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.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–0623. Please note that late, untimely filed comments will not be considered. The docket will close on April 14, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 14, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before April 3, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–0623 for ''Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, email: *AMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 216974, for sulbactam-durlobactam for injection, submitted by Entasis Therapeutics, Inc. The Applicant's proposed indication is for the treatment of infections due to *Acinetobacter baumannii-calcoaceticus* complex including multidrug-resistant and carbapenem-resistant strains.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a

manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 3, 2023, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 24, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 27, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Takyiah Stevenson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05068 Filed 3–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2007–D–0369, FDA–2008–D–0610, FDA–2015–D–1211, FDA–2021–D–0409, FDA–2020–D–0987, FDA–2020–D–1057, FDA–2020–D–1106, FDA–2020–D–1106–0002, FDA–2020–D–1108, FDA–2020–D–1136, FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–1139, FDA–2020–D–1140, FDA–2020–D–1304, FDA–2020–D–1370, FDA–2020–D–1386, FDA–2020–D–1414, FDA–2020–D–1824, FDA–2020–D–1825, FDA–2020–D–2016, FDA–2021–D–1311]

Guidance Documents Related to Coronavirus Disease 2019 (COVID–19)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: On February 9, 2023, the Secretary of Health and Human Services (HHS) renewed the Coronavirus Disease 2019 (COVID–19) public health emergency declaration issued under section 319 of the Public Health Service Act (PHS Act) (''PHE declaration''), effective February 11, 2023. The declaration is expected to expire at the end of the day on May 11, 2023. The Food and Drug Administration (FDA, Agency, or we) has issued guidance documents to address the circumstances of the public health emergency and, more generally, COVID–19. Many of those guidance documents are tied to the duration of the PHE declaration. This notice is intended to provide clarity to stakeholders with respect to the guidance documents that will no longer be effective with the expiration of the PHE declaration and the guidances that FDA is revising to continue in effect after the expiration of the PHE declaration.

FOR FURTHER INFORMATION CONTACT: Diane Maloney, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; Kimberly Thomas, Center for Drug Evaluation and Research, Food and Drug Administration (CDER), 10903 New Hampshire Ave., Bldg. 51, Rm. 6282, Silver Spring, MD 20993–0002, 301–796–2357; Philip Chao, Center for Food Safety and Applied Nutrition (CFSAN), CPK1 Rm. 1C001, HFS–024, Food and Drug Administration, College Park, MD 20740, 240–402–2112; Diane Heinz, Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., HFV–6, Rockville, MD 20855, 240–402–5692; Amanda Wulf, Office of Regulatory Affairs (ORA), Food and Drug Administration, 12420 Parklawn Dr., ELEM–4044, Rockville, MD 20857, 301–796–8856.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, the prior Secretary of HHS, pursuant to the authority under section 319 of the PHS Act (42 U.S.C. 247d), determined that a PHE existed (COVID–19 PHE) and had existed since January 27, 2020, nationwide.[1] On February 9, 2023, the Secretary of HHS renewed the COVID–19 PHE declaration, effective February 11, 2023. On February 9, based on current COVID–19 trends, HHS announced that it is planning for the declaration to expire at the end of the day on May 11, 2023. (HHS, Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap (February 9, 2023), available at *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html#:~:text=Based%20on%20current%20COVID%2D19,day%20on%20May%2011%2C%202023*).

Since the start of the COVID–19 pandemic in 2020, FDA has issued more than 80 COVID–19-related guidances (not including revisions). In the **Federal Register** of March 25, 2020 (85 FR 16949) (available at *https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf*), FDA announced general procedures for making available FDA guidances related to the COVID–19 PHE. We have updated or otherwise modified our COVID–19-related guidances in response to comments received, as appropriate, and as relevant needs and circumstances evolved throughout the COVID–19 PHE. We have withdrawn, and announced the

[1] Secretary of HHS, ''Determination that a Public Health Emergency Exists'' (originally issued on January 31, 2020, and subsequently renewed, pursuant to the authority under section 319 of the PHS Act), available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.* There are additional types of determinations and declarations related to emergencies, including public health emergencies, that are distinct from a PHE declared pursuant to section 319 of the PHS Act. For instance, the determination and declarations made under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which enable the issuance of Emergency Use Authorizations (EUAs), are independent from a declaration under section 319 of the PHS Act.