Medicare—Supplementary Medical Insurance Program)

Section 1833(t)(9)(A) of the Act (42 U.S.C. 1395l(t)(9)(A)). The Panel is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Dated: February 8, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–3643 Filed 2–15–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0123]

Design and Methodology for Postmarket Surveillance Studies Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Design and Methodology for Postmarket Surveillance Studies under Section 522 of the Federal Food, Drug and Cosmetic Act''. The purpose of the public workshop is to provide a forum for discussion among FDA, industry, governmental agencies, academia, clinicians and various stakeholders with experience in epidemiology, statistics, and biomedical research to advance the design and methodologies for medical device surveillance studies in the ''postmarket'' setting, i.e., after FDA premarket approval or clearance of the device and marketing of the device has begun.

DATES: The meeting will be held on March 7, 2012, from 8 a.m. to 5:30 p.m.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm 1503 (the Great Room), Silver Spring, MD 20993. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* The public workshop will also be available to be viewed online via webcast.

FOR FURTHER INFORMATION CONTACT: Samantha Jacobs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4201C, Silver Spring, MD 20993, 301–796–6897, email: *samantha.jacobs@fda.hhs.gov*; or Mary Beth Ritchey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4118, Silver Spring, MD 20993, 301–796–6638, email: *maryelizabeth.ritchey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: To register for the public workshop, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm289465.htm* (or go to *http://www.fda.gov* and select the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. For persons interested in attending this workshop and without Internet access, please call one of the people listed in the **FOR FURTHER INFORMATION CONTACT** section in this document in order to register. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist. There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis. Persons interesting in attending this workshop must register online by February 29, 2012. Registration is mandatory as space is limited and onsite registration will not be available. FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Susan Monahan at *susan.monahan@fda.hhs.gov* no later than March 1, 2012.

Security: Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please visit the Web site address in the **ADDRESSES** section of this document.

Streaming Webcast of the Public Workshop: This workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. on February 29, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information after March 1, 2012. If you have never attended a Connect Pro meeting before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Background: Under section 522(a) of the Federal Food, Drug and Cosmetic Act (FD&C Act), enacted by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115, § 212, 111 Stat. 2346), codified at 21 U.S.C. 360*l*(a), FDA may order a manufacturer to conduct postmarket surveillance for any Class II or Class III device (i) Intended to be implanted in the human body for more than 1 year or to be used to sustain or support life outside a device user facility, or (ii) whose failure would be reasonably likely to have serious adverse health consequences. The Food and Drug Administration Amendments of 2007 (FDAAA) (Pub. L. 110–85, § 307, 121 Stat. 865) expanded the scope of section 522 to include devices intended for pediatric use.

Agenda for the Public Workshop

1. Why are we holding this public workshop?

The purpose of the proposed workshop is to facilitate discussion among the FDA, industry, governmental agencies, academia, clinicians, and key stakeholders with experience in epidemiology, statistics, and biomedical research in the scientific community to advance the design and methodologies for medical device surveillance studies in the postmarket setting.

2. Who is the target audience for this public workshop? Who should attend this public workshop?

This workshop is open to all interested parties. The target audience is professionals in the scientific community interested in advancing the infrastructure and methodology for postmarket surveillance studies.

3. What are the topics we intend to address at the public workshop?

We intend to discuss a large number of issues at the workshop, including, but not limited to the following:

• Regulations for postmarket surveillance studies,

• Challenges and opportunities for collaborative efforts,

• Innovative methodologies and scientific infrastructure to promote innovation,

• Role of networks, registries and observational studies,

4. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cdrh/meetings.html.*

Comments: Regardless of attendance at the public workshop, interested persons may submit electronic comments, or written comments by April 6, 2012. Submit electronic comments to *http://www.regulations.gov.* Submit written comment to the Division of Dockets Management (HFA–305), Food and Drug Administration 5630 Fishers Lane, rm, 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics listed in paragraph 3 of the ''Agenda for the Public Workshop'' section of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Any written request for a transcript is to be sent to the Division of Freedom of Information. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated February 10, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2012–3606 Filed 2–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program Information System (OMB No. 0915–xxxx)—[New]

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), historic and transformative legislation designed to make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce. Through a provision authorizing the creation of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, the Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs. The MIECHV Program is designed: (1) To strengthen and improve the programs and activities carried out under Title V; (2) to improve coordination of services for at-risk communities; and (3) to identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities.

The Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended by the Patient Protection and Affordable Care Act of 2010, requires that MIECHV grantees collect data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program. The Supplemental Information Request for the Submission of the Updated State Plan for a State Home Visiting Program (SIR), published on February 8, 2011, further listed a variety of constructs under each benchmark area for which grantees were to select and submit relevant performance measures. Per Section 511(d)(1)(B)(i) of the legislation, no later than 30 days after the end of the third year of the program, grantees are required to demonstrate improvement in at least four of the six benchmark areas. The SIR and subsequent MIECHV guidance documents for both competitive and formula grants also require that grantees report annually on the constructs under each benchmark area, as well as on demographic, service utilization, budgetary and other administrative data related to program implementation.

The proposed data collection and reporting forms were developed by an internal MIECHV workgroup in consultation with Home Visiting Model Developers and selected grantees. The data collected from the proposed forms will be used to track the grantees' progress in demonstrating improvement under each benchmark area and to provide an overall picture of the population being served. The proposed data collection forms are as follows:

Form 1—Demographic and Service Utilization Data for Enrollees and Children: This form will request data to determine the unduplicated number of participants and of participant groups by primary insurance coverage. This form will also request data on the demographic characteristics of program participants. For example, data will be