Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program (Formerly Requests for Inspection Under the Inspection by Accredited Persons Program)—(OMB Control Number 0910–0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled ''Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007.'' This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm.* This guidance is intended to assist device establishments in determining whether they are eligible to participate in the Accredited Person (AP) Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 20 of these manufacturers may use an AP in any given year.

In the **Federal Register** of May 28, 2014 (79 FR 30619), 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]

Activity/21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification regarding use of an accredited person—374(g)	20	1	20	15	300

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

Dated: November 24, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28184 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

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 31, 2014.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Medical Devices; Humanitarian Use Devices—21 CFR 814 (OMB Control Number 0910–0332)—Extension

This collection of information implements the Humanitarian Use Devices (HUD) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless an exemption is granted because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes

into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, *i.e.,* fiscal years 2011 through 2013. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 32 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 247.

In the **Federal Register** of June 10, 2014 (79 FR 33197), 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]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	16	1	16	40	640
Humanitarian device exemption (HDE) application—814.104	7	1	7	320	2,240
HDE amendments and resubmitted HDEs—814.106	14	5	70	50	3,500
HDE supplements—814.108	112	1	112	80	8,960
Notification of withdrawal of an HDE—814.116(e)(3)	8	1	8	1	8
Notification of withdrawal of institutional review board approval—814.124(b)	3	1	3	2	6
Periodic reports—814.126(b)(1)	32	1	32	120	3,840
Total					19,194

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	247	1	247	2	494

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

Dated: November 24, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28183 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1952]

Seventh Annual Sentinel Initiative; Public Workshop; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; amendment of notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a public workshop entitled ''Seventh Annual Sentinel Initiative'' to be held on February 5, 2015. The workshop was announced in the **Federal Register** of October 22, 2014. This amendment reflects the addition of a *Comments* section and updates an incorrect Web site in the *Meeting Materials* section.

FOR FURTHER INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993, 301–796–3714, FAX: 301–847–3529, email: *SentinelInitiative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of October 22, 2014 (79 FR 63130), FDA announced that a public workshop entitled ''Seventh Annual Sentinel Initiative'' will be held on February 5, 2015.

1. On page 63131, in the second column, in the sixth line of the *Meeting Materials* section, the Web site ''*http://www.brookings.edu//health/events*'' is changed to read ''*http://www.brookings.edu/events*''.

2. On page 63131, in the second column, a *Comments* section is added between the *Meeting Materials* section and the *Transcripts* section to read:

''*Comments:* FDA is holding this public workshop to obtain information about a variety of topics on active medical product surveillance. The deadline for submitting comments regarding this public workshop is March 10, 2015.

Regardless of attendance in person or through the Web cast, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and