this screening tool will help ensure the health and safety of children and staff at care provider facilities by helping to identify and reduce potential exposure to COVID–19.

Respondents: Staff and visitors at ORR care provider facilities.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual responses per respondent	Average burden hours per response	Annual burden hours
COVID–19 Verbal Screening and Temperature Check	15,000	260	.033	128,700

Authority: 6 U.S.C. 279.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–22477 Filed 10–14–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1004]

Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a virtual public meeting entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act (DSCSA).'' This public meeting is intended to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss enhanced drug distribution security requirements of the DSCSA related to system attributes necessary to enable secure tracing of product at the package level.

DATES: The public meeting will be held on November 16, 2021, from 9 a.m. to 4 p.m., and will take place virtually. Submit either electronic or written comments on this public meeting by January 18, 2022.

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/public-meeting-enhanced-drug-distribution-security-package-level-under-drug-supply-chain-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. Please note that the deadline for submitting either electronic or written comments is 60 days after the meeting, January 18, 2022, 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 11:59 p.m. Eastern Time at the end of the specified 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–2021–N–1004 for ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; 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*.

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 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(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1(g)(1)) imposed requirements for the enhanced drug distribution security that go into effect on November 27, 2023. 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 tracing of product at the package level.

II. Topics for Discussion at the Public Meeting

FDA will hold a virtual public meeting on November 16, 2021, on enhanced drug distribution security at the package level. The purpose of this public meeting is to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to provide input to FDA on the implementation of the enhanced drug distribution security provisions of the DSCSA that go into effect in 2023. FDA requests that stakeholders prepare comments responding to the following questions for one or more of the topics listed below:

- How is implementation of the 2023 enhanced system requirements progressing for your organization?
- What challenges are your organization facing?
- Are the proposed recommendations in FDA's draft guidance entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act'' (June 2021) helpful to achieve compliance with 2023 enhanced system requirements? If not, what additional information would be useful?
- Are there areas in which FDA could provide more clarity?

Topics

1. Enhanced Drug Distribution Security
   - System Attributes
   - Aggregation, Inference, and Physical Security Features
2. System Structure
   - Data Architecture
   - Adoption of Data and System Security
   - Protecting Confidential Commercial Information and Trade Secrets
   - System Access and Data Retrieval
3. Enhanced Product Tracing
   - Serialized Transaction Information and Data Exchange (Incorporation of the Product Identifier into Product Tracing Information)
   - Responsibilities of the Selling and Buying Trading Partners in Regard to the Product Tracing Information
   - Handling Aggregation Errors and Other Discrepancies
4. Gathering of Relevant Product Tracing Information
5. Enhanced Verification
   - Verification of Distributed Product
   - Verification of Saleable Return Product
   - Alerts for Illegitimate Product
6. Trading Partner Readiness
   - Your organization's Overall Readiness for Implementation of the Enhanced Drug Distribution Security Provisions of the DSCSA That Go into Effect in 2023
   - Components That Your Organization Is Furthest Along in Developing, Including the Components Being Prioritized and the Components That Are Easier or More Challenging to Implement:

i. Technical Components
ii. Technical Infrastructure
iii. Business Processes
iv. Employee Training

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/public-meeting-enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security* 7 days before the public meeting.

III. Participating in the Public Meeting

Registration: This will be a virtual public meeting and attendance is free. Individuals who wish to attend must register on or before October 26, 2021. To register for the public meeting, provide the following information on the public meeting registration page: Your name, organization name, stakeholder type, email address, and telephone number to FDA at *https://dscsapublicmeeting2021.eventbrite.com.* There will be no onsite or same-day 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/public-meeting-enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security.*

Request for Oral Presentations: This public meeting will include public comment sessions. Individuals who wish to present during a public comment session during this meeting must register as noted at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security* and identify the topics (see section II) they wish to address in their presentation and the stakeholder group they best associate with, if any, to help FDA organize the presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Presenters should submit an electronic copy of their presentation to *CDERODSIRPublicMeetings@fda.hhs.gov* on or before November 2, 2021.

FDA will do its best to accommodate requests to present during the public

comment session and will determine the amount of time allotted for each oral presentation and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times and make available an agenda and background material at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security* on or before November 5, 2021.

If you need special accommodations due to a disability, please contact Kristle Green (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the public meeting.

IV. Post-Public Meeting Materials

FDA will provide a recording of the public meeting and materials from the meeting at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security* after the public meeting.

Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22474 Filed 10–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Cybersecurity and Infrastructure Security Agency

[Docket No. CISA–2021–0016]

Notice of President's National Security Telecommunications Advisory Committee Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of Federal Advisory Committee Act (FACA) meeting; request for comments.

SUMMARY: CISA is publishing this notice to announce the following President's National Security Telecommunications Advisory Committee (NSTAC) meeting. This meeting will be partially closed to the public.

DATES: *Meeting Registration:* Registration to attend the meeting is required and must be received no later than 5:00 p.m. Eastern Time (ET) on October 26, 2021. For more information on how to participate, please contact *NSTAC@cisa.dhs.gov.*

Speaker Registration: Registration to speak during the meeting's public comment period must be received no later than 5:00 p.m. ET on October 26, 2021.

Written Comments: Written comments must be received no later than 5:00 p.m. ET on October 26, 2021.

Meeting Date: The NSTAC will meet on November 2, 2021, from 10:00 a.m. to 3:15 p.m. ET. The meeting may close early if the committee has completed its business.

ADDRESSES: The November 2021 NSTAC Meeting's open session is set to be held in person at 1717 H Street NW, Washington, DC. Capacity and location are subject to change based on DHS protocol regarding COVID–19 pandemic restrictions at the time of the meeting. Due to pandemic restrictions, members of the public may only participate via teleconference. Requests to participate will be accepted and processed in the order in which they are received. For access to the conference call bridge, information on services for individuals with disabilities, or to request special assistance, please email *NSTAC@cisa.dhs.gov* by 5:00 p.m. ET on October 26, 2021.

Comments: Members of the public are invited to provide comment on issues that will be considered by the committee as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated materials that may be discussed during the meeting will be made available for review at *https://www.cisa.gov/nstac* on October 18, 2021. Comments should be submitted by 5:00 p.m. ET on October 26, 2021 and must be identified by Docket Number CISA–2021–0016. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Please follow the instructions for submitting written comments.
- *Email: NSTAC@cisa.dhs.gov.* Include the Docket Number CISA–2021–0016 in the subject line of the email.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the Docket Number for this action. Comments received will be posted without alteration to *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket and comments received by the NSTAC, please go to *www.regulations.gov* and enter docket number CISA–2021–0016.

A public comment period is scheduled to be held during the meeting from 2:40 p.m. to 2:50 p.m. ET. Speakers who wish to participate in the public comment period must email *NSTAC@cisa.dhs.gov* to register. Speakers should limit their comments to 3 minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, following the last request for comments.

FOR FURTHER INFORMATION CONTACT: Elizabeth Gauthier, 202–821–6620, *NSTAC@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The NSTAC was established by Executive Order (E.O.) 12382, 47 FR 40531 (September 13, 1982), as amended and continued under the authority of E.O. 13889, dated September 27, 2019. Notice of this meeting is given under FACA, 5 U.S.C. Appendix (Pub. L. 92–463). The NSTAC advises the President on matters related to national security and emergency preparedness (NS/EP) telecommunications and cybersecurity policy.

Agenda: The NSTAC will meet in an open session on Thursday, November 2, 2021, to discuss current NSTAC activities and the Government's ongoing cybersecurity and NS/EP communications initiatives. This open session will include: (1) A keynote address on fortifying the Nation's cybersecurity posture; (2) an update on Administration actions to NSTAC and joint NS/EP communications; (3) a deliberation and vote on the *NSTAC Report to the President on Software Assurance in the Information and Communications Technology and Services Supply Chain;* and (4) a status update from the NSTAC Zero-Trust and Trusted Identity Management Subcommittee.

The committee will also meet in a closed session from 10:00 a.m. to 12:00 p.m. during which time senior Government intelligence officials will provide a threat briefing concerning threats to NS/EP communications and engage NSTAC members in follow-on discussion.

Basis for Closure: In accordance with section 10(d) of FACA and 5 U.S.C. 552b(c)(9)(B), *The Government in the Sunshine Act,* it has been determined that a portion of the agenda requires closure, as the disclosure of the information that will be discussed would not be in the public interest.

This agenda item is the classified threat briefing and discussion, which will provide NSTAC members the opportunity to discuss information concerning threats to NS/EP communications with senior Government intelligence officials. The briefing is anticipated to be classified at