

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.*  
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**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