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)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jessica Gillum, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a document entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' The guidance document provides recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early phase clinical trial for a single disease. Sponsors have expressed interest in gathering preliminary evidence of safety and activity using multiple versions of a cellular or gene therapy product in a single clinical trial, where each version of the product is distinct and is generally submitted to FDA in a separate IND. The objective of these early phase clinical studies is to guide which version(s) of the product to pursue for further development in later phase studies. Thus, these studies are not intended to provide primary evidence of effectiveness to support a marketing application and generally are not adequately powered to demonstrate a statistically significant difference in efficacy between the study arms. The guidance provides recommendations for conducting such studies, including how to organize and structure the INDs, submit new information, and report adverse events.

In the **Federal Register** of September 30, 2021 (86 FR 54207), FDA announced the availability of the draft guidance entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early Phase Clinical Trial.'' FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifying how to continue the umbrella trial after a study arm has been closed and adding examples of changes that result in multiple versions of a cellular or gene therapy product. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2021.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial.'' 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.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 and Form FDA 1572 have been approved under OMB control number 0910–0014.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 1, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–24112 Filed 11–4–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–2671]**

### Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; 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, the Agency, or we) is announcing the following virtual public meeting entitled ''Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023'' to allow supply chain stakeholders an opportunity to share their perspectives. The topics to be discussed are stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023, standards for the interoperable data exchange of product tracing information, requests for product tracing information or verification from FDA for the purpose of investigating suspect or illegitimate products or for recalls, steps taken to build capacity for package-level tracing, pharmaceutical distribution supply chain best practices, and, in general, the impact that the Drug Supply Chain Security Act (DSCSA) requirements would have on public health, including patient safety and access to prescription drugs, and on

stakeholders, in terms of costs, benefits, and regulatory burden.

**DATES:** The public meeting will be held on December 7 and 8, 2022, from 10 a.m. to 3 p.m. eastern time and will take place virtually. Either electronic or written comments on this public meeting must be submitted by February 6, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public meeting will be held virtually and hosted by FDA.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. eastern time at the end of February 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2022–N–2671 for ''Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; 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 achieve electronic, interoperable tracing at the package level by 2023 to identify and trace certain prescription drugs as they are distributed within the United States. DSCSA requirements 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 enhanced drug distribution security that go into effect on November 27, 2023. 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. Since enactment of the law, FDA has held multiple public meetings that address specific topics as they relate to implementation of DSCSA requirements. As the capabilities of the pharmaceutical distribution supply chain have progressed and matured, this public meeting will be used to gather stakeholder perspectives on DSCSA implementation.

## II. Topics for Discussion at the Public Meeting

- Stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023.
- DSCSA standards for the interoperable data exchange of product tracing information for enhanced product tracing and verification.
- FDA requests to trading partners for product tracing information, verification for the purpose of investigations of suspect or illegitimate products, or recalls to support enhanced drug

distribution requirements under section 582(g) of the FD&C Act.

- Steps taken by the pharmaceutical distribution supply chain to build capacity for package-level tracing, including the ability of the healthcare system to maintain patient access to medicines, scalability of DSCSA requirements, and best practices.
- Technical capabilities and legal authorities, if any, needed to establish interoperable, electronic product tracing at the package level.
- General impact that the DSCSA requirements would have on public health, including patient safety and access to prescription drugs, and on stakeholders, in terms of costs, benefits, and regulatory burden.

If other topics are identified as appropriate, FDA will post these on the designated public meeting web page prior to the meeting.

**III. Participating in the Public Meeting**

*Registration:* This will be a virtual public meeting and there are no fees for this meeting. FDA may limit registration once the meeting capacity is reached. Individuals who wish to attend the general session of the public meeting must register by December 2, 2022, and 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://dscsapublicmeeting2022.eventbrite.com.* Meeting information for virtual participation will be emailed by December 5, 2022, to those that registered.

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.

*Breakout Sessions:* Any person interested in participating in small group discussions must register by November 28, 2022, following the instructions above, and indicate your request for breakout session participation. There will be no same-day registration for breakout sessions. FDA will organize breakout sessions based on registration and interest to help ensure varied stakeholder representation, including across the pharmaceutical distribution supply chain. FDA may limit the number of participants from each organization if interest exceeds breakout session capacity.

*Request for Oral Presentations:* Any person interested in presenting during the public meeting must register by November 28, 2022, following the instructions above, and indicate your request to present. There will be no same-day registration for oral presentations. FDA will do its best to accommodate requests for oral presentations. Individuals and organizations with common interests are encouraged to consolidate or coordinate their presentations and can submit a single request to present. Time allotted for each presentation will depend on the number of requests received and may be limited.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*Other Issues for Consideration:* FDA will provide a recording of the public meeting and materials from the meeting at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa-implementation-and-readiness-efforts-2023-12072022* after the public meeting.

Dated: November 2, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–24212 Filed 11–4–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Pathway to Independence Awards (K99/R00).

*Date:* December 2, 2022.

*Time:* 9:30 a.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

*Contact Person:* Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center/Room 6150/MSC 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 1, 2022.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–24115 Filed 11–4–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; 60-Day Comment Request; NCI Genomic Data Commons (GDC) Data Submission Request Form (National Cancer Institute)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Zhining Wang, Ph.D., Project Officer, Center for Cancer Genomics (CCG), National Cancer Institute, Building 31, Room 3A20, 31 Center Drive, Bethesda, MD 20814 or call non-toll-free number 301–402–1892 or Email your request, including your address to: *zhining.wang@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and suggestions from the public, and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the