document instructs that Custom Device Annual Reports should be written in English and explains that respondents should direct two copies, including at least one hard copy, to:

Attn: Custom Device Annual Report Submission Coordinator, Division of Analysis and Program Operations, Office of Compliance, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Bldg. 66, Rm. 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

Although the submission of Custom Device Annual Reports are not required electronically, we strongly encourage submitting one of the two required copies as an eCopy (*i.e.,* a PDF file on a CD, DVD, or flash drive). Technical instructions are also provided in the guidance document entitled ''eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff'' (April 2020); available for download at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf* for more information about submitting an eCopy.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reporting for custom devices under 520(b) of the FD&C Act	34	1	34	40	1,360

[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.

Dated: March 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05051 Filed 3–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0973]

Revocation of Three 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 (EUAs) (the Authorizations) issued to Abbott Diagnostics Scarborough, Inc. (Abbott) for the BinaxNOW COVID–19 Ag 2 Card, and Standard BioTools, Inc. (Standard) for the Advanta Dx SARS–CoV–2 RT–PCR Assay and Advanta Dx COVID–19 EASE Assay. 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 Authorization for the BinaxNOW COVID–19 Ag 2 Card is revoked as of January 31, 2023. The Authorizations for the Advanta Dx SARS–CoV–2 RT–PCR Assay and Advanta Dx COVID–19 EASE Assay are revoked as of February 1, 2023.

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 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) 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 2 Card, 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. On August 25, 2020, FDA issued an EUA to Standard (then known as Fluidigm Corp.) for the Advanta Dx SARS–CoV–2 RT–PCR 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 February 7, 2022, FDA issued an EUA to Standard (then known as Fluidigm Corp.) for the Advanta Dx COVID–19 EASE Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 22, 2022 (87 FR 43877), as required by section 564(h)(1) of the FD&C Act. Subsequent revisions 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

On January 20, 2023, FDA received a request from Abbott for the revocation of, and on January 31, 2023, FDA revoked, the Authorization for the BinaxNOW COVID–19 Ag 2 Card. Because Abbott requested FDA revoke the EUA for the BinaxNOW COVID–19 Ag 2 Card, FDA has determined that it is appropriate to protect the public health or safety to revoke this

Authorization. On January 30, 2023, FDA received a request from Standard for the withdrawal of, and on February 1, 2023, FDA revoked, the Authorizations for the Advanta Dx SARS–CoV–2 RT–PCR Assay and Advanta Dx COVID–19 EASE Assay. Because Standard requested FDA withdraw the EUAs for the Advanta Dx SARS–CoV–2 RT–PCR Assay and Advanta Dx COVID–19 EASE Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke these Authorizations.

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 for Abbott's BinaxNOW COVID–19 Ag 2 Card, and Standard's Advanta Dx SARS–CoV–2 RT–PCR Assay and Advanta Dx COVID–19 EASE Assay. 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.

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U.S. FOOD & DRUG ADMINISTRATION

January 31, 2023

Angela Drysdale
DVP, Regulatory Affairs
Infectious Disease
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Re: Revocation of EUA210275

Dear Ms. Drysdale:

This letter is in response to the request from Abbott Diagnostics Scarborough, Inc., received via email on January 20, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the BinaxNOW COVID-19 Ag 2 Card issued on March 31, 2021, amended on September 23, 2021, January 7, 2022, and November 1, 2022, and reissued on February 4, 2022. Abbott Diagnostics Scarborough, Inc., indicated that they no longer required the authorization of the BinaxNOW COVID-19 Ag 2 Card and requested that the EUA be revoked. FDA understands that no products associated with this EUA were released to the United States market.

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 Diagnostics Scarborough, Inc. has requested FDA revoke the EUA for the BinaxNOW COVID-19 Ag 2 Card, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210275 for the BinaxNOW COVID-19 Ag 2 Card, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BinaxNOW COVID-19 Ag 2 Card 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

February 1, 2023

Alex Kim
Chief Operating Officer
Standard BioTools Inc.
2 Tower Place Suite 2000
South San Francisco, CA 94080

Re: Revocation of EUA210664

Dear Alex Kim:

This letter is in response to the request from Standard BioTools Inc., received via email on January 30, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Advanta Dx COVID-19 EASE Assay issued on February 7, 2022, and reissued on June 14, 2022. Standard BioTools Inc. indicated that they have discontinued the Advanta Dx COVID-19 EASE Assay and are no longer selling this EUA product. FDA understands that as of the date of this letter there will no longer be any viable Advanta Dx COVID-19 EASE Assay reagents remaining in distribution in the United States.

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 Standard BioTools Inc. has requested FDA withdraw the EUA for the Advanta Dx COVID-19 EASE Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210664 for the Advanta Dx COVID-19 EASE Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Advanta Dx COVID-19 EASE 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

U.S. FOOD & DRUG ADMINISTRATION

January 31, 2023

Angela Drysdale
DVP, Regulatory Affairs
Infectious Disease
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Re: Revocation of EUA210275

Dear Ms. Drysdale:

This letter is in response to the request from Abbott Diagnostics Scarborough, Inc., received via email on January 20, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the BinaxNOW COVID-19 Ag 2 Card issued on March 31, 2021, amended on September 23, 2021, January 7, 2022, and November 1, 2022, and reissued on February 4, 2022. Abbott Diagnostics Scarborough, Inc., indicated that they no longer required the authorization of the BinaxNOW COVID-19 Ag 2 Card and requested that the EUA be revoked. FDA understands that no products associated with this EUA were released to the United States market.

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 Diagnostics Scarborough, Inc. has requested FDA revoke the EUA for the BinaxNOW COVID-19 Ag 2 Card, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210275 for the BinaxNOW COVID-19 Ag 2 Card, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BinaxNOW COVID-19 Ag 2 Card 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: March 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05053 Filed 3–10–23; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0623]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on April 17, 2023, from 9 a.m. to 4:30 p.m. Eastern Time.