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]

BILLING CODE 4164–01–P

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]

BILLING CODE 0099–10–D

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.

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) publishes a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the **Federal Register** during the first week of each month, in accordance with Section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and Section 9.17 of the Mandatory Guidelines using Oral Fluid. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list.*

HHS separately notifies Federal agencies of the laboratories and IITFs currently certified to meet the standards of the Mandatory Guidelines using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70768).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020, and subsequently revised in the **Federal Register** on October 12, 2023 (88 FR 70814).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid effective October 10, 2023 (88 FR 70814), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare*, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Desert Tox, LLC, 5425 E Bell Rd, Suite 125, Scottsdale, AZ, 85254, 602–457–5411/623–748–5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088. Testing for Veterans Affairs (VA) Employees Only

Omega Laboratories, Inc.*, 2150 Dunwin Drive, Unit 1 & 2, Mississauga, ON, Canada L5L 5M8, 289–919–3188
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)
Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840
U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

The following laboratory is voluntarily withdrawing from the National Laboratory Certification Program effective January 10, 2025:

Laboratory Corporation of America, 1225 NE 2nd Ave., Portland, OR 97323, 503–413–5295/800–950–5295, (Formerly: Legacy Laboratory Services Toxicology MetroLab)

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories continued under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory as meeting the minimum standards of the current Mandatory Guidelines published in the **Federal Register**. After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program. DOT established this process in July 1996 (61 FR 37015) to allow foreign laboratories to participate in the DOT drug testing program.

Anastasia D. Flanagan,

Public Health Advisor, Division of Workplace Programs.

[FR Doc. 2025–07627 Filed 5–1–25; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–1066]

Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Infrastructure Investment and Jobs Act; Fiscal Year 2024

ACTION: Notice.

SUMMARY: The Coast Guard is publishing this notice to satisfy a requirement of the Infrastructure Investment and Jobs Act that requires a detailed accounting of the projects, programs, and activities funded under the national recreational boating safety program provision of the Act be published annually in the **Federal Register**. This notice specifies the funding amounts the Coast Guard has committed, obligated, or expended during fiscal year 2024, as of September 30, 2024.

FOR FURTHER INFORMATION CONTACT: For questions on this notice please contact Mr. Jeff Decker, U.S. Coast Guard, Regulations Development Manager, (571) 607–8235 or mail to: *RBSInfo@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Since 1998, Congress has passed a series of laws providing funding for projects, programs, and activities funded under the national recreational boating safety program, which is administered by the U.S. Coast Guard. On November 15, 2021, the Infrastructure Investment and Jobs Act (Pub. L. 117–58, Sec. 28001) set aside funding for Coast Guard administration, which for fiscal year 2024 was $15.061 million. Of that, not less than $2.1 million shall be made available to ensure compliance with Chapter 43 of Title 46, U.S. Code, and not more than $1.5 million is available to conduct by grant or contract a survey of levels of recreational boating participation and related matters in the United States.

These funds are available to the Secretary from the Sport Fish Restoration and Boating Trust Fund (Trust Fund) established under 26 U.S.C. 9504(a) for payment of Coast Guard expenses for personnel and activities directly related to coordinating and carrying out the national recreational boating safety program. Amounts made available under this subsection remain available during the two succeeding fiscal years. Any amount that is unexpended or unobligated at the end of the three-year period during which it is available shall be withdrawn by the Secretary and allocated to the States in addition to any other amounts available for allocation in the fiscal year in which they are withdrawn or the following fiscal year.

Use of these funds requires compliance with standard Federal contracting rules with associated lead and processing times resulting in a lag time between available funds and spending.

Specific Accounting of Funds

The total amount of funding transferred to the Coast Guard from the Sport Fish Restoration and Boating Trust Fund and committed, obligated, and/or expended during fiscal year 2024 for each project is shown in the chart below.

Project	Description	Cost
46 U.S.C. 43 Compliance: Inspection Program/Boat Testing Program.	Provided for continuance of the national recreational boat compliance inspection program, which began in January 2001.	$2,484,775
46 U.S.C. 43 Compliance: Staff Salaries	Provided for 3 personnel to oversee manufacturer compliance with 46 USC 43 requirements.	608,472
46 U.S.C. 43 Compliance: Staff Travel	Provided for travel by employees of the Boating Safety Division to oversee manufacturer compliance with 46 USC 43 requirements.	90,124
Administrative Overhead	Provide for supplies and Materials to support the RBS Program	95,649
Boating Accident Report Database (BARD) Web System.	Provided for maintaining the BARD Web System, which enables reporting authorities in the 50 States, five U.S. Territories, and the District of Columbia to submit their accident reports electronically over a secure Internet connection.	117,388