III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14360 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0280 and FDA–2021–N–0371]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Financial Disclosure by Clinical Investigators	0910–0396	5/31/2025
Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites	0910–0872	5/31/2025
Infant Formula Enforcement Discretion Policy	0910–0903	11/30/2022

Dated: June 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14358 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1981]

Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Draft Guidance for Industry; 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 draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' This guidance identifies the standards necessary to facilitate adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain, and clarifies the trading partners, products, and transactions subject to such standards. This guidance is a revision of the draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information,'' issued in November 2014 as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by September 6, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2014–D–1981 for ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' 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)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Stephen Ripley, 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 revised draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' The Drug Supply Chain Security Act (DSCSA) outlines requirements for enhanced drug distribution security, which include the steps to achieve interoperable, electronic tracing of products at the package level. These requirements for enhanced drug distribution security go into effect on November 27, 2023. Section 582(g)(1) of the FD&C Act (21 U.S.C. 360eee–1(g)(1)) sets forth enhanced drug distribution security requirements for trading partners, including adherence to standards established by FDA for the exchange of transaction information and transaction statements in a secure, interoperable, electronic manner and the verification of product at the package level. Additionally, section 582(h)(4)(A) of the FD&C Act specifies that FDA issue a draft guidance, and revise the draft guidance as appropriate, to identify and make recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

In this revised draft guidance, FDA considered the standards established pursuant to sections 505D of the FD&C Act (21 U.S.C. 355e) and 582(a)(2) of the FD&C Act in the November 2014 draft guidance entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information'' (available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs*). The pilot projects conducted per section 582(j) of the FD&C Act also informed revisions made to this draft guidance.

This revised draft guidance updates the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect on November 27, 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required, unless a waiver, exception, or exemption applies. This revised draft guidance is intended to facilitate the creation of a uniform methodology for product tracing while ensuring the protection of confidential commercial information and trade secrets. FDA also published other guidances describing recommendations for enhanced drug distribution security, including the attributes necessary for enhanced product tracing and verification, which should be read in conjunction with this draft guidance (see FDA's Drug Supply Chain Security Law and Policies web page at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies*).

This draft guidance is being issued 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 ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' 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

This draft guidance includes information collection provisions that 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). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *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: June 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14342 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given for the meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention National Advisory Council (CSAP NAC) on August 8, 2022. The Council was established to advise the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and Director, CSAP concerning matters relating to the activities carried out by and through the Center and the policies respecting such activities.

The meeting will be open to the public and will consist of discussions of substance use prevention priorities and updates on CSAP program developments.

The meeting will be held via webcast and phone only. Attendance by the public on-site will not be available. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before one week prior to the meeting. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations should notify the contact on or before one week prior to the meeting. A maximum of five minutes will be allotted for each presentation, as time permits.

To participate in the meeting, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Committees' website: *https://snacregister.samhsa.gov,* or communicate with the CSAP Council's Designated Federal Officer (see contact information below).

Substantive program information may be obtained after the meeting by accessing the SAMHSA Committee website, *https://www.samhsa.gov/about-us/advisory-councils/csap-national-advisory-council,* or by contacting the Designated Federal Officer.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/Time/Type: August 8, 2022, from 12:00 p.m. to 4:00 p.m. EDT: (Open).

Place: (Virtual). For Webcast information: please register at the SAMHSA Committees' website, listed above.

Contact: Michelle McVay, Designated Federal Officer, SAMHSA CSAP NAC, 5600 Fishers Lane, Rockville, MD 20852, Telephone: 240–276–0446, Email: *michelle.mcvay@samhsa.hhs.gov.*

Dated: June 29, 2022.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2022–14311 Filed 7–5–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency; Department of Homeland Security.

ACTION: Notice; correction.

SUMMARY: On June 1, 2022, FEMA published in the **Federal Register** a changes in flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table to be used in lieu of the erroneous information. The table provided here represents the changes in flood hazard determinations and communities affected for the City of Margaret and Unincorporated Areas of St. Clair County, Alabama.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 1, 2022, in FR Doc. 2022–11679, in the table on page 33186, the entries for Alabama: St. Clair County are corrected to read as follows (after the signature):

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.