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: marylizabeth.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 interested 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. Attendance 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(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:
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) 443–1061, Rockville, MD 20852. 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 are required to demonstrate improvement in at least four of the six benchmark areas. The SIR and subsequent MIECHV guidance documents identified five 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