



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6230]

Tenth Annual Sentinel Initiative; 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 “Tenth Annual Sentinel Initiative Public Workshop.” The purpose of this 2-day public workshop is to bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Attendees will leave with a deeper understanding of how to use the Sentinel System tools to address safety questions.

DATES: The public workshop will be held on February 7 and 8, 2018. Day 1 of the public workshop will be held on February 7, 2018, from 9 a.m. to 4:30 p.m. Day 2 of the public workshop will be held on February 8, 2018, from 9 a.m. to 2 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at two separate locations. On Day 1 the public workshop will be held at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814. On Day 2 the public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993-0002.

Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Jamila Mwidau, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 4481, Silver Spring, MD 20993; 301-796-4989, Jamila.Mwidau@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this 2-day public workshop is to bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Day 1 will be convened by the Duke-Margolis Center for Health Policy at Duke University with support by a cooperative agreement with FDA. Key discussion topics will include an update on the state of FDA's Sentinel Initiative, key safety surveillance activities, and emerging uses of the Sentinel System. In addition, panelists, representing diverse stakeholder perspectives, will provide comments on Sentinel and opportunities to expand its analytic capabilities. This workshop will also provide an opportunity for stakeholder engagement and input on Sentinel's continued modernization.

Day 2 will be a public workshop sponsored by FDA targeting researchers who are experienced in using claims data and will build upon prior public training conducted by FDA on July 10, 2017 (82 FR 19063, April 25, 2017). This second day of the workshop will address more advanced training topics, including Sentinel's inferential analytic capabilities and methods of identifying unexpected safety concerns. Attendees will leave with a deeper understanding of how to use the Sentinel System tools to address safety questions. Attendees are encouraged to

review the material FDA presented on July 10, 2017, by visiting the website:

<https://www.sentinelinitiative.org/communications/sentinel-initiative-events/public-sentinel-training-fda>.

II. Participating in the Public Workshop

Registration: To attend the public workshop, you may register for one or both days, but you must register for each day of the workshop separately. The Duke-Margolis Center for Health Policy at Duke University will manage registration for Day 1 and FDA will manage registration for Day 2.

Day 1: To attend the public workshop on Day 1, you must register before February 6, 2018, by visiting <https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop>. 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. There is no registration fee. However, registration will be on a first-come, first-served basis because seating is limited. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of Hyatt Regency Bethesda. If you need special accommodations due to a disability, please contact Elizabeth Murphy at the Duke-Margolis Center for Health Policy (202-621-2801, email: elizabeth.g.murphy@duke.edu) no later than February 6, 2018.

Streaming Webcast for Day 1: The workshop will be webcast (archived video footage will be available following the workshop at <https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop>). Persons interested in viewing the live webcast must register online

before February 6, 2018. Early registration is recommended because webcast connections are limited. 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.

All Day 1 event materials will be available to registered attendees via email before the workshop at the Duke-Margolis website at <https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop>.

Day 2: To register to attend Day 2 of the workshop in person or virtually via webcast, you must register before February 6, 2018, by visiting: <https://www.eventbrite.com/e/february-8-2018-training-at-fda-tickets-37914164286>.

Please provide complete contact information for each attendee, including name, title, affiliation, telephone number, and email address. Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lieutenant Commander Jamila Mwidau no later than January 24, 2018.

Streaming Webcast of the Public Workshop Day 2: The FDA training public workshop will also be webcast at <https://collaboration.fda.gov/sentinelworkshop>.

If you have never attended a Connect Pro event 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 https://www.adobe.com/go/connectpro_overview.

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that transcripts of the 2-day public workshop will not be available.

Dated: November 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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