Federal Register: Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Pilot Program for Medical Products

U.S. Food & Drug Administration

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[Notices]
[Page 39535-39537]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0316]

Agency Information Collection Activities; Proposed Collection; 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 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 the continuation of a pilot project to evaluate the electronic collection of the 3500A Form for adverse events related to the use of medical products to obtain data from user facilities participating in the Medical Product Safety Network (MedSun). Additionally, the electronic form will include hospital profile information and several other questions related to the use of medical products. It will no longer contain the page called

Device-Safety Exchange (DS-X) (formerly called M-Den), which was a moderated site where MedSun members shared information with each other. This will be replaced by a page where questions about possible emerging

Page 39536 [1]

signals will be asked of the MedSun sites.

DATES: Submit either electronic or written comments on the collection of information by September 7, 2010.

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov [2]. 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 [3].

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 Products--21 U.S.C. 360(i) (OMB

Control Number 0910-0471)--Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), 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 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 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 MedSun.
FDA is continuing to conduct a pilot of the MedSun system before the agency issues a 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 also is proposing to collect additional information from participating sites about reported problems emerging from the MedSun Network 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.

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

Table 1.--Estimated Annual Reporting Burden\1\

Activity	Annual Frequency No. of Respondents	Total Annual Responses	Hours per Response	Total Response Hours
Facilities participating in the electronic reporting of adverse events programs	400 15	6,000	.75	4,500
Facilities responding to emerging signal questions (not used by all sites)	300 10	3,000	.50	1,500
Total				6,000

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

Page 39537 [4]

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.

Dated: July 1, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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SOURCE [5]

Source URL (retrieved on *08/28/2014 - 8:10pm*):
http://www.mdtmag.com/news/2010/07/federal-register-agency-information-collection-activities-proposed-collection-comment-request-adverse-event-pilot-program-medical-products?qt-video_of_the_day=0

Links:
[1] http://www.mdtmag.com/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=10386
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