

customer service goals that include providing accurate, timely, and relevant information to its customers. With these goals in mind, we periodically survey our customers to ensure that the needs of Medicare beneficiaries are being met. This survey will be used to measure overall satisfaction of the customer service that the Medicare Ombudsman Group (MOG) within CMS provides to Medicare beneficiaries and their representatives. The information provided will be used by management and staff to measure and improve the quality and timeliness of responses to written and verbal correspondence.

*Form Numbers:* CMS-10068 (OMB control number: 0938-0894); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,380; *Total Annual Responses:* 2,380; *Total Annual Hours:* 317. (For policy questions regarding this collection contact Nancy Conn at 410-786-8374.)

**3. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Independent Renal Dialysis Facility Cost Report Form; **Use:** Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Independent Renal Dialysis Facility Cost Report (Form CMS-265-11) cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries. The cost reports are required to be filed with the provider's Medicare Administrative Contractor (MAC). The functions of the MAC are described in section 1816 of the Social Security Act. However, the collection of data is a secondary function of the cost report. We use the data to support program operations, payment refinement activities, and to make Medicare Trust Fund projections.

*Form Numbers:* CMS-10068 (OMB control number: 0938-0894); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,380; *Total Annual Responses:* 2,380; *Total Annual Hours:* 317. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278.)

Dated: June 3, 2014.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1164]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Biological 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 July 9, 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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0687. 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](mailto: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.

#### Testing Communications on Biological Products—(OMB Control Number 0910-0687)—Extension

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational

and public information programs relating to the safety of regulated biological products. FDA conducts needed research to help ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about biological products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys. The information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about biological product use. Knowledge of consumer and health care professional decisionmaking processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using biological products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the **Federal Register** of October 1, 2013 (78 FR 60287), 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 based on prior experience with the various types of data collection methods described in this document:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| 21 U.S.C. Section 393(d)(2)(D) (various data collection methods) | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Individual Indepth Interviews .....                              | 360                   | 1                                  | 360                    | 0.75 (45 minutes) .....     | 270         |
| General Public Focus Group Interviews.                           | 288                   | 1                                  | 288                    | 1.50 (90 minutes) .....     | 432         |
| Intercept Interviews: Central Location.                          | 200                   | 1                                  | 200                    | 0.25 (15 minutes) .....     | 50          |
| Intercept Interviews: Telephone .....                            | 4,000                 | 1                                  | 4,000                  | 0.08 (5 minutes) .....      | 320         |
| Self-Administered Surveys .....                                  | 2,400                 | 1                                  | 2,400                  | 0.25 (15 minutes) .....     | 600         |
| Gatekeeper Reviews .....   | 400                   | 1                                  | 400                    | 0.50 (30 minutes) .....     | 200         |
| Omnibus Surveys .....  | 1,200                 | 1                                  | 1,200                  | 0.17 (10 minutes) .....     | 204         |
| Total (General Public) .....                                     | 8,848                 | 1                                  | 8,848                  | .....                       | 2,076       |
| Physician Focus Group Interviews ...                             | 432                   | 1                                  | 432                    | 1.50 (90 minutes) .....     | 648         |
| Total (Physician) .....  | 432                   | .....                              | .....                  | .....                       | 648         |
| Total (Overall) .....  | 9,280                 | 1                                  | 9,280                  | 0.29 (17 minutes) .....     | 2,724       |

Dated: June 3, 2014.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2014–13292 Filed 6–6–14; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
**[Docket No. FDA–2010–D–0194]**

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Safety Assurance Case**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Safety Assurance Case” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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:** On April 10, 2014, the Agency submitted a proposed collection of information entitled “Safety Assurance Case” 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 0910–0766. The approval expires on May 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 3, 2014.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2014–13291 Filed 6–6–14; 8:45 am]  
**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
**[Docket No. FDA–2014–N–0736]**

**Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA’s regulatory issues.

*Date and Time:* The meeting will be held on July 10 and 11, 2014, from 8 a.m. to 6 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special

accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6639, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On July 10 and 11, 2014, the committee will discuss the safety of laparoscopic power morcellator devices as it pertains to their potential to disseminate and upstage a confined, but undetected (occult) uterine malignancy during laparoscopic hysterectomy or myomectomy. FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of these types of devices when used for these procedures, based on available scientific data. The committee will make recommendations regarding the appropriate use, premarket testing, labeling, and other risk mitigations