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 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0407]

Proposed Pilot Project(s) Under the Drug Supply Chain Security Act; 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 ''Proposed Pilot Project(s) under the Drug Supply Chain Security Act (DSCSA).'' This public workshop will provide a forum for discussing proposed design objectives of pilot projects that will explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. FDA would like to obtain information and input from interested pharmaceutical distribution supply chain members about issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying the system attributes that are necessary to implement the requirements established under the DSCSA. The information gathered from the workshop and the public comments submitted to the docket will further inform FDA's development of its pilot project program.

DATES: The public workshop will be held on April 5, 2016, from 9 a.m. to 5 p.m. and April 6, 2016, from 9 a.m. to 12:15 p.m. The deadline for submitting either electronic or written comments on this workshop is April 21, 2016. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the confirmed 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 *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.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–0407 for ''Proposed Pilot Project(s) under the Drug Supply Chain Security Act; 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: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *CDERODSIRpublicmeetings@fda.hhs.gov* (include ''DSCSA pilot projects'' in the subject line).

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added the new sections 581 and 582 to the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee–1). Under section 582(j), FDA is required to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

FDA intends to establish a pilot project program to implement section 582(j) of the FD&C Act. The overarching goals of this program include assessing the ability of supply chain members to satisfy the requirements of section 582 and to identify, manage, and prevent the distribution of suspect and illegitimate drugs; identifying the system attributes needed to implement the requirements of section 582, particularly the requirement to utilize a product identifier for product tracing purposes; and demonstrating the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain. FDA intends to coordinate its pilot project program efforts with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors.

II. Purpose of the Public Workshop

This public workshop is intended to provide an opportunity for interested persons to provide comments on and discuss the proposed design objectives of pilot projects that will explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. FDA would like to obtain information and input from interested pharmaceutical distribution supply chain members about issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the pharmaceutical distribution supply chain, and identifying the system attributes that are necessary to implement the requirements under section 582. FDA would also like to learn more about the practices, processes, and systems that supply chain stakeholders currently use or plan to use to meet the requirements under section 582, particularly the product tracing and verification requirements. These practices, processes, and systems may include those that supply chain stakeholders would consider using in pilot projects or those that supply chain stakeholders have already used in other previous pilot projects.

By March 29, 2016, FDA will post the workshop agenda and other relevant materials under the DSCSA section of its Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm.* Supply chain stakeholders that might be interested in attending the public workshop include manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, and standards organizations. Participants at the workshop will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives.

Regardless of attendance at the public workshop, interested stakeholders may submit comments to the public docket related to any of the public workshop materials, including the agenda and other posted materials on FDA's Web site, in addition to comments specific to the design of pilot projects that will explore and evaluate methods to

enhance the safety and security of the pharmaceutical distribution supply chain. Stakeholders may comment on utilizing the product identifier for product tracing and the technical capabilities of the pharmaceutical distribution supply chain and the system attributes that are necessary to implement the requirements under section 582. The information gathered from the workshop participants and from the comments submitted to the docket for the public workshop will further inform FDA's development of its pilot project program under section 582(j) of the FD&C Act.

III. Registration for the Public Workshop

To request registration for the public workshop, provide your information including name, company or organization, address, telephone number, and email address to FDA at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm.* Registration requests should be received by March 11, 2016. FDA is limiting workshop attendance due to limited space. FDA may limit the number of participants from each organization based on space limitations. FDA recommends that each organization determine who should register for the workshop to represent his/her organization. This will help ensure that the workshop will have broad and varied representation across the pharmaceutical distribution supply chain. Registrants will receive confirmation of participation for the workshop from FDA by March 18, 2016. There is no registration fee for the public workshop. There will be no onsite registration. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop on FDA's Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm.* If you need special accommodations due to a disability, please contact Daniel Bellingham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the public workshop.

IV. Webcasting of the Public Workshop

Portions of this public workshop will be recorded and Webcasted on the day of the workshop. Information for how to access the Webcast will be available at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm* by March 29, 2016. The Webcast will be conducted in listening-mode only.

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02977 Filed 2–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0437]

Evaluation of the Safety of Drugs and Biological Products Used During Lactation; 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 ''Evaluation of the Safety of Drugs and Biological Products used during Lactation.'' The purpose of this workshop is to provide a forum to discuss the current state and future directions of the collection of data on the potential risks to breastfed infants with maternal use of medications during lactation. The workshop will review current approaches to the collection of data when drugs are used or expected to be used during lactation. The workshop will also discuss and consider novel approaches to improve the quality and quantity of data, to inform of the potential risks of medication use during lactation, and to raise awareness and engage stakeholders about communication of safety information related to maternal use of medications during lactation.

DATES: The public workshop will be held on April 27, 2016, from 8 a.m. to 5 p.m.; and April 28, 2016, from 8 a.m. to 1 p.m. Registration closes on April 8, 2016. Submit electronic or written comments to the public docket by May 28, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), 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 *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.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–0437 for ''Evaluation of the Safety of Drugs and Biological Products used during Lactation; 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