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]

BILLING CODE 4160–01–P

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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Item	Nunber of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
MedSun facilities participating in the electronic reporting of adverse events program	400	15	6,000	0.75	4,500
MedSun facilities' electronic responses to Public Health Questions (PHQs)	400	10	4,000	0.5	2,000
Total hours					6,500

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

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30583 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0083]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 18, 2010 (75 FR 34744), 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 0910–0339. The approval expires on November 30, 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. 2010–30556 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0056] (formerly 2004N–0234)

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to seek public comment on possible topics for future guidance document development or revisions of existing ones.

DATES: Submit either electronic or written comments on this list and on any agency guidance document at any time.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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: For general information regarding FDA's GGP policy contact: Lisa Helmanis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., WO32, rm. 3216, Silver Spring, MD 20993–0002, 301–796–9135.

For information regarding specific topics or guidances, please see contact persons or specific offices listed in the table in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA issued its final rule on GGPs (21 CFR 10.115). GGPs are intended to ensure involvement of the public in the development of guidance documents and to enhance understanding of the availability, nature, and legal effect of such guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the Agency committed to publishing an annual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The Agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents (65 FR 56468 at 56477; 21 CFR 10.115(f)(5)).

The Agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the Agency is considering. The Agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

The guidance documents are organized by the issuing Center or Office within FDA, and in some cases are further grouped within the issuing Center or Office by topic categories.

II. Center for Biologics Evaluation and Research (CBER)