

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IFG (States and Territories) .....	54	18	0.30	291.60
IFR: State User Guide—Foreign Countries .....	26	2	0.10	5.20
IFR: Tribal Profile Guidance .....	52	18	0.30	280.80

*Estimated Total Annual Burden Hours: 577.60.*

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Health Resources and Services Administration

### Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App. 2), notice is hereby given of the following meeting:

*Name:* Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation (MIECHVE).

*Dates and Times:* Tuesday, December 6, 2011: 9 a.m.–5 p.m. EST. Wednesday, December 7, 2011: 9 a.m.–1 p.m. EST.

*Place:* Four Points by Sheraton Washington DC Downtown, 1201 K Street NW., Washington, DC 20005. (202) 289-7600.

The Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation (Committee) will meet for its third session on December 6, 2011, from 9 a.m.–5 p.m. EST, and on December 7, 2011, from 9 a.m.–1 p.m. EST. The purpose of the meeting is to allow the Committee to comment on the progress of the evaluation design of the MIECHV program.

*Meeting Registration:* General public participants are asked to register for the conference by going to the registration Web site <http://www.regonline.com/advisorycommitteeHV>.

*Agenda:* The meeting will primarily focus on measurement issues related to the revised evaluation design. Specifically, this will include a discussion by benchmark domain/participant outcome for impact, implementation measurement, cost analysis measurement, and administrative data. Agenda items are subject to change as priorities dictate.

*Public Comments:* Members of the public may submit written comments that will be distributed to Committee

members prior to the meeting. In order to be considered, written comments should be received by Friday, December 2, 2011. Comments can be submitted via email to T'Pring Westbrook at [tpring.westbrook@acf.hhs.gov](mailto:tpring.westbrook@acf.hhs.gov).

*Special Accommodations:* Attendees with special needs requiring accommodations (such as large print materials or other reasonable adjustments) may make requests when registering at the online Web site by clicking on the "Special Accommodations" link on the registration page <http://www.regonline.com/advisorycommitteeHV>.

**FOR FURTHER INFORMATION CONTACT:** Any person interested in obtaining other relevant information can contact Carolyn Swaney via email at [cSwaney@icfi.com](mailto:cSwaney@icfi.com).

**SUPPLEMENTARY INFORMATION:** The Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation is authorized by subsection 511(g)(1) of Title V of the Social Security Act (42 U.S.C. 711(g)(1)) as amended by section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (the Affordable Care Act). The purpose of the Committee is to advise the Secretary of Health and Human Services on the design, plan, progress, and findings of the evaluation required for the home visiting program under the Affordable Care Act. More specifically, the Committee is to review, and make recommendations on, the design and plan for this evaluation; maintain and advise the Secretary regarding the progress of the evaluation; and comment, if the Committee so desires, on the report submitted to Congress under subsection 511(g)(3) of Title V.

The Department of Health and Human Services has contracted with MDRC (a nonprofit, nonpartisan education and social policy research organization formerly known as Manpower Demonstration Research Corporation), to conduct the evaluation of the MIECHV program.

As specified in the legislation, the evaluation will provide a state-by-state analysis of the needs assessments and

the States' actions in response to the assessments. Additionally, as specified in the legislation, the evaluation will provide an assessment of: (a) The effect of early childhood home visiting programs on outcomes for parents, children, and communities with respect to domains specified in the Affordable Care Act (e.g., maternal and child health status, school readiness, and domestic violence); (b) the effectiveness of such programs on different populations, including the extent to which the ability to improve participant outcomes varies across programs and populations; and (c) the potential for the activities conducted under such programs, if scaled broadly, to enhance health care practices, eliminate health disparities, improve health care system quality, and reduce costs.

Dated: November 15, 2011.

**Mary K. Wakefield,**

*Administrator, Health Resources and Services Administration.*

Dated: November 15, 2011.

**George H. Sheldon,**

*Acting Assistant Secretary, Administration for Children and Families.*

[FR Doc. 2011-29945 Filed 11-18-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-P-0176]

#### **SEDASYS Computer-Assisted Personalized Sedation System; Ethicon Endo-Surgery, Incorporated's Petition for Review of the Food and Drug Administration's Denial of Premarket Approval; 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 topic to be discussed is the Center for Device and Radiological Health's (CDRH's) denial of a premarket approval application (PMA) for the SEDASYS computer-assisted personalized sedation system (SEDASYS) submitted by Ethicon Endo-Surgery Inc. (EES)—the sponsor for SEDASYS. The meeting will be open to the public.

*Name of Committee:* Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and

recommendations to the Agency on scientific disputes between CDRH and sponsors, applicants, and manufacturers.

*Date and Time:* The meeting will be held on December 14, 2011, from 8 a.m. to 6 p.m.

*Location:* The meeting will be held at the Hilton Washington, DC/North, Salons A, B, C, and D of the Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Nancy Braier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993, (301) 796-5676, FAX: (301) 847-8510, email: [nancy.braier@fda.hhs.gov](mailto:nancy.braier@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that affect 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Registration and Presentations:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions from persons other than EES and CDRH may be made to the docket on or before December 7, 2011. 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify all written and electronic comments and submissions with the docket number found in brackets in the heading of this document. All written and electronic comments and submissions will be considered to be publicly disclosable.

Oral presentations from persons other than EES and CDRH will be scheduled between approximately 8:15 to 8:45 a.m., and 2:15 to 2:45 p.m. on December 14, 2011. If you wish to make an oral presentation during the meeting, you should register on or before November 30, 2011. Send registration information (including name, title, firm name, address, telephone, and FAX number), and requests to make oral presentations to Nancy Braier (see *Contact Person*).

You should provide the docket number appearing in the heading of this notice. You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. The amount of time to be allotted to each presenter may be limited to provide opportunities to as many persons wishing to present as possible. 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 that session. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Nancy Braier will notify interested persons regarding their request to speak by December 5, 2011. On the day of the meeting scheduled open public speakers should identify themselves at the registration desk.

After the scheduled speakers have spoken, the Chair of the advisory committee may ask them to remain if the advisory committee wishes to question them further. The Chair may recognize unscheduled speakers should time allow.

### I. Background

FDA is announcing that, in accordance with section 515(g)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e(g)(2)), a public advisory committee will review CDRH's denial of a PMA for the SEDASYS Computer-Assisted Personalized Sedation System submitted by EES—the sponsor for SEDASYS.

On March 25, 2008, EES submitted a PMA (PMA P080009) for SEDASYS. SEDASYS is an integrated patient monitoring and drug delivery system. The device's proposed indication is for the intravenous administration of 1 percent (10 milligrams per milliliter (mg/mL)) propofol injectable emulsion for the initiation and maintenance of minimal-to-moderate sedation in adult patients (American Society of Anesthesiology physical status I and II) undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures.

At a May 28, 2009 meeting, the Anesthesiology and Respiratory Therapy Devices Panel met to discuss, and provide recommendations regarding, the PMA. The panel recommended, by a vote of 8-2, that the PMA be found "approvable with conditions."