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.

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