

Agency issued an interim final rule controlling the product under section 201(j) of the Controlled Substances Act on October 31, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application(s) for patent extension, this applicant seeks 69, 954, 1,045, or 1,294 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2026–00026 Filed 1–5–26; 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) provides notice 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** monthly, 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>.

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-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)

Note: DOT does not allow IITFs to test DOT-regulated specimens.

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

Anastasia D. Flanagan,
Public Health Advisor, Division of Workplace Programs.

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DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NERO-CACO-39905; PPNECACOS0, PMPD1Z.YM0000]

Request for Nominations for the Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior, is requesting nominations for qualified persons to serve as members of the Cape Cod National Seashore Advisory Commission (Commission).

DATES: Written nominations must be postmarked by February 5, 2026.

ADDRESSES: Nominations should be sent to Jennifer Flynn, Superintendent and Designated Federal Officer, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, Massachusetts 02667, or at (508) 771-2144 or via email to CACO_Superintendent@nps.gov.

FOR FURTHER INFORMATION CONTACT: Jennifer Flynn, via telephone (508) 771-2144. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make

international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Commission was established by section 8 of Public Law 87-126, as amended, and expired on September 26, 2018. The Commission was reestablished by Div. DD, title VI, subtitle B, section 613 of Public Law 117-328, the Consolidated Appropriations Act, 2023. The Commission's new termination date is September 26, 2029. The purpose of the Commission is to consult with the Secretary of the Interior, or his designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of the Act establishing the Seashore.

The Commission is composed of 10 members appointed by the Secretary of the Interior for 2-year terms, as follows: (a) six members from recommendations made by the boards of selectmen of the towns of Chatham, Eastham, Orleans, Provincetown, Truro and Wellfleet, in the Commonwealth of Massachusetts, one member from the recommendations made by each such board; (b) one member from recommendations of the county commissioners of Barnstable County, Commonwealth of Massachusetts; (c) two members from recommendations of the Governor of the Commonwealth of Massachusetts; and (d) one member appointed at the discretion of the Secretary.

The NPS is seeking nominees to represent the Town of Truro, Barnstable County and a member appointed at the discretion of the Secretary.

The individual selected to serve at the discretion of the Secretary will be appointed as a Special Government Employee (SGE). Individuals selected from the other categories will be appointed as representative members. Please be aware that members selected to serve as SGEs will be required, prior to appointment, to file a Confidential Financial Disclosure Report in order to avoid involvement in real or apparent conflicts of interest. You may find a copy of the Confidential Financial Disclosure Report and more information about ethics requirements for SGEs at the following website: <https://www.doi.gov/ethics/special-government-employees>. Additionally, after appointment, members appointed as SGEs will be required to meet applicable financial disclosure and ethics training requirements annually. Please contact 202-208-7960 or DOI_Ethics@sol.doi.gov with any questions about the ethics requirements for members appointed as SGEs.

Nominations received by the park will be sent directly to local municipalities