This document is scheduled to be published in the
Federal Register on 02/16/2016 and available online at
http://federalregister.gov/a/2016-02966, and on **FDsys.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0382]

Building the National Evaluation System for Medical Devices: Using Real-World Evidence to Improve Device Safety and Effectiveness; 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), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop titled "Building the National Evaluation System for Medical Devices: Using Real-World Evidence to Improve Device Safety and Effectiveness." The objective of the workshop is to discuss the scientific progress being made in harnessing evidence generated from the real-world use of medical devices to improve device safety and effectiveness. A national evaluation system for medical devices, which leverages real-world evidence, can help FDA more efficiently strike the right balance between premarket and postmarket data collection, facilitate access to medical devices, and more quickly and robustly identify safety signals that may arise in the postmarket period. The promise of using real-world evidence to promote the safety and effectiveness of medical devices can only be achieved through robust public-private partnerships and new approaches to informatics, epidemiology, biostatistics, and healthcare data systems integration.

DATES: The public workshop will be held on March 24, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The public workshop will be held at the University of Maryland, Pharmacy Hall, 20 North Pine St., Baltimore, MD 21201. For additional travel and hotel information, please refer to www.pharmacy.umaryland.edu/DeviceEval. (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).

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-0382 for "Building the National Evaluation System for Medical Devices: Using Real-World Evidence to Improve Device Safety and Effectiveness; Public Workshop; 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: Ann Anonsen, University of Maryland, Fischell Department of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301-405-0285, FAX: 304-405-9953, aanonsen@umd.edu; or Audrey Thomas, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4220, Silver Spring, MD 20993-0002, Audrey.Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to discuss the scientific progress being made in harnessing evidence generated from the real-world use of medical devices to improve device safety and effectiveness. The role that unique device identification plays in improving device evaluation, to support more informed clinical and patient decision-making, and device innovation will also be discussed.

The foundation (strategy and steps) for the development of a national evaluation system for medical devices has been developed by FDA's Center for Devices and Radiological Health (available at www.pharmacy.umaryland.edu/DeviceEval). In 2015, two multistakeholder groups issued reports that develop the science and provide recommendations that further the establishment of this system: "Building an Effective National Medical Device Surveillance System" and "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research" (available at www.pharmacy.umaryland.edu/DeviceEval).

To successfully harness relevant information from the diverse set of real-world evidence, the United States must develop the necessary infrastructure which is not yet in place today. We continue to explore ways to improve the efficiency and cost-effectiveness of data generation in traditional medical device clinical trials while maintaining data quality. The goal is to streamline the process and restore the United States to the country of first choice to conduct clinical research for medical technology innovation and ultimately bring their products first to U.S. patients. Limitations of current postmarket surveillance tools, such as passive reporting, also constrain ability to rapidly address safety concerns. A national evaluation system for medical devices, which leverages real-world evidence, can help FDA more efficiently strike the right balance between premarket and postmarket data collection, facilitate access to medical devices, and more quickly and robustly identify safety signals that may arise in the postmarket period. The promise of using real-world evidence to promote the safety and effectiveness of medical devices can only be achieved through robust public-private partnerships and new approaches to informatics, epidemiology, biostatistics, and healthcare data systems integration.

This workshop will provide clinicians, researchers, and others from the medical device industry, professional societies, health care delivery systems groups, patient advocacy groups, and FDA the opportunity to discuss this important topic.

Agenda: The agenda is located at www.pharmacy.umaryland.edu/DeviceEval.

Registration: There is a registration fee to attend this public workshop. The registration fee is charged to help defray the costs for facilities, materials, and food. Seats are limited and registration will be on a first-come, first-served basis.

To register, please complete registration online at: www.pharmacy.umaryland.edu/DeviceEval. The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representative	$50
Charitable Nonprofit and Academic Other Than University of Maryland	$50
University of Maryland, College Park and Baltimore	0
Government	0

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Ann Anonsen (see FOR FURTHER INFORMATION CONTACT).

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-02966 Filed: 2/12/2016 8:45 am; Publication Date: 2/16/2016]