unless the Secretary grants a request for waiver of the requirement, because the use of electronic means is not reasonable for the person requesting the waiver. The collections of information under sections 222, 223, and 224 of FDAAA have been approved under OMB control number 0910–0625. Registration by electronic means for device establishments replaced FDA Forms 2891 and 2891a, "Registration of Device Establishment," and FDA Form 2892, "Medical Device Listing," with FDA Form 3673, "Device Registration and Listing Module." The scope of this information collection addresses only the reporting and recordkeeping requirements by non-electronic means under § 807.31 (21 CFR 807.31).

Under § 807.31(a) through (d), each owner or operator is required to maintain an historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but not before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Section 807.31(e) requires that the owner or operator be prepared to submit to FDA copies of: (1) All device labeling, (2) all device labeling and representative advertising, or (3) only representative package inserts, depending upon whether the device is subject to the regulatory controls under sections 514 and 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d and 360e), or restrictions imposed by 21 CFR 801.109 or otherwise by section 520(e) of the FD&C Act.

The information collected under these provisions is used by FDA to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution of firms in order to effectively allocate FDA's field resources for inspections, and (3) the class of the device that determines the frequency of inspection. As a result, when complications occur with a particular device or component, all manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection are domestic and foreign device establishments who must register and submit a device list to FDA, *e.g.,* establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency of response	Total annual responses	Hours per response	Total hours
807.31(d)(2)	2,250	1	2,250	.5	1,125
807.31(e)	22,500	1	22,500	.5	11,250
Total					12,375

[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	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
807.31(a–c)	22,500	4	90,000	0.50	45,000
Total					45,000

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

The annual respondent reporting burden for device establishment registrations and listings for additional information is estimated to be 12,375 hours and the annual respondent recordkeeping burden is estimated to be 45,000 hours. Therefore, the total burden hours for this collection are estimated to be 57,375. The estimates cited in tables 1 and 2 of this document are based primarily on fiscal year 2010 data from current systems and on conversations with industry and trade association representatives.

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30582 Filed 12–6–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0088]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Products—General Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Electronic Products—General Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of May 13, 2010 (75 FR 26964), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned

OMB control number 0910–0025. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: *December 1, 2010.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30555 Filed 12–6–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0316]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Pilot Program for Medical 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: Fax written comments on the collection of information by January 6, 2011.

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 0910–0471. 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, *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.

Adverse Event Pilot Program for Medical Products—(OMB Control Number 0910–0471)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i), FDA is authorized to require: Manufacturers to report medical device-related deaths, serious injuries, and malfunctions; and user facilities to report device-related deaths directly to manufacturers and FDA, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a "* * * subset of user facilities that constitutes a representative profile of user reports" for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. The current universal reporting system remains in place during the pilot stages of the new program and until FDA implements the new national system by regulation. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is continuing to conduct a pilot of the MedSun system before the Agency issues regulation to change from universal mandatory reporting for medical device user facilities to reporting by a representative sample of facilities. This data collection has been ongoing since February 20, 2002, and this notice is for continuation of this data collection.

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on the 3500A Form related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and to pilot additional questions, which will permit FDA to better understand the cause of reported adverse events. During the pilot program, participants will be asked to complete an annual outcome measures form, as a Customer/Partner Service Survey (approved under OMB control number 0910–0360) to aid FDA in evaluating the effectiveness of the program. Participation in this pilot is voluntary and currently includes 400 facilities. The use of an interactive electronic data collection system is easier and more efficient for the participating user facilities to use than the alternative paper system.

In addition to collecting data on the electronic adverse event report form, MedSun is proposing to collect additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and will be collected on the same Web site as the report information. This will replace the Device-Safety Exchange (DS–X). The burden to respond to these questions will take the same time as that used for DS–X: 30 minutes.

The total burden hours for MedSun and emerging signal questions equals 6,000 hours (4,500 for MedSun and 1,500 for emerging signals). The burden estimate for the electronic reporting of adverse events is based on the number of facilities currently participating in MedSun (400). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, electrophysiology laboratories, and the hospital laboratories. The burden estimate for the emerging signal portion of MedSun is based on the assumption that not all sites will use this part of the software each time questions are asked because not all sites will use the device in question.

In the **Federal Register** of July 9, 2010 (75 FR 39535), 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: