



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-3857]

Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing three public meetings entitled “Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA).” These public meetings are intended to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss with FDA, and provide input on, strategies and issues related to the enhanced drug distribution security provisions of the DSCSA.

DATES: The public meetings will be held on: August 23, 2017, from 9 a.m. to 4 p.m.; December 5 and 6, 2017, from 9 a.m. to 4 p.m.; and February 28, 2018, from 9 a.m. to 4 p.m.

ADDRESSES: The public meetings will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503A, Silver Spring, MD 20993. Entrance for the public meeting 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>.

Comments: To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. You may submit comments as follows. Please note that the deadlines for submitting either electronic or written comments are 30 days after the meeting to which the comments relate. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of the specified date. See the SUPPLEMENTARY INFORMATION section for registration dates and for the deadlines for submitting electronic or written comments related to these public meetings (table 1).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2017-N-3857 for “Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 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, 301-796-3130, CDERODSIRPublicMeetings@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they are distributed within the United States. This system will enhance FDA's ability to protect U.S. consumers from exposure to drugs that may be counterfeit, diverted, stolen, intentionally adulterated, or otherwise harmful by improving the detection and removal of potentially dangerous drugs from the drug supply chain. Section 582(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee-1(i)), which was added by the DSCSA, directs FDA to hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide opportunities for comment from stakeholders.

II. Purpose of the Public Meetings

FDA will hold public meetings on August 23, 2017, December 5 and 6, 2017, and February 28, 2018, on enhanced drug distribution security. The purpose of these public meetings is to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss with FDA, and provide input on, strategies and issues related to the enhanced drug distribution security provisions of the DSCSA. These public meetings will focus on the following topics for discussion:

- What supply chain security should look like in 2023
- What is needed for enhanced drug distribution security
- What is needed for electronic interoperability
- Standards for product tracing
- Data architecture options for an electronic interoperable system
- The management and maintenance of product tracing data

- The use of aggregation and inference for enhanced product tracing and verification
- Building capacity for a unit-level system for product tracing and verification

FDA may include additional discussion topics. Materials for each public meeting will be provided on FDA's website at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm> 10 days before each public meeting.

III. Registration for the Public Meetings

To request registration for the public meetings, provide your information including name, company or organization, address, telephone number, and email address to FDA at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm>. Registration requests for each meeting should be received during the time periods specified in table 1. FDA is limiting attendance due to restricted space. In addition, 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 public meeting to represent his/her organization. This will help ensure that the meeting will have broad and varied representation, including across the pharmaceutical distribution supply chain. Registrants will receive confirmation of participation for their chosen meeting from FDA within 14 days of the date of each meeting. There is no registration fee for the public meetings. There will be no onsite registration. If registration reaches maximum capacity, FDA will post a notice closing registration for the meeting on FDA's website at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.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 meeting.

Table 1.--Public Meeting Information

Public Meeting	Topics	Date/Time	Relevant Section of this Document or Electronic Address
# 1	<ul style="list-style-type: none"> • Supply chain security in 2023 • Enhanced drug distribution security needs 	August 23, 2017, 9 a.m. to 4 p.m.	
	Advance registration	by July 31, 2017	Online registration only at https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm No onsite registration
	Comment period closes	September 22, 2017	See “Comments”
	Request special accommodations due to a disability	by August 16, 2017	See FOR FURTHER INFORMATION CONTACT
# 2	<ul style="list-style-type: none"> • Electronic interoperability • Standards for data exchange • Data architecture • Aggregation and inference 	December 5-6, 2017, 9 a.m. to 4 p.m.	
	Advance registration	October 2-27, 2017	Online registration only at https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm No onsite registration
	Comment period closes	January 5, 2018	See “Comments”
	Request special accommodations due to a disability	by November 28, 2017	See FOR FURTHER INFORMATION CONTACT
# 3	<ul style="list-style-type: none"> • Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system 	February 28, 2018, 9 a.m. to 4 p.m.	
	Advance registration	January 2-26, 2018	Online registration only at https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm No onsite registration
	Comment period closes	March 30, 2018	See “Comments”
	Request special accommodations due to a disability	by February 21, 2018	See FOR FURTHER INFORMATION CONTACT

IV. Webcasting of the Public Meeting

Portions of each public meeting will be recorded and webcast on the day of the meeting.

Information for how to access the webcast will be available at

<https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm> within 7 days prior to each public meeting. The webcast will be conducted in listening mode only.

Dated: July 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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