Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *CRDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Cardiovascular and Renal Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm094743.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21041 Filed 8–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

The Sentinel Post-Licensure Rapid Immunization Safety Monitoring Program; 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 ''The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program.'' The purpose of the workshop is to describe the Sentinel Initiative and PRISM program, illustrate how PRISM is used by FDA for regulatory responsibilities (including how it has been integrated into FDA's regulatory review process and case examples), and discuss the future direction of PRISM in terms of expansion and further integration into the regulatory review process.

DATES: The public workshop will be held on December 7, 2016, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the National Institutes of Health, 8600 Rockville Pike, Lister Hill Center Auditorium, Building 38A, Bethesda, MD 20894.

FOR FURTHER INFORMATION CONTACT: Chris Nguyen, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4124, Silver Spring, MD 20993–0002; or Cynthia Whitmarsh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4122, Silver Spring, MD 20993–0002: For questions, email: *CBERPublicEvents@fda.hhs.gov* (Subject Line: Sentinel PRISM Workshop).

SUPPLEMENTARY INFORMATION: The Sentinel Initiative is FDA's national electronic surveillance system for the post-market safety monitoring of medical products. The Sentinel System was implemented as an Active Post-Market Risk Identification and Analysis program in response to section 905 of the Food and Drug Administration Amendments Act of 2007. PRISM was initiated in 2009 as one of several national vaccine safety surveillance systems deployed during the H1N1 influenza pandemic. PRISM was integrated into the FDA Sentinel Initiative in September 2010. PRISM has been used on multiple occasions to evaluate for vaccine-adverse events, such as the risk of intussusception following rotavirus vaccination, and the risk of febrile seizure among children receiving the trivalent inactivated influenza vaccine.

The PRISM distributed database covers more than 171 million individuals in a number of data partner organizations. The database is enhanced by linkages to State-wide registries and birth registries. PRISM is being used to develop broad-based signal detection tools that can be used to further evaluate vaccine safety. There are currently several active vaccine protocol-based assessments underway. More information can be found at: *http://www.mini-sentinel.org/assessments/medical_events/default.aspx.*

The workshop will bring together other government agencies, academia, industry, and other stakeholder participants involved in vaccine development and safety. The goal of the workshop is to present and discuss the current capabilities of PRISM. Topics include: (1) The available data infrastructure, (2) methods, and (3) tools. In addition, a few representative examples of PRISM studies will be presented to demonstrate the program's success in safety signal refinement and evaluation and informing the regulatory process. There will also be a discussion of possible future directions for PRISM.

Registration: Please visit the following Web site to register for the workshop by November 23, 2016, midnight Eastern Standard Time: *https://www.eventbrite.com/e/the-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system-public-workshop-tickets-22494636062.* There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been

accepted. FDA may limit the number of participants from each organization based on space limitations. Registration on the day of the public meeting will be provided on a space available basis beginning at 8:30 a.m. Those who are unable to attend the meeting in person can register to view a live Web cast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Web cast. FDA will post the agenda approximately 5 days before the workshop at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm490175.htm.*

If you need special accommodations because of disability, please contact Chris Nguyen (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm490175.htm.*

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21046 Filed 8–31–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1660]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 5, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–1660 for ''Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2648, Silver Spring, MD 20993, *aden.asefa@fda.hhs.gov,* 301–796–0400, 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