Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 4, 2025.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President), 1 Memorial Drive, Kansas City, Missouri, 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *Emma Ryan, Heartwell, Nebraska;* to join the Ryan Family Group, a group acting in concert, to acquire voting shares of First Central Nebraska Co., and thereby indirectly acquire voting shares of Nebraska State Bank and Trust Company, both of Broken Bow, Nebraska.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–04781 Filed 3–19–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

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 Beckman Coulter, Inc., for the Access SARS–CoV–2 IgG, Access SARS–CoV–2 IgM, and Access SARS–CoV–2 IgG II tests. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorization for the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG, Access SARS–CoV–2 IgM, and Access SARS–CoV–2 IgG II tests are effective as of January 8, 2025.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (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, radiological, or nuclear agent or 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 June 26, 2020, FDA issued the Authorization to Beckman Coulter, Inc., for the Access SARS–CoV–2 IgG test, 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 October 8, 2020, FDA issued the Authorization to Beckman Coulter, Inc., for the Access SARS–CoV–2 IgM test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act.

On March 22, 2021, FDA issued the Authorization to Beckman Coulter, Inc., for the Access SARS–CoV–2 IgG II 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 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. Authorizations Revocation Requests

In a request received by FDA on November 22, 2024, Beckman Coulter, Inc., requested the revocation of, and on January 8, 2025, FDA revoked, the Authorization for the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG test. Beckman Coulter, Inc., notified FDA of their intent to discontinue distribution of the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG test as of January 1, 2025, and requested FDA revoke the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG test. 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 November 22, 2024, Beckman Coulter, Inc., requested the revocation of, and on January 8, 2025, FDA revoked, the Authorization for the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgM test. Beckman Coulter, Inc., notified FDA of their intent to discontinue distribution of the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgM test as of January 1, 2025, and requested FDA revoke the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgM test. 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 November 22, 2024, Beckman Coulter, Inc., requested the revocation of, and on January 8, 2025, FDA revoked, the Authorization for the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG II test. Beckman Coulter, Inc., notified FDA of their intent to discontinue distribution of the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG II test as of January 1, 2025, and requested FDA revoke the Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG II 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 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 Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG, Access SARS–CoV–2 IgM, and Access SARS–CoV–2 IgG II tests. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

January 8, 2025

Veronica Colinayo, Ph.D.
Staff Regulatory Affairs
Beckman Coulter, Inc.
250 S Kraemer Blvd,
Brea, CA 92821
Re: Revocation of EUA201527

Dear Dr. Colinayo:
This letter is in response to a notification from Beckman Coulter, Inc., in a letter dated November 22, 2024, of their intent to discontinue, as of January 1, 2025, distribution of the Access SARS-CoV-2 IgG that was issued an EUA on June 26, 2020, and amended on September 23, 2021, December 17, 2021, and February 7, 2022. Beckman Coulter, Inc. confirmed in an email dated December 10, 2024, in response to clarifying questions from FDA, that they would have ceased distribution of the authorized product effective January 1, 2025, and that they intended to have FDA revoke the EUA. FDA understands that as of the date of this letter there are no viable Access SARS-CoV-2 IgG 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 Beckman Coulter, Inc. has requested that FDA revoke the EUA for the Access SARS-CoV-2 IgG, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201527 for the Access SARS-CoV-2 IgG, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Access SARS-CoV-2 IgG 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

January 8, 2025

Veronica Colinayo, Ph.D.
Staff Regulatory Affairs
Beckman Coulter, Inc.
250 S Kraemer Blvd,
Brea, CA 92821
Re: Revocation of EUA202631

Dear Dr. Colinayo:
This letter is in response to a notification from Beckman Coulter, Inc., in a letter dated November 22, 2024, of their intent to discontinue, as of January 1, 2025, distribution of the Access SARS-CoV-2 IgM that was issued an EUA on October 8, 2020, and amended on September 23, 2021, December 13, 2021, and February 7, 2022. Beckman Coulter, Inc. confirmed in an email dated December 10, 2024, in response to clarifying questions from FDA, that they would have ceased distribution of the authorized product effective January 1, 2025, and that they intended to have FDA revoke the EUA. FDA understands that as of the date of this letter there are no viable Access SARS-CoV-2 IgM 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 Beckman Coulter, Inc. has requested that FDA revoke the EUA for the Access SARS-CoV-2 IgM, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202631 for the Access SARS-CoV-2 IgM, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Access SARS-CoV-2 IgM 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

January 8, 2025

Veronica Colinayo, Ph.D.
Staff Regulatory Affairs
Beckman Coulter, Inc.
250 S Kraemer Blvd,
Brea, CA 92821
Re: Revocation of EUA203021

Dear Dr. Colinayo:
This letter is in response to a notification from Beckman Coulter, Inc., in a letter dated November 22, 2024, of their intent to discontinue, as of January 1, 2025, distribution of the Access SARS-CoV-2 IgG II that was issued an EUA on March 22, 2021, revised and reissued on August 18, 2021, and amended on December 20, 2021. Beckman Coulter, Inc. confirmed in an email dated December 10, 2024, in response to clarifying questions from FDA, that they would have ceased distribution of the authorized product effective January 1, 2025, and that they intended to have FDA revoke the EUA. FDA understands that as of the date of this letter there are no viable Access SARS-CoV-2 IgG II 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 Beckman Coulter, Inc. has requested that FDA revoke the EUA for the Access SARS-CoV-2 IgG II, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203021 for the Access SARS-CoV-2 IgG II, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Access SARS-CoV-2 IgG II 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Dated: March 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04710 Filed 3–19–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 063

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 063'' (Recognition List Number: 063), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.