Head Start's participation in or use of coordinated funding, defined as the piecing together or combining of multiple funding sources. The data collection effort will consist of two surveys: (1) a census survey of Head Start program directors (of any grant recipient with a Head Start grant, Early Head Start grant, or both, or one of their delegate programs), and (2) a census survey of three state government administrative positions in each of the 50 states and Washington, DC (the Head Start Collaboration Office Director, the administrator of state pre-kindergarten funds, and the administrator of the federal Child Care and Development Fund [CCDF]). The surveys will identify the most common approaches to coordinated funding; examine how these approaches relate to the provision of high-quality, comprehensive ECE services in Head Start programs; understand policy levers and conditions that influence Head Start programs' decisions around and ability to coordinate funding; and document how participation in coordinated funding relates to Head Start's engagement with other ECE programs and system efforts. The resulting insights will inform ACF about the prevalence of coordinated funding in Head Start, facilitators and challenges of coordinated funding for Head Start programs, and potential associations with program quality. They will also inform future case studies.

Respondents: Head Start Program Directors, state-based Head Start Collaboration Office Directors, state administrators of state pre-kindergarten funds, and state-based administrators of federal CCDF.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Program Director Survey (Head Start Program Directors or financial administrators)	1,642	1	.83	1,363
ECE State Administrator Survey (State-based Head Start Collaboration Office Directors, administrators of state pre-kindergarten funds, state-based administrators of federal CCDF)	138	1	.67	93

Estimated Total Annual Burden Hours: 1,456.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9835; 42 U.S.C. 9844.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–25607 Filed 11–17–23; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4806]

Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is publishing this request for information to better understand the status of trading partners' interoperable systems and processes for enhanced drug distribution security as required by the Food, Drug and Cosmetic Act (FD&C Act).

DATES: Although you can comment at any time, submit either electronic or written information and comments by February 20, 2024 to ensure that the Agency considers your comments for potential future actions.

ADDRESSES: You may submit information and comments 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–2023–N–4806 for ''Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act.'' 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.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4258, Silver Spring, MD 20993, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Supply Chain Security Act (DSCSA) (Pub. L. 113–54), enacted in 2013, requires trading partners—primarily manufacturers, wholesale distributors, dispensers, and repackagers—to provide, receive and maintain documentation about prescription drugs and their chain of ownership from manufacturer to dispenser as the drugs are distributed in the U.S. supply chain. Before November 27, 2023, trading partners could choose to provide and maintain such information either electronically or in paper format. However, beginning November 27, 2023, the DSCSA requirements changed to include requiring trading partners to provide, receive and maintain documentation about products and ownership only electronically using interoperable systems and processes. Under enhanced drug distribution security requirements in section 582(g)(1) of the FD&C Act (21 U.S.C. 360eee–1(g)(1)), amongst other requirements, trading partners are required to: (1) exchange transaction information and transaction statements in a secure, interoperable, electronic manner for each package; (2) implement systems and processes for package-level verification, including the standardized numerical identifier; and (3) implement systems and processes to facilitate gathering the information necessary to produce the transaction information and statement for each transaction going back to the manufacturer if FDA or a trading partner requests an investigation in the event of a recall or a suspect or illegitimate product.

In August 2023, the Agency published the ''Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies (Enhanced Drug Distribution Security Compliance Policies). (See *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhanced-drug-distribution-security-requirements-under-section-582g1-federal-food-drug-and-cosmetic.*) This guidance establishes a 1-year ''stabilization period'' to accommodate the additional time trading partners need to implement, troubleshoot, and mature their secure, interoperable, electronic systems and processes while supporting the continued availability of products to patients. Specifically, the guidance describes that, until November 27, 2024, FDA does not intend to take action to enforce requirements for the interoperable, electronic, package level product tracing under section 582(g)(1) of the FD&C Act that went into effect on November 27, 2023. In addition, FDA does not intend to take action to enforce section 582(g)(1)(B) of the FD&C Act with respect to drug product that is introduced in a transaction into commerce by the product's manufacturer or repackager before November 27, 2024, and for subsequent transactions of such product through the product's expiry.

The Enhanced Drug Distribution Security Compliance Policies are intended to provide clarity and flexibility to trading partners to help ensure continued patient access to prescription drugs as the supply chain transitions to the secure, interoperable, electronic product tracing at the package level. The guidance does not provide, and should not be viewed as providing, a justification in delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act.

Because FDA expects trading partners to use this stabilization period to continue to build and validate secure, interoperable, electronic systems and processes, we are seeking information to confirm trading partners' commitment to and progress on implementing DSCSA requirements for enhanced drug distribution security.

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on the progress of their enhanced drug distribution security implementation. This information is intended to facilitate knowledge sharing among trading partners in order to help support successful implementation of secure, interoperable, electronic product tracing at the package level by November 27, 2024. FDA is particularly interested in information related to how your current and planned implementation ensures supply chain

readiness and a stronger and safer drug supply chain including the following:

1. How are you using the stabilization period to:

a. Troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with upstream trading partners?

b. Troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with downstream trading partners?

2. What are the most significant challenges you have overcome? What strategies did you employ to overcome those challenges?

3. What aspects of your systems and processes have you successfully operationalized?

4. What are the next steps in your strategy to ensure successful implementation of the enhanced drug distribution security requirements by November 27, 2024?

Dated: November 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25609 Filed 11–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4718]

Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement

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 public meeting entitled ''Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement.'' Convened by the Duke-Robert J. Margolis, MD Center for Health Policy (Duke-Margolis) in collaboration with FDA and supported by a cooperative agreement between FDA and Duke-Margolis, the workshop will focus on how best to understand patients' experiences living with a rare disease and how to incorporate those experiences, as well as patients' priorities for treatment goals, throughout the drug development process.

DATES: The public meeting will be held virtually on December 14, 2023, from 12 p.m. to 5 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by February 12, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually using the Zoom platform.

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 12, 2024. 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–2023–N–4718 for ''Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement.'' 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: Stuti Ganatra, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 301–796–8112, *PatientFocused@fda.hhs.gov.*