in favor of private sector initiatives, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. In addition, FDA has been responsible for setting and tracking Healthy People 2010 goals for the receipt of medication information by patients.

Surveys of consumers about their receipt of Rx drug information were carried out in 1992, 1994, 1996, 1998, and 2001. This notice is in regard to conducting the survey in 2004.

The survey is conducted by telephone on a national random sample of adults who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which information was received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are obtained. The survey enables FDA to determine the frequency with which such information is provided to consumers. Without this information, the agency would be unable to assess the degree to which adequate oral patient information about Rx drugs is provided.

Respondents to this collection of information are adults (18 years or older) in the continental United States who have obtained a new (nonrefill) prescription at a pharmacy for themselves or a member of their household in the last 4 weeks.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener					
2004	15,319	1	15,319	02	306
Survey					
2004	1,000	1	1,000	.32	320

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

This total estimate of 626 total annual burden hours is based on the 2001 survey administration, in which 15,319 potential respondents were contacted to obtain 1,000 interviews.

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1586 Filed 1–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0425]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Pilot Program for Medical Devices

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 reporting requirements related to the adverse event pilot program for medical devices.

DATES: Submit written or electronic comments on the collection of information byMarch 29, 2004.

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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

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

FDA is requesting approval from OMB for clearance to continue to conduct a pilot project to evaluate aspects of a national reporting system mandated by the Food and Drug Modernization Act (FDAMA) of 1997. Under section 519(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)(b)), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions; user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient diagnostic and treatment facilities) to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of FDAMA amended section 519(b) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(b)). This amendment legislated the replacement of a universal user facility reporting by a system that is limited to a ''* * * subject 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 act.

FDA is the regulatory agency responsible for the safety and effectiveness of medical products including medical devices and radiological products. Important questions about medical devices, such as those concerning user experience, durability, and rare effects may not be answered until after the device has been marketed. To protect the public health, FDA must be able to rapidly collect information pertaining to adverse events associated with medical devices after they have been marketed. This system is called the Medical Product Surveillance Network (MedSun). 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.

Before writing a regulation to implement the large-scale national MedSun reporting system, FDA has been conducting a pilot project to ensure all aspects of the new system address the needs of both the reporting facilities and FDA. This pilot project began with a small sample (approximately 25) and was planned to increase to a larger sample of approximately 250 facilities over a period of approximately 3 years. Data collection began in February 2002 and has been increasing since that time. FDA has achieved its recruitment goals each year, reaching 180 sites at the end of fiscal year (FY) 2003. FDA will reach a total of 240 for FY 2004 and will reach the final goal of 250 by FY 2005. The program has proven to be very popular with sites as FDA has gained a national reputation, with hospitals waiting in line to join. However, FDA's current resources will not permit FDA to expand beyond 250 sites at this time.

The pilot originally had 3 parts to the data collection: (1) Collecting demographic profile information about the participation facilities, (2) implementing an electronic version of the portions of the MedWatch form (FDA Form No. 3500A, OMB control number 0910–0291) used to report adverse events occurring with medical devices, and (3) adding additional voluntary questions to the data collection. To date, these 3 features remain unchanged. However, there has been an addition to the data collection that was approved by OMB in the spring of 2004. Therefore, the fourth part of the collection system is the Medical Device Engineering Network (M–DEN)—a place on the MedSun software for the reporters to share information with each other.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Data Type	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
MedSun	250	8	2,000	.75	1,500
M–DEN	83	10	830	.50	415
Total					1,915

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

Currently, FDA has 180 sites participating in MedSun pilot program, but expects to have 250 sites over the next 2 years. The frequency of response reflects what FDA has actually been receiving as the average number of submissions in the MedSun Program. While 6 is the actual average for submissions, FDA hopes to increase this number to 8 once their educational materials reach potential respondents. The time estimated to respond is based on feedback FDA has received from current MedSun reporters.

At this time, FDA estimates that 1/3 of the total number of respondents will access M–DEN aspect of the MedSun software, or approximately 83 persons per year. Each respondent is expected to post 5 problems and respond to 5 problems posted by other MedSun participants for a total of 10 responses per year. It is expected that each visit to the bulletin will not take longer than 30 minutes.

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0014]

Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.'' FDA is revising its March 2002 guidance