TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section and Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and format when seeking written recommendations; results of studies; amendments (§§ 316.10, 316.12, 316.14)	2	1	2	100	200
Content and format of a request for orphan-drug designation; request for verification of orphan-drug status; amendments (§§ 316.20, 316.21, 316.26) Form FDA 3671	214	2	428	150	64,200
Notifications of changes in agents (§ 316.22)	55	1	55	2	110
Submissions to change ownership of orphan-drug designation (§ 316.27)	43	1	43	5	215
Annual reports (§ 316.30)	1,652	1	1,652	3	4,956
Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug (§ 316.36)	1	3	3	15	45
Total					69,726

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

Dated: June 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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, subpart 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 noncompliances 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 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 (ARO)''
- 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 Report on Cephalometric Devices Intended for Diagnostic Use''
- FDA Form 3663 ''Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)''
- FDA Form 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	FDA form	Number of respondents	Number 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.	1,500	1.1	1,650	24	39,600

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
	3630—Sunlamp. 3646—Mercury vapor lamp. 3644—Ultrasonic therapy. 3659—TV. 3660—Microwave oven. 3801—UV lamps.					
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
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
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	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	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	Number of respondents	Number 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
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
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)–(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 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: June 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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