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.

In the **Federal Register** of July 23, 2024 (89 FR 59742), FDA published a 60-day notice requesting public comment on the proposed collection of information. Five comments were received, of which one was PRA-related and supported necessity and practical utility of the FDA's recordkeeping requirements in this collection of information. Four comments were not related to the PRA and will not be addressed here.

FDA estimates the burden of this collection of information 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
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
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: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07629 Filed 5–1–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform

Correction

In notice document 2025–06878 beginning on page 16878 in the issue of Tuesday, April 22, 2025, make the following correction:

On page 16878, in the second column, in the fifth line from the bottom, ''April 22, 2025'' should read ''May 7, 2025''.

[FR Doc. C1–2025–06878 Filed 5–1–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.