annual responses in FY 2005 included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of June 29, 2006 (71 FR 37082), FDA published a 60-day notice soliciting comments on the proposed collection of information. In response to that notice, one comment was received regarding the MDUFMA cover sheet. FDA responded as follows ''The current layout of the online form is to ensure information and questions presented on the Web site are easy to read for all users. When this system was constructed, the Food and Drug Administration was limited to the format and the layout of questions and answers. FDA took an already approved form and created an interactive system that determines the payments of requested applications based on the answers to the questions. The questions are sequential. After completing the first question, the system decides and chooses the next question for the customers. This **Federal Register** notice renews the current construction. Careful consideration during the next review will be given and FDA will certainly consider the commenter's suggestion of saving screen refresh time.''

As noted previously, FDA will be glad to take under consideration the commenter's template and the ability to download the form, when the next update or review is initiated. You can, however, retrieve an existing cover sheet by logging into the system, and clicking on the name of the cover sheet. The retrieved form is a photo shot html format. Thus, no changes can be made directly onto the form. To print the cover sheet, please select ''Print Cover Sheet'' on the bottom of the form. Currently, the printed cover sheet contains all information on one page. Again, FDA will be glad to consider this request during the next review. The current cover sheet is designed to contain all information on one page. By creating more room on the left margin, the form may extend to two pages.

Having instructions 1 through 6 on the cover sheet seems redundant. However, at the time, when creating the interactive system, FDA took into consideration that once a cover sheet is completed and ready to mail, all information would be displayed on the same page. Instructions 1 through 6 are very important information for all customers to follow in order to expedite the application review process. The instructions printed on the cover sheet provide easy access for all customers to learn about them, especially for new users. FDA will continue to use the current form. For other questions regarding submitted cover sheets, please contact the User Fee Hotline at 301–827–9539, or e-mail the User Fee Financial Support Team at *userfees@fda.gov*.

The most likely respondents would be medical device manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3601	4,600	1	4,600	0.30	1,380
Total					1,380

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

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18557 Filed 11–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0427]

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 information collection, 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 January 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 the Code of Federal Regulations, title 21, chapter I, subpart J. Specifically, subpart A regulations, 21 CFR 5.10(a)(3), 5.25(b), 5.35(a)(4), and 5.600 through 5.606, delegate administrative authorities to FDA.

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.

Parts 1002 through 1010 (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 (21 CFR 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''

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''

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		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	540	1.6	850	24	20,400
1002.11		1,000	1.5	1,500	0.5	750
1002.12	3629—Abbreviated Report	150	1	150	5	750
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	900	1	900	26	23,400
1002.13		250	2.4	600	0.5	300
1002.20	3649—ARO	40	1	40	2	80
1002.41(a)		1	1	1	1	1
1002.50(a) and 1002.51	3642—General Correspondence	10	1.5	15	1	15
1005.10	2767—Sample Product	145	11.03	1,600	0.09	144
1005.25(b)		1	1	1	1	1
	2877—Imports Declaration	600	32	19,200	0.2	3,840
1010.2 and 1010.3		1	1	1	5	5
1010.4(b)	3633—General Variance Request 3147—Laser Show Variance Request 3635—Laser Show Notification	1	1	1	120	120
1010.5(c) and (d)		2	1	2	22	44
1010.13		1	1	1	10	10
1020.20(c)(4)		1	1	1	1	1
1020.30(d), (d)(1), and (d)(2)	2579—Assembler Report	2,345	8.96	21,000	0.30	6,300
1020.30(g)		200	1.33	265	35	9,275
1020.30(h)(1) through (h)(4), 1020.32(a)(1) and (g)		200	1.33	265	35	9,275
1020.30(h)(5) and (h)(6) and 1020.32(j)(4)		20	5	100	180	18,000

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
1020.32(g) and 1020.33(c), (d), (g)(4), (j)(3), and (j)(4)		9	1.00	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)		8	1.00	8	40	320
1030.10(c)(4)		41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)		41	1.61	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)		1	1	1	1	1
1040.10(a)(3)(i)	3637—OEM Report	83	1	83	3	249
1040.10(h)(1)(i) through (h)(1)(vi)		805	1.00	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)		100	1.00	100	8	800
1040.11(a)(2)		190	1.00	190	10	1,900
1040.20 (d)(1)(ii)-(vi), (e)(1), and (e)(2)		110	1.00	110	10	1,100
1040.30(c)(1)(ii)		1	1.00	1	1	1
1040.30(c)(2)		7	1.00	7	1	7
1050.10(d)(1)-(d)(4) and (f)(1)-(f)(2)(iii)		10	1.00	10	56	560
Total						107,209

[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 Recordkeeper	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					235,679

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

The information collection, OMB control number 0910–0564 (i.e. FDA Form 3626) has been consolidated under this information collection thus, requiring an adjustment of the burden estimate.

The burden estimates were derived by consultation with FDA and industry personnel and 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. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the ''Estimated Annual Reporting Burden'' table.

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

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18559 Filed 11–2–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0326]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

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 December 4, 2006.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Medical Devices: Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002 (OMB Control Number 0910–0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph ''g'' to section 704 of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program.

FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.''

In the **Federal Register** of August 24, 2006 (71 FR 50067), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents are expected to be businesses or other for profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Information Collection	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation	3	1	3	80	240
Total Hours					240

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

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18603 Filed 11–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 016'' (Recognition List Number: 016), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 016'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological