroscopic x-ray system safety and technical information--1020.30(h)(5)-(h)(6) and 1020.32(a)(1), (g), and (j)(4)	15	2	30	25	750
CT equipment--1020.33(c)-(d), (g)(4), and (j)	25	2	50	150	7,500
Cabinet x-ray systems information--1020.40(c)(9)(i)-(c)(9)(ii)	30	2	60	40	2,400
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)	1,000	1.2	1,200	20	24,000
Laser product service information--1040.10(h)(2)(i)-(h)(2)(ii)	1,000	1.2	1,200	20	24,000
Medical laser product instructions--1040.11(a)(2)	35	1	35	10	350
Sunlamp products instructions--1040.20	10	5	50	10	500
Mercury vapor lamp labeling--1040.30(c)(1)(ii)	2	1	2	1	2

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
Mercury vapor lamp permanently affixed labels--1040.30(c)(2)	2	1	2	1	2
Ultrasonic therapy products--1050.10(d)(1)-(d)(4), (f)(1), and (f)(2)(iii)	5	1	5	56	280
Total					111,139

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

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) through (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 investigations or audits (5 CFR 1320.4).

The following labeling requirements 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)): Sections 1030.10(c)(6); 1040.10(g); 1040.20(d)(1)(i), (d)(2)(i), and (d)(2)(iii); and 1040.30(c)(1).

Dated: October 25, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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