Dated: February 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0088]

Agency Information Collection Activities; Proposed Collection; 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 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 written or electronic comments on the collection of information by April 27, 2010.

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.

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.

21 CFR 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 Reports on Cephalometric Devices Intended for Diagnostic Use"
- FDA Form 3663 "Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)"

The most likely respondents to this information collection will be electronic product and x-ray manufacturers, importers, and assemblers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form Number	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	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	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 3663—Non-Oven Microwave Product	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

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

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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
1005.3	2877—Imports Declaration	600	32	19,200	0.2	3,840
1010.2 and 1010.3	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) and 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) and 1020.33(c), (d), (g)(4), (j)(1), and (j)(2)	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) and (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

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

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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 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 per 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
Total					235,767

[1] There are no 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: February 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Grant Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Noncompetitive Program Extension Supplemental Awards.

SUMMARY: HRSA will be providing extensions with funds ranging from 5 to 10 months to program grantees for the following programs in order to bring these programs into alignment with changes resulting from HRSA's Maternal and Child Health Bureau's developing strategic plan and the Early Learning and Development Initiative of the HHS and Department of Education. The programs are:

- Alliance for Information in Maternal and Child Health (AIM)
  - Improving Understanding of MCH—10 grants
  - Partnerships to Promote MCH—5 grants
- AIM Policy Center—1 grant
- Mental Health and Schools Resource Centers—2 grants
- Public Policy Analysis and Education Center for Early Childhood—1 grant
- National Healthy Child Care America Program
  - National Training Institute for Health Consultants—1 grant
  - Child Care Health Partnership Program—1 grant
  - Resource Center for Childcare Health and Safety—1 grant
- National Sudden and Unexpected Infant/Child Death and Pregnancy Loss Centers—3 grants

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Award

The intended recipients are the incumbent grantees. They are either national membership organizations whose members impact maternal and child health programming or institutions of higher learning. They share a common purpose of providing education and technical assistance to either their individual members or State and community Maternal and Child Health programs.

Authority: Section 501(a) (3) of the Social Security Act, as amended

CFDA Number: 93.110.

Project Period: The period of supplemental support is from the grantee's original project end date