The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between January 1, 2008, and December 31, 2008 (96 x hours per response (.08) = 7.7 total hours).

Dated: May 10, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–11453 Filed 5–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0088]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of 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 (the PRA).

DATES: Fax written comments on the collection of information by June 14, 2010.

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 e-mailed 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, email: *Daniel.Gittleson@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.

Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products (OMB Control Number 0910–0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the 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 (parts 1002 through 1050).

Section 532 of the 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 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 act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the 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 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 act or were developed to aid the Agency in performing its obligations under the 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 most likely respondents to this information collection will be electronic product and x-ray manufacturers, importers, and assemblers.

In the **Federal Register** of February 26, 2010 (75 FR 8963), 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]

21 CFR Section/ Part	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1002.3	N/A	10	1	10	12	120
1002.10	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	1,000	1.2	1,200	24	28,800
1002.11	N/A	400	0.6	240	0.5	120
1002.12	3629—General Abbreviated Report 3661—X-Ray Tables, etc. 3662—Cephalometric Device 3663—non-Oven Microwave Product	50	1	50	5	250
1002.13	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	1,000	1	1,000	18	18,000
1002.13(c)	N/A	100	2.4	240	0.5	120
1002.20	3649—ARO	25	1	25	2	50
1002.41(a)	N/A	1	1	1	1	1
1002.50(a) and 1002.51	3642—General Correspondence	10	0.5	5	1	5
1005.10	2767—Sample Product	50	1	50	0.1	5
1005.25(b)	N/A	1	1	1	1	1
1005	2877—Imports Declaration	600	32	19,200	0.2	3,840

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

21 CFR Section/ Part	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1010.2	N/A	1	1	1	5	5
1010.4(b)	3633—General Variance Request 3147—Laser Show Variance Request 3635—Laser Show Notification	160	0.3	48	1.2	58
1010.5(c) and (d)	N/A	4	1	4	22	88
1010.13	N/A	1	1	1	10	10
1020.20(c)(4)	N/A	1	1	1	1	1
1020.30(d), (d)(1), and (d)(2)	2579—Assembler Report	1,150	10.7	12,305	0.30	3,692
1020.30(g)	N/A	200	1.33	266	35	9,310
1020.30(h)(1) through (h)(4), 1020.32(a)(1) and (g)	N/A	200	1.33	266	35	9,310
1020.30(h)(5) and (h)(6) and 1020.32(j)(4)	N/A	20	5	100	18	1,800
1020.32(g), 1020.33(c), (d), (g)(4), (j)(3), and (j)(4)	N/A	9	1	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)	N/A	8	1	8	40	320
1030.10(c)(4)	N/A	41	1.6	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)	N/A	41	1.6	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)	N/A	1	1	1	1	1
1040.10(a)(3)(i)	3637—OEM Report	40	1	40	3	120
1040.10(h)(1)(i) through (h)(1)(vi)	N/A	805	1	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)	N/A	100	1	100	8	800
1040.11(a)(2)	N/A	50	1	50	10	500
1040.20(d)(1)(ii) through (d)(1)(vi), (e)(1), and (e)(2)	N/A	110	1	110	10	1,100
1040.30(c)(1)(ii)	N/A	1	1	1	1	1
1040.30(c)(2)	N/A	7	1	7	1	7
1050.10(d)(1) through (d)(4) and (f)(1) through (f)(2)(iii)	N/A	10	1	10	56	560
Total Annual Reporting Burden						88,435

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	0.12	228,459
1002.40 and 1002.41	2,950	49.2	145,140	0.05	7,257
1020.30(g)	22	1	22	0.5	11
1040.10(a)(3)(ii)	40	1	40	1.0	40
Totals					235,767

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

The burden estimates were derived by consultation with FDA and industry personnel, and are based on actual data collected from industry. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry.

The following information collection 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), (b), and (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 general investigations or audits (5 CFR 1320.4(b)).

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 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: May 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–11396 Filed 5–12–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0236]

Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory." This guidance is intended to advise food manufacturers that once a boil-water advisory has been issued they should stop using the water subject to the advisory until the water again meets the applicable Federal and State drinking water quality standards. Further, this guidance is intended to assist food manufacturers in evaluating food that already was produced with water subject to the advisory. The guidance is in response to the recent major water pipe break in Massachusetts that interrupted service to 30 Massachusetts Water Resources Authority (MWRA) customer communities (serving approximately 2 million residents).

DATES: Submit electronic or written comments on the guidance at any time.

ADDRESSES: Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA—305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1700

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory." This guidance is intended to advise food manufacturers that once a boil-water advisory has been issued they should stop using the water subject to the advisory until the water again meets the applicable Federal and State drinking water quality standards. Further, this guidance is intended to assist food manufacturers in evaluating food that already was produced with water subject the advisory.

FDA is issuing this guidance as Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with 21 CFR 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the recent major water pipe break in Massachusetts that interrupted service to 30 MWRA customer communities (serving approximately 2 million residents). The guidance represents the agency's current thinking on the use of water by food manufacturers in areas subject to a "Boil-Water Advisory." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be