comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Manufactured Food Regulatory Program Standards

OMB Control Number 0910–0601—Extension

This information collection supports FDA's ''Manufactured Food Regulatory Program Standards'' (2019) (*https://www.fda.gov/media/131392/download*). We recommend that States use these program standards as the framework to design and manage their manufactured food programs. There are 44 State programs currently enrolled in the Manufactured Food Regulatory Program Standards (MFRPS) under cooperative agreements.

The goal of the MFRPS is to implement a nationally integrated, risk-based, food safety system focused on protecting public health. The MFRPS establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the United States. The development and implementation of the standards will help Federal and State programs better direct their regulatory activities toward reducing foodborne illness. For more information we invite you to visit our website at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/manufactured-food-regulatory-program-standards-mfrps.*

FDA recommends that a State program enrolled in the MFRPS use the worksheets and forms contained in the standards; however, alternate forms that are equivalent may be used. The State program maintains documentation (guidance, procedures, documents, and forms) required by the 10 standards, which must be current and fit for use. In the first year of implementing the program standards, the State program conducts a baseline self-assessment of the documentation to determine if it meets the elements of each standard. The State program must participate in additional verification audits in subsequent years. After 5 years, FDA will conduct a comprehensive program audit of the documentation. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's level of conformance with each of the standards. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

Description of Respondents: Respondents are State Departments of Agriculture or Health enrolled in the MFRPS (State Governments).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Governments; Development and reporting of data consistent with MFRPS	44	1	44	569	25,036

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Governments; Maintenance of data records consistent with MFRPS	44	10	440	40	17,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted the number of respondents to the information collection to reflect the enrollment of an additional State since our last evaluation.

Dated: January 6, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00559 Filed 1–12–22; 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 Becton, Dickinson & Company (BD) for the BioGX SARS–CoV–2 Reagents for BD MAX System, Boston Medical Center for the BMC–CReM COVID–19 Test, and Akron Children's Hospital for the Akron Children's Hospital SARS–CoV–2 Assay. FDA revoked these Authorizations on December 8, 2021, 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 BioGX SARS–CoV–2 Reagents for BD MAX System, BMC–CReM COVID–19 Test, and Akron Children's Hospital SARS–CoV–2 Assay are revoked as of December 8, 2021.

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, 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 April 2, 2020, FDA issued an EUA to BD for the BioGX SARS–CoV–2 Reagents for BD MAX System, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act. On July 10, 2020, FDA issued an EUA to Boston Medical Center for the BMC–CReM COVID–19 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 September 29, 2020, FDA issued an EUA to Akron Children's Hospital for the Akron Children's Hospital 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 April 23, 2021 (86 FR 21749), 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

On December 3, 2021, FDA received a request from BD for the revocation of, and on December 8, 2021, FDA revoked, the Authorization for the BioGX SARS–CoV–2 Reagents for BD MAX System. Because BD notified FDA that BD discontinued the sale of the authorized product and requested FDA revoke the Authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On October 4, 2021 (and reconfirmed December 6, 2021), FDA received a request from Boston Medical Center for the revocation of, and on December 8, 2021, FDA revoked, the Authorization for the BMC–CReM COVID–19 Test. Because Boston Medical Center notified FDA that the BMC–CReM COVID–19 Test is no longer performed pursuant to the EUA and requested FDA withdraw the Authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On December 3, 2021, FDA received a request from Akron Children's Hospital for the revocation of, and on December 8, 2021, FDA revoked, the Authorization for the Akron Children's Hospital SARS–CoV–2 Assay. Because Akron Children's Hospital notified FDA that it stopped performing the Akron Children's Hospital SARS–CoV–2 Assay and requested that FDA revoke the Authorization, 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 for BD's BioGX SARS–CoV–2 Reagents for BD MAX System, Boston Medical Center's BMC–CReM COVID–19 Test, and Akron Children's Hospital's Akron Children's Hospital SARS–CoV–2 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.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

December 8, 2021

Colton Muraira, J.D.
Staff Regulatory Affairs Specialist
Becton, Dickinson & Company (BD)
7 Loveton Circle
Sparks, MD 21152
Re: Revocation of EUA200098

Dear Colton Muraira:

This letter is in response to Becton, Dickinson & Company's (BD's) request received December 3, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200098) for the BioGX SARS-CoV-2 Reagents for BD MAX System issued on April 2, 2020, and amended on April 7, 2020, May 29, 2020, September 25, 2020 and September 23, 2021. BD indicated that to simplify and focus their BD MAX Portfolio, BD made the decision to discontinue the sale of the authorized product.

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 BD has notified FDA that BD discontinued the sale of the authorized product and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200098 for the BioGX SARS-CoV-2 Reagents for BD MAX System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BioGX SARS-CoV-2 Reagents for BD MAX System 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

U.S. FOOD & DRUG ADMINISTRATION

December 8, 2021

Chris Andry, MPhil, Ph.D.
Professor and Chair
Department of Pathology & Laboratory Medicine
Boston University School of Medicine
Chief of Pathology & Laboratory Medicine
Boston Medical Center
670 Albany Street, 7th Floor, Room 736
Boston, MA 02118
Re: Revocation of EUA201811

Dear Dr. Andry:

This letter is in response to Boston Medical Center's request received October 4, 2021, and reconfirmed December 6, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA201811) for the BMC-CReM COVID-19 Test issued on July 10, 2020, and amended on September 25, 2020, and September 23, 2021. Boston Medical Center confirmed that the BMC-CReM COVID-19 Test is no longer performed pursuant to the EUA.

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 Boston Medical Center has notified FDA that the BMC-CReM COVID-19 Test is no longer performed pursuant to the EUA and requests FDA withdraw the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201811 for the BMC-CReM COVID-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BMC-CReM COVID-19 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

U.S. FOOD & DRUG ADMINISTRATION

December 8, 2021

Ilka Warshawsky, M.D., Ph.D.
Director, Molecular Diagnostics Laboratory
Akron Children's Hospital
One Perkins Square
Akron, OH 44308
Re: Revocation of EUA202545

Dear Dr. Warshawsky:

This letter is in response to Akron Children's Hospital's request received December 3, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA202545) for the Akron Children's Hospital SARS-CoV-2 Assay issued on September 29, 2020 and amended on September 23, 2021. Akron Children's Hospital confirmed that it stopped performing the Akron Children's Hospital SARS-CoV-2 Assay, having implemented a number of additional SARS-CoV-2 molecular assays which have received EUA.

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 Akron Children's Hospital has notified FDA that it stopped performing the Akron Children's Hospital SARS-CoV-2 Assay and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202545 for the Akron Children's Hospital SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Akron Children's Hospital 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/

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

Dated: January 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00521 Filed 1–12–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Translational Imaging Science Study Section.

Date: February 17–18, 2022.