

information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 201.56 and 201.57 pertaining to prescription product labeling requirements have been approved under OMB control number 0910–0572; the collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139; the collections of information in section 351(k) of the PHS Act pertaining to biosimilar and interchangeable biosimilar product applications have been approved under OMB control number 0910–0718; and the collections of information in section 351 of the PHS Act and 21 CFR part 601 have been approved under OMB control number 0910–0338.

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Persons with access to the internet may obtain the draft guidance at 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: July 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16128 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0795]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled “Electronic Records: Electronic Signatures” has been approved by the Office of Management and Budget (OMB) under

the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

On December 21, 2023, the Agency submitted a proposed collection of information entitled “Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising” to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0929. The approval expires on June 30, 2027. A copy of the supporting statement for this information collection is available on the internet at <https://www.reginfo.gov/public/do/PRAMain>.

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16096 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2931]

Agency Information Collection Activities; Proposed Collection; Comment Request; Microbiological Testing and Corrective Measures for Bottled Water

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which both domestic and foreign bottled

water manufacturers that sell bottled water in the United States maintain records of microbiological testing and corrective measures, in addition to existing recordkeeping requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by September 23, 2024.

ADDRESSES: 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 September 23, 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–2024–N–2931 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water.” 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.

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FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, 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.

Microbiological Testing and Corrective Measures for Bottled Water—21 CFR 129.35(a)(3)(i), 129.80(g), and 129.80(h)

OMB Control Number 0910–0658—Extension

This information collection supports FDA regulations. The bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) require that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, followup testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli* (*E. coli*). The adulteration provision of the bottled water standard (21 CFR 165.110(d)) provides that a finished product that tests positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.342(a)(3)). In addition, the current good manufacturing practice (CGMP) regulations for bottled water in part 129 require that source water from other than a public water system be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, bottled water manufacturers are required to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality and would be unsuitable for bottled water production. Before a bottler may use source water from a source that has tested positive for *E. coli*, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site are tested and found to be *E. coli* negative.

Description of Respondents: The respondents to this information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
129.35(a)(3)(i), 129.80(h); bottlers subject to source water and finished product testing.	319	6	1,914	0.08 (5 minutes) ...	153
129.80(g), 129.80(h); bottlers testing finished product only	95	3	285	0.08 (5 minutes) ...	23
129.35(a)(3)(i), 129.80(h); bottlers conducting secondary testing of source water.	3	5	15	0.08 (5 minutes) ...	1

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
129.35(a)(3)(i), 129.80(h); bottlers rectifying contamination	3	3	9	0.25 (15 minutes)	2
Total					179

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. We therefore conclude that any additional burden and costs in recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for *E. coli* are negligible.

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16100 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council on Migrant Health (NACMH or Council) has scheduled a public meeting.

DATES: October 22, 2024, 8:30 a.m.–5:00 p.m. Eastern Time and October 23, 2024, 8:30 a.m.–5:00 p.m. Eastern Time.

ADDRESSES: This meeting will be held in-person and via webinar. The address of the meeting is 5600 Fishers Lane, Rockville, MD 20857. Instructions for joining the meeting by webinar will be posted on the NACMH website 30 business days before the meeting date. For meeting information updates, go to the NACMH website at [https://](https://www.hrsa.gov/advisory-committees/migrant-health)

www.hrsa.gov/advisory-committees/migrant-health.

FOR FURTHER INFORMATION CONTACT: Liz Rhee, NACMH Designated Federal Official (DFO), Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, Rockville, MD 20857; 301–443–1082 or hrsabphcoppdnacmh@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACMH advises, consults with, and makes recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under section 217 of the Public Health Service Act, as amended (42 U.S.C. 218). Specifically, NACMH provides recommendations concerning policy related to the organization, operation, selection, and funding of migrant health centers and other entities that receive grants and contracts under section 330 of the Public Health Service Act (42 U.S.C. 254b). NACMH meets twice each calendar year, or at the discretion of the DFO, in consultation with the NACMH Chair.

The agenda items for the October meeting will include topics and issues related to migratory and seasonal agricultural worker health, including impacts of heat and wildfire smoke, farmworker data, and best practices for fostering partnerships between farmworkers, health centers, growers, and community organizations. Refer to the NACMH website listed above for all current and updated information concerning the October 2024 NACMH meeting, including a draft agenda that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide written comments to the Council prior to the meeting. Written statements should be sent to Liz Rhee, DFO, using the contact information above, at least 3 business days prior to the meeting. All public comments will be reviewed by the Council for consideration during the meeting, as time permits.

Individuals who plan to attend and need special assistance or another reasonable accommodation should

notify Liz Rhee using the contact information listed above at least 10 business days prior to the meeting. Registration is required to attend the meeting. Registration and meeting attendance instructions will be posted on the NACHM website 30 business days prior to the meeting date. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–16119 Filed 7–22–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Literature Selection Technical Review Committee.

The meeting will be open to the public as indicated below. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

The meeting is devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine and will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the