

20993–0002, 240–506–4946, respectively at [CBERVBPAC@fda.hhs.gov](mailto:CBERVBPAC@fda.hhs.gov); or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before joining the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2022–2023 influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before February 23, 2022, will be provided to the committee. Comments received after February 23, 2022, and by March 2, 2022, will be taken into consideration by FDA. Oral presentations from the public will be scheduled on March 3, 2022, between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to

present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 17, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 18, 2022.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya (see **FOR FURTHER INFORMATION CONTACT**), at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 19, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–01368 Filed 1–24–22; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–N–4130]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping Requirements for 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 that a proposed collection

of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by February 24, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0658. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Recordkeeping Requirements for 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*

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.

In the **Federal Register** of November 1, 2021 (86 FR 60258), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

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) and 129.80(h); bottlers subject to both source water and finished product testing.	319	6	1,914	0.08 (5 minutes) ...	153
§ 129.80(g) and (h); bottlers only subject to finished product testing.	95	3	285	0.08 (5 minutes) ...	23
§§ 129.35(a)(3)(i) and 129.80(h); bottlers conducting secondary testing of source water.	3	5	15	0.08 (5 minutes) ...	1
§§ 129.35(a)(3)(i) and 129.80(h); bottlers rectifying contamination.	3	3	9	0.25 (15 minutes)	2
Total .....	.....	.....	.....	.....	179

<sup>1</sup> 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: January 19, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-01370 Filed 1-24-22; 8:45 am]

BILLING CODE 4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Tribal Management Grant Program**

*Announcement Type:* New.

*Funding Announcement Number:* HHS-2022-IHS-TMD-0001.

*Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:* 93.228.

*Key Dates*

*Application Deadline Date:* April 25, 2022.

*Earliest Anticipated Start Date:* June 9, 2022.

**I. Funding Opportunity Description**

**Statutory Authority**

The Indian Health Service (IHS) is accepting applications for grants for the Tribal Management Grant (TMG) Program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Self-Determination and Education Assistance Act (ISDEAA), Public Law (Pub. L.) 93-638, as amended, 25 U.S.C. 5322(b)(2) and 25 U.S.C. 5322(e). This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as the CFDA) under 93.228.

**Background**

The TMG Program is a competitive grant program that is capacity building and developmental in nature and has been available for federally recognized Indian Tribes and Tribal Organizations (T/TO) since shortly after enactment of the ISDEAA in 1975. The TMG Program was established to assist T/TOs to prepare for assuming all or part of existing IHS programs, functions, services, and activities (PFSAs) and further develop and improve Tribal health management capabilities. The TMG Program provides competitive grants to T/TOs to establish goals and performance measures for current health programs, assess current management capacity to determine if new

components are appropriate, analyze programs to determine if a T/TO's management is practicable, and develop infrastructure systems to manage or organize PFSAs.

**Purpose**

The purpose of this program is to enhance and develop health management infrastructure and assist T/TOs in assuming all or part of existing IHS PFSAs through a Title I ISDEAA contract and assist established Title I ISDEAA contractors and Title V ISDEAA compactors to further develop and improve management capability. In addition, Tribal Management Grants are available to T/TOs under the authority of 25 U.S.C. 5322(e) for the following:

1. Obtaining technical assistance from providers designated by the T/TO (including T/TOs that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management, and the development of cost allocation plans for indirect cost rates.

2. planning, designing, monitoring, and evaluating Federal programs serving T/TOs, including Federal administrative functions.

**II. Award Information**

**Funding Instrument—Grant**

**Estimated Funds Available**

The total funding identified for fiscal year (FY) 2022 is approximately \$2,465,000. Individual award amounts