

increase of any size must continue to submit an actuarial memorandum (Part III of the Rate Filing Justification). *Form Number:* CMS-10379 (OMB control number: 0938-1141); *Frequency:* Annually; *Affected Public:* Private Sector; Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 626; *Total Annual Responses:* 820; *Total Annual Hours:* 17,788. (For policy questions regarding this collection contact Lisa Cuzzo at 410-786-1746.)

Dated: November 1, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022-24098 Filed 11-3-22; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Administration for Children and Families Uniform Project Description

AGENCY: Office of Administration, Office of Grants Policy, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a revision of the approved ACF Uniform Project Description (UPD) (Office of Management and Budget (OMB) # 0970-0139, expiration March 31, 2025).

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review-Open for Public Comments" or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed information collection would revise the approved ACF UPD. The UPD provides a uniform format for applicants to submit project information in response to ACF discretionary Notices of Funding

Opportunity. The UPD requires applicants to describe how program objectives will be achieved and provide a rationale for the project's budgeted costs. All ACF discretionary grant programs are required to use the UPD.

ACF uses this information, along with other OMB-approved information collections (Standard Forms), to evaluate and rank applications. Use of the UPD protects the integrity of the ACF award selection process.

The UPD has been revised as follows:

(1) included a text field for the Geographic Location standardized text, which will allow ACF program offices to enter project-specific language; (2) under Organizational Capacity, inserted an option to allow submission of an Audit Summary report in lieu of a full audit report; (3) inserted a checkbox and standardized language to request current and pending funding support; (4) added a prior written approval requirement to Plan for Oversight of Federal Award Funds and Activities; (5) included Memoranda of Agreement (MOA) under Third Party Agreements; and (6) updated The Project Budget and Budget Justification standardized language related to salary limitation, budget preparation, fringe benefits, definition of supplies, contractual costs, accounting for real property, the Other Costs category, and Indirect Costs.

Respondents: Applicants responding to ACF Discretionary Notices of Funding Opportunity.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF Uniform Project Description	3,218	1	60	193,080

Estimated Total Annual Burden Hours: 64,360.

Authority: 45 CFR 75.203 and 75.204, and 45 CFR part 75, appendix I.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022-23976 Filed 11-3-22; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUs) (the

Authorizations) issued to Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute (Cleveland Clinic) for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorizations for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR are revoked as of October 19, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the

SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT:

Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On August 3, 2020, FDA issued an EUA to Cleveland Clinic for the Cleveland Clinic SARS-CoV-2 Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was

published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On August 9, 2021, FDA issued an EUA to Cleveland Clinic for the SelfCheck COVID-19 TaqPath Multiplex PCR, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on October 28, 2021 (86 FR 59738), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

In a request received by FDA on October 7, 2022, Cleveland Clinic requested revocation of, and on October 19, 2022, FDA revoked, the Authorization for the Cleveland Clinic SARS-CoV-2 Assay. Because Cleveland Clinic notified FDA that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future and requested FDA revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay, FDA has determined that

it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on October 7, 2022, Cleveland Clinic requested revocation of, and on October 19, 2022, FDA revoked, the Authorization for the SelfCheck COVID-19 TaqPath Multiplex PCR. Because Cleveland Clinic notified FDA that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR and does not plan to use it in the future and requested FDA revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov/>.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs of Cleveland Clinic for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164-01-P



FDA U.S. FOOD & DRUG
ADMINISTRATION

October 19, 2022

Susan Harrington, Ph.D.
Medical Director
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195
Re: Revocation of EUA200313

Dear Dr. Harrington:

This letter is in response to the request from Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute ("Cleveland Clinic"), received via email on October 7, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay issued on August 3, 2020, and amended on January 19, 2021, and September 23, 2021. Cleveland Clinic indicated that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cleveland Clinic has notified FDA that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future and requested FDA revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200313 for the Cleveland Clinic SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cleveland Clinic SARS-CoV-2 Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration



**FDA U.S. FOOD & DRUG
ADMINISTRATION**

October 19, 2022

Susan Harrington, Ph.D.
Medical Director
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195
Re: Revocation of EUA210363

Dear Dr. Harrington:

This letter is in response to the request from Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute ("Cleveland Clinic"), received via email on October 7, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR assay issued on August 9, 2021. Cleveland Clinic indicated that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR assay and does not plan to use it in the future.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cleveland Clinic has notified FDA that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR assay and does not plan to use it in the future and requested FDA revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210363 for the SelfCheck COVID-19 TaqPath Multiplex PCR assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SelfCheck COVID-19 TaqPath Multiplex PCR assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Dated: October 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-24072 Filed 11-3-22; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant
Secretary for Health, Office of the

Secretary, Department of Health and
Human Services.

ACTION: Notice; revision to meeting date.

SUMMARY: The Office of the Assistant Secretary for Health published a notice in the **Federal Register** on September 16, 2022, concerning a meeting of the Tick-Borne Disease Working Group (TBDWG) that was scheduled to occur on December 7, 2022. This notice is being amended to announce that the meeting has been rescheduled to November 21, 2022. This will be the final TBDWG meeting.

DATES: The meeting date announced in the **Federal Register** at 87 FR 5693 on September 16, 2022 is amended. The public can view the meeting online via webcast on November 21, 2022 from approximately 10 a.m. to 12 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> when this information becomes available.