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]

BILLING CODE 4160–01–P

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

(including the use of containment bags) for these devices.

On July 11, 2014, during the afternoon session, the committee will also be asked to discuss the regulatory classification of laparoscopic power morcellator devices when used to cut and extract tissue during gynecologic laparoscopic procedures and to assist FDA in determining the appropriate level of regulatory control necessary for this device type, including discussion of class II (special controls) or reclassification to class III (subject to premarket approval application (PMA)).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The Center for Devices and Radiological Health (CDRH) plans to provide a live webcast of the July 10 and 11, 2014, meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee. While CDRH is working to make webcasts available to the public for all advisory committee meetings held at the White Oak campus, there are instances where the webcast transmission is not successful; staff will work to reestablish the transmission as soon as possible. The link for the webcast is available at: *https://colaboration.fda.gov/obgyd/,* or further information regarding the webcast, including the Web address for the webcast, will be made available at least 2 days in advance of the meeting at the following Web site: *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/default.htm.* Select the link for 2014 Meeting Materials.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 24, 2014. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. for both days of this meeting. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 16, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 19, 2014.

FDA will work with the manufacturers of laparoscopic morcellators and containment bags who wish to make presentations to ensure that adequate time, separate from the approximate time slots for the general open public hearing session, is provided. Manufacturers interested in making formal presentations to the committee should notify the contact person on or before June 18, 2014. Manufacturers with common interests are urged to coordinate their oral presentations.

FDA is opening a docket for public comment on this document. The docket number is FDA–2014–N–0736. The docket will close on August 11, 2014. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Submit electronic comments to *http://www.regulations.gov.* Comments received on or before July 1, 2014, will be provided to the committee for their consideration. Comments received after July 1, 2014, will be taken into consideration by the Agency.

Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, at *Annmarie.Williams@fda.hhs.gov,* or 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13290 Filed 6–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 18, 2014, Vol. #79, page 15133 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.