

introduced or delivered for introduction into interstate commerce. The FD&C Act establishes three pathways to market for new tobacco products:

- Submission of a PMTA under section 910(b) of the FD&C Act (21 U.S.C. 387j(b)) and receipt of a marketing order under section 910(c)(1)(A)(i),
- Submission of a SE report under section 905(j)(1)(A) (21 U.S.C. 387e(j)(1)(A)) and receipt of an SE marketing order, or
- Submission of a request for an exemption from the requirements of demonstrating SE under section 905(j)(3) and receipt of an exemption from FDA (implemented at § 1107.1 (21 CFR 1107.1)).

To introduce or deliver for introduction into interstate commerce a modified risk tobacco product, there must be in effect an order under section 911(g) of the FD&C Act (21 U.S.C. 387k(g)) and the applicant must satisfy any applicable premarket review requirements under section 910 of the FD&C Act.

The draft guidance is intended to assist applicants design and conduct TPPI studies that may be submitted as part of an MRTPA, a PMTA, or a SE report. Conducting TPPI studies can assist applicants submitting tobacco product applications demonstrate that their product meets applicable requirements to receive marketing authorization under the appropriate pathway. For example, TPPI studies can be used to assess, among other things, individuals' perceptions of tobacco products, understanding of tobacco product information, and intention to use tobacco products. The draft guidance is intended to address a variety of scientific issues applicants may consider as they design and conduct TPPI studies to support tobacco product applications.

## II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on designing and conducting tobacco product perception and intention studies. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.

These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 1107.1(b) and (c) have been approved under OMB control number 0910–0684. The collections of information under section 910 of the FD&C Act have been approved under OMB control number 0910–0768. The collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673.

## IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at either <https://www.regulations.gov> or <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>.

Dated: October 22, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–N–1862]

#### The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the following virtual public meeting entitled “The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security.” The purpose of the public meeting 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 Drug Supply Chain Security Act (DSCSA) and the results of FDA's DSCSA Pilot Project Program.

**DATES:** The public meeting will be held on December 8 and 9, 2020, from 9 a.m. to 4 p.m., Eastern Time, each day, and

will take place virtually (by webcast only). Submit either electronic or written comments on this public meeting by December 28, 2020.

**ADDRESSES:** The public meeting will be held virtually and hosted by FDA. Registration to participate in this meeting and other information can be found at <https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security>. See the

**SUPPLEMENTARY INFORMATION** section for registration date and other information.

**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 late, untimely filed comments will not be considered. Electronic and written comments must be submitted on or before December 28, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2020. 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.

#### 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-2020-N-1862 for “The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

#### FOR FURTHER INFORMATION CONTACT:

Kristle Green, 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](mailto:CDERODSIRPublicMeetings@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

On November 27, 2013, the DSCSA (Title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps for building 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(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(j)), which was added by the DSCSA, directs FDA 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. Additionally, section 582(i) of the FD&C Act directs FDA to hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide opportunities for comment from members of the pharmaceutical distribution supply chain and other interested stakeholders. Section 582(h)(3) of the FD&C Act directs FDA to conduct a public meeting and issue guidance addressing the system attributes necessary to enable secure product tracing of product at the package level.

### II. Topics for Discussion at the Public Meeting

FDA will hold a virtual public meeting on December 8 and 9, 2020, on FDA’s DSCSA Pilot Project Program and

related enhanced drug distribution security issues. The purpose of this public meeting 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 and FDA’s DSCSA Pilot Project Program. The public meeting will focus on the following topics for discussion:

- Findings and lessons learned from FDA’s DSCSA Pilot Project Program.
- Other piloting or piloted activities related to DSCSA implementation.
- System attributes necessary for enabling secure product tracing of product at the package level. Examples of discussion topics include, but are not limited to, the system attributes, circumstances, and processes necessary for facilitating:

- Interoperability among trading partners in the pharmaceutical distribution supply chain, FDA, and other appropriate Federal or State official(s);
- enhanced product tracing activities involving the exchange of data in a secure manner, including management and maintenance of the data;
- the use of aggregation and inference for product tracing and/or verification; and
- enhanced verification activities involving communications between trading partners and FDA and exchange of data in a secure manner, including management and maintenance of the data.

FDA may include additional discussion topics. Materials for the public meeting will be provided on FDA’s website at <https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security> 7 days before the public meeting.

### III. Participating in the Public Meeting

*Registration:* To request registration for the public meeting, provide your information, including name, company or organization, address, telephone number, and email address, to FDA at <https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security>. FDA may limit attendance to ensure manageability of the virtual public meeting and breakout sessions. In addition, FDA may limit the number of participants from each organization to help ensure that meeting participants represent the diversity of the pharmaceutical supply chain and other stakeholders. FDA recommends that

each organization determine who should register for the public meeting to represent his/her organization.

Registrants will receive confirmation of participation for the meeting from FDA within 14 days before the meeting. There is no registration fee for the public meeting, and 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/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security>.

If you need special accommodations due to a disability, please contact Kristle Green (see **FOR FURTHER INFORMATION CONTACT**) no later than 7 days before the public meeting.

**Streaming Webcast of the Public Meeting:** Portions of the public meeting will be recorded and webcast on the day of the meeting. Information on how to access the webcast will be available at <https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security> within 7 days before the public meeting. The webcast will be conducted in listening mode only.

Dated: October 22, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-1877]

#### **Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date; Immediately in Effect Guidance for Industry, Stakeholders, Health Care Professionals, and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date." FDA is issuing this guidance to revise its compliance policy regarding the deadline for filing premarket approval (PMA) applications

for previously cleared accessories necessary to the operation of automated external defibrillator (AED) systems.

**DATES:** The announcement of the guidance is published in the **Federal Register** on October 28, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *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-2020-D-1877 for "Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date." Received comments 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring,