431.428 and in accordance with a framework to be provided by CMS. The STCs also provide that the monitoring framework be subject to change as monitoring systems are developed and evolve, and that states are required to report in a structured manner that supports federal tracking and analysis.

In this 2022 information collection request, we have revised the following monitoring tools:

- Monitoring protocol tools:
  - Monitoring protocol workbook (updated to Version 6.0)
  - Monitoring protocol template (updated to Version 4.0)
- Monitoring report tools:
  - Monitoring report template (updated to Version 4.0)
  - Monitoring report workbook (updated to Version 6.0)

This 2022 release incorporates updated guidance on reporting metrics, narrative information, and other clarifications. This release also reflects modifications to align with the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics Manual Version 4.0 (released September 2021).

In addition, this release incorporates updated functionality in the Performance Metrics Database & Analytics (PMDA) system aimed to automate aspects of reporting and customize tools to ease state burden. Updated functionality includes:

- Auto-population of certain fields within the monitoring report tools in alignment with the state's CMS-approved monitoring protocol.
- Reporting flagged items early in the process to reduce resubmission and allow CMS to engage with the state faster and on a more detailed level.
- Ensuring the latest version of the monitoring tools are utilized by sending an email notification to all designated demonstration contacts when customized monitoring report tools are available.

Form Number: CMS–10398 (#57) (OMB control number: 0938–1148); *Frequency:* Once, yearly, and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Total Annual Responses:* 596; *Total Annual Hours:* 6,394. For policy questions regarding this collection contact: Danielle Daly at 410–786–0897.

Dated: February 18, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–03936 Filed 2–23–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0013]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with the sanitary transportation of human and animal food.

DATES: Submit either electronic or written comments on the collection of information by April 25, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 25, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 25, 2022. 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–2013–N–0013 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Sanitary Transportation of Human and Animal Food.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Sanitary Transportation of Human and Animal Food—21 CFR Part 1, Subpart O

OMB Control Number 0910–0773—Extension

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. The regulations are intended to focus on preventing food safety problems throughout the food chain and were issued under the Sanitary Food Transportation Act of 2005 (2005 SFTA), and the FDA Food Safety Modernization Act, enacted in 2011. The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), in part, by creating section 416 (21 U.S.C. 350e), which directs us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416 also directs that we prescribe appropriate human and animal food transportation practice requirements relating to: (1) Sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping.

In addition, the 2005 SFTA created section 402(i) of the FD&C Act (21 U.S.C. 342(i)), which provides that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated and section 301(hh) of the FD&C Act (21 U.S.C. 331(hh)), which prohibits the failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the regulations issued under section 416.

The 2005 SFTA also amended section 703 of the FD&C Act (21 U.S.C. 373) by providing that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416.

Accordingly, we issued regulations in 21 CFR part 1, subpart O (21 CFR 1.900 through 1.934) that establish requirements for the sanitary transportation of human and animal food, as well as prescribe procedures for respondents who wish to request a waiver for any requirement. For additional information regarding Agency implementation of the SFTA, visit our website at *https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/sanitation-transportation-guidance-documents-regulatory-information.*

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.912; Record retention	1,502,032	1	1,502,032	0.083 (5 minutes)	124,669

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate an annual recordkeeping burden of 124,669, which assumes 1,502,032 workers will spend an average of 5 minutes on activities related to the record retention requirements under 21 CFR 1.912. We expect these activities will likely include documenting procedures and training, as well as sanitary transportation operations and specification requirements.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.914; Waiver petitions	2	1	2	24	48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1.908; Disclosure of sanitary specifications; operating temperature conditions.	226	1	226	0.5833 (~35 minutes)	132

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Finally, we estimate an annual third-party disclosure burden of 132 hours, assuming each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under 21 CFR 1.908.

Based on an evaluation of the information collection, we have made no adjustments to our burden estimate.

Dated: February 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03916 Filed 2–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2252]

Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act; 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 ''Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (BsUFA)'' (the Program) and an opportunity for public comment. The topics to be discussed are the final assessment and public stakeholder views of the Program.

DATES: The public meeting will be held on March 22, 2022, from 9:30 a.m. to 12:30 p.m. Eastern Time and will be held by webcast only. Submit either electronic or written comments on this public meeting by May 23, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://www.eventbrite.com/e/public-meeting-on-the-final-assessment-of-the-bsufa-ii-program-tickets-229459628927.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 23, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 23, 2022. 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–2252 for ''Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (BsUFA); 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