4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3972]

Eighth Annual Sentinel Initiative; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Eighth Annual Sentinel Initiative Public Workshop." Convened by the Center for Health Policy at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an update on the state of FDA's Sentinel Initiative, including an overview of the transition from the Mini-Sentinel pilot to the full Sentinel System, and key activities and uses of the Sentinel System accomplished in 2015. In addition, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel projects.

DATES: The public workshop will be held on February 3, 2016, from 9 a.m. to 4 p.m., Eastern Standard Time (EST).

LOCATION: The public workshop will be held at the Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Ave. NW., Washington, DC 20037. For additional travel and hotel information, please refer to http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456. (FDA has verified the Web site addresses throughout this notice, but FDA

is not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register.)

There will also be a live webcast for those unable to attend the meeting in person (see Streaming Webcast of the Public Workshop).

ADDRESSES: 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-2015-N-3972 for "Eighth Annual Sentinel Initiative; Public Workshop." 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 MORE INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4343, Silver Spring, MD 20993-0002, 301-796-3714, FAX: 301-796-9832, email: SentinelInitiative@fda.hhs.gov.

REGISTRATION: To attend the public workshop, you must register before February 3, 2016, by visiting http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456. You may also register for the live webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (see FOR MORE INFORMATION CONTACT). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. A 1-hour lunch break is scheduled, but food will not be provided.

There are multiple restaurants within walking distance of the Renaissance Washington, DC Dupont Circle Hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (phone: 813-586-1201, email: jklatzman@brookings.edu) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast (archived video footage will be available following the workshop). Persons interested in viewing the live webcast must register online by February 2, 2016, at 5 p.m. EST. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

Meeting Materials: All event materials will be available to registered attendees via email before the workshop at the Eventbrite Web site at http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.

Transcripts: Please be advised that transcripts will not be available.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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