other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved information collection.

Title of Information Collection: Indirect Medical Education (IME) and Supporting Regulations 42 CFR 412.105; Direct Graduate Medical Education (GME) and Supporting Regulations in 42 CFR 413.75–413.73.

Use: The collection of information on interns and residents (IR) is needed to properly calculate Medicare program payments to hospitals that incur indirect and direct costs for medical education. The agency's Intern and Resident Information System (IRIS) and similar contractor systems use the information for producing reports of duplicate full-time equivalent IR counts for IME and GME. The contractors also use this information to ensure that hospitals are properly reimbursed for IME and GME, and help eliminate duplicate reporting of IR counts which inflate payments. The collection of this information affects 1,215 hospitals which participate in approved medical education programs.

Form Number: CMS-R–64 (OMB#: 0938–0456).

Frequency: Recordkeeping and Reporting—Annually.

Affected Public: Not-for-profit and Business or other for-profit institutions.

Number of Respondents: 1,215.

Total Annual Responses: 1,215.

Total Annual Hours: 2,430.

2. *Type of Information Collection Request:* Extension of a currently approved information collection.

Title of Information Collection: Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions ICF/MR Survey Report Form and Supporting Regulations at 42 CFR 442.30, 483.410, 483.420, 483.440, 483.50, and 483.460.

Use: The survey forms are needed to ensure provider compliance. In order to participate in the Medicaid program as an ICF/MR, providers must meet Federal standards. The survey report form is used to record providers' level of compliance with the individual standard requirements and report it to the Federal government.

Form Number: CMS–3070G-I (OMB#: 0938–0062).

Frequency: Recordkeeping and Reporting—Annually.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Number of Respondents: 6,428.

Total Annual Responses: 6,428.

Total Annual Hours: 19,284.

3. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations at 42 CFR 486.301–486.348.

Use: The information provided on this form serves as a basis for continuing the agreements with CMS and the 58 OPOs for participation in the Medicare and Medicaid programs and for reimbursement of service.

Form Number: CMS–576A (OMB#: 0938–0512.

Frequency: Reporting—Every 4 years and as needed.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Number of Respondents: 58.

Total Annual Responses: 58.

Total Annual Hours: 116.

4. *Type of Information Collection Request:* Extension of a currently approved information collection.

Title of Information Collection: Reconciliation of State Invoice and Prior Quarter Adjustment Statement.

Use: Section 1927 of the Social Security Act requires drug labelers to enter into and have in effect a rebate agreement with CMS for States to receive funding for drugs dispensed to Medicaid recipients. Drug manufacturers must complete and submit to States the CMS–304 form to explain any rebate payment adjustments for the current quarter, and complete and submit the CMS–304A form to States to explain rebate payment adjustments to any prior quarters. Both forms are used to reconcile drug rebate payments made by manufacturers with the States invoices of rebates due.

Form Number: CMS–304/304A (OMB#: 0938–0676).

Frequency: Recordkeeping and Reporting—Quarterly.

Affected Public: Business or other for-profit.

Number of Respondents: 550.

Total Annual Responses: 3,740.

Total Annual Hours: 139,480.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: October 24, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–18413 Filed 11–2–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0425]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification

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 premarket notification.

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.

Premarket Notification—21 CFR Part 807; Subpart E—(OMB Control Number 0910–0120)

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) require a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol or be reclassified into class I or class II before being marketed. The FDA makes the final decision of whether a device is equivalent or not equivalent.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) added section 510(o) to the act to establish new regulatory requirements for reprocessed single-use devices (SUDs). MDUFMA was signed into law on October 26, 2002.

Section 510(o) of the act requires that FDA review the types of reprocessed SUDs subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. Section 510(o) also requires that FDA review critical and semicritical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submission of premarket notifications to ensure their substantial equivalence to predicate devices.

FDA has identified the reprocessed SUDs that require the submission of validation data to date. The requirement to submit validation data for certain reprocessed SUDs has been incorporated into the premarket notification program. As with all other devices, new premarket notifications for reprocessed SUDs will be required as new manufacturers enter the market or manufacturers with cleared premarket notifications make significant changes to their device. The burden estimates below include the burden for submitting premarket notifications for reprocessed SUDs with the burden for all other devices. FDA may amend the lists of reprocessed SUDs that require the submission of premarket notifications with validation data as necessary.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is:

- Introducing a device to the market for the first time;
- Introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Section 807.87 specifies information required in a premarket notification submission.

Section 204 of the Food and Drug Administration Modernization Act (FDAMA) amended section 514 of the act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Certification of conformance to a recognized standard may allow a manufacturer to submit an abbreviated 510(k). FDA is now seeking approval of a form (Form FDA 3654) that will standardize certification of conformance to a recognized standard. FDA believes that use of this form will simplify the certification process for 510(k) submitters and the review process for FDA.

Form FDA 3514, a summary cover sheet form, has been created to assist respondents in categorizing 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, and humanitarian device exemptions. The total burden (1,000 hours) for Form FDA 3514 has been included in this information collection. Form FDA 3654 is used in the following information collections: 0910–0078, 0910–0231, and 0910–0332, but the burden is approved under this information collection (0910–0120).

Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the submission, § 807.93 requires that the official correspondent of the firm make available within 30 days of a request all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the premarket notification submission is determined to be substantially equivalent. The information provided will be a duplicate of the premarket notification submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and confidential information.

The most likely respondents to this information collection will primarily be medical device manufacturers including

reprocessors of SUDs, and initial importers of devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form FDA Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807, subpart E (807.81 and 807.87/510(k))		3,700	1	3,700	80	296,000
	3514	2,000	1	2,000	0.5	1,000
	3654	150	1	150	1	150
Totals						297,150

[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	Form FDA Number	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93		2,000	10	20,000	0.5	10,000
Total						10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2.

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18553 Filed 11–2–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0247]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Medical Device User Fee Cover Sheet

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 Device User Fee Cover Sheet; Form FDA 3601 (OMB Control Number 0910–0511)—Extension

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, determine the amount of the fee required, and account for and track user fees. The form provides a cross-reference of the fees submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

According to the FDA database system, there are an estimated 4,600 manufacturers of products subject to MDUFMA. However, not all manufacturers will have any cover sheet submissions in a given year and some may have multiple cover sheet submissions. The total number of annual responses is based on the number of coversheet submissions received by FDA in fiscal year (FY) 2005. CDRH received 4,436 annual responses that included the following: 43 premarket approval applications, 4,071 premarket notifications, 22 modular premarket applications, 1 product development protocol, 1 premarket report, 15 panel track supplements, 174 real-time supplements, and 109 180-day supplements. CBER received 106 annual responses that included the following: 2 premarket approval applications, 16 biologics license applications, 84 premarket notifications, 1 modular premarket application, 2 180-day supplements, and 1 real-time supplement. The number of received