Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate 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; 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: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0025. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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

OMB Control Number 0910–0025—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (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 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:

- 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 [Computed Tomography] 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 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 January 23, 2020 (85 FR 3925), 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Product reports—1002.10(a) through (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) and (b).	.....	480	2.5	1,200	0.5 (30 minutes)	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) and (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
Quarterly updates for new models—1002.13(c).	.....	120	1.4	168	0.5 (30 minutes)	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 (6 minutes)	1

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]
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
Report of assembly of diagnostic x-ray components—1020.30(d), and (d)(1) and (2).	2579—Assembler report	1,230	34	41,820	0.3 (18 minutes)	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—OEM report	70	2.9	203	3	609
Total						134,366

[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 recordkeeping	Total hours [2]
Manufacturers records—1002.30 and 1002.31(a)	1,650	1,650	2,722,500	0.12 (7 minutes)	326,700
Dealer/distributor records—1002.40 and 1002.41	3,110	50	155,500	0.05 (3 minutes)	7,775
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					334,570

[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	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) through (4)	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5) and (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) and (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 [1]—Continued

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Microwave oven safety information and instructions—1030.10(c)(5)(i) through (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) through (vi)	3	1	3	20	60
Laser product service information—1040.10(h)(2)(i) and (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) through (d), (f)(1), and (f)(2)(iii)	1	1	1	56	56
Total					3,058

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

Based on a review of the information collection, we have made no adjustments to our burden estimate.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10373 Filed 5–13–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3065]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Revision

This information collection supports Agency implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For efficiency of Agency operations, we are revising the information collection currently approved under OMB control number 0910–0800 pertaining to human drug compounding and section 503B of the FD&C Act (21 U.S.C. 355b) to include reference to Agency guidance regarding section 503A of the FD&C Act (21 U.S.C. 355a), and to also include information collection that we attribute to a final standard memorandum of understanding (MOU) provided for by section 503A (''final standard MOU''). Finally, we are revising the title of the information collection from ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' to ''Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.'' As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources.

Agency Guidance Regarding Section 503A

We are revising the information collection to include reference to the guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The guidance is available from our website at: *https://www.fda.gov/media/94393/download.* The guidance was issued consistent with our Good Guidance Practice regulations (21 CFR 10.115), which provide for comment at any time. The guidance communicates FDA's intention with regard to enforcement of section 503A of the FD&C Act to regulate entities that compound drugs and notes that parts of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement and explains how the provisions will be applied pending those consultations and rulemaking. Although the guidance does not include recommended information collection, we are including the guidance as a supplemental reference for respondents.