the size and composition of the RHC survey team and AAAASF's comparable criteria on determining the parameters for each survey to be comparable to those of the State Survey Agency as outlined per § 488.5(a)(4).

B. Term of Approval

Based on our review and observations described in section III. of this final notice, we approve AAAASF as a national accreditation organization for RHCs that request participation in the Medicare program. The decision announced in this final notice is effective March 23, 2022 through March 23, 2026. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID–19) Public Health Emergency (PHE), CMS was unable to observe an RHC survey completed by AAAASF surveyors as part of the application review process, which is typically one component of the comparability evaluation. Therefore, we are providing AAAASF with a shorter period of approval. Based on our discussions with AAAASF and the information provided in its application, we are confident that AAAASF will continue to ensure that its accredited RHCs will continue to meet or exceed the required standards. While AAAASF has taken actions based on the findings noted in section IV. of this final notice (Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements), as authorized under § 488.8, we will continue ongoing review of AAAASF's RHC survey processes and will conduct a survey observation once the COVID–19 PHE has expired.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 16, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–05910 Filed 3–18–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0412]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device 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 Authorization (EUA) (the Authorization) issued to Abbott Diagnostics Scarborough, Inc. (Abbott) for the BinaxNOW COVID–19 Ag Card 2 Home Test. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the BinaxNOW COVID–19 Ag Card 2 Home Test is revoked as of February 24, 2022.

ADDRESSES: Submit a written request for a single copy of the revocation 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

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, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) 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 March 31, 2021, FDA issued an EUA to Abbott for the BinaxNOW COVID–19 Ag Card 2 Home Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization 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 Request

In a request received by FDA on February 21, 2022, Abbott requested revocation of, and on February 24, 2022, FDA revoked, the Authorization for the BinaxNOW COVID–19 Ag Card 2 Home Test. Because Abbott notified FDA that the EUA for BinaxNOW COVID–19 Ag Card 2 Home Test is no longer required and requested FDA revoke the EUA for the BinaxNOW COVID–19 Ag Card 2 Home Test, 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 revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Abbott for the BinaxNOW COVID–19 Ag Card 2 Home Test. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

February 24, 2022

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074
Re: Revocation of EUA210272

Dear Ms. Drysdale:

This letter is in response to the request from Abbott Diagnostics Scarborough, Inc. ("Abbott"), received via email on February 21, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the BinaxNOW COVID-19 Ag Card 2 Home Test issued on March 31, 2021 and amended on September 23, 2021 and January 7, 2022. FDA understands no product was distributed under the EUA. Abbott indicated that authorization of the BinaxNOW COVID-19 Ag Card 2 Home Test is no longer required, in consideration of Abbott's product available under another EUA issued to Abbott.

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 Abbott has notified FDA that the EUA for BinaxNOW COVID-19 Ag Card 2 Home Test is no longer required and requested FDA revoke the EUA for the BinaxNOW COVID-19 Ag Card 2 Home Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210272 for the BinaxNOW COVID-19 Ag Card 2 Home Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BinaxNOW COVID-19 Ag Card 2 Home Test 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/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: March 15, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

[FR Doc. 2022–05892 Filed 3–18–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Molecular Entity New Drug Applications and Original Biologics License Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in