information collected and reported in an oversight role of state Medicaid managed care programs.

Among the proposed changes, this iteration also accommodates the use of reporting templates for existing reporting requirements at 42 CFR 438.207(d) for network adequacy and access and § 438.74 for medical loss ratio. The templates are intended to help states by articulating the specific data elements needed and by providing an easy to use format that facilitates CMS' tracking and analysis. The data gathered from these reports will enable CMS to ensure state compliance with regulatory requirements.

Form Number: CMS–10108 (OMB control number: 0938–0920); *Frequency:* Occasionally; *Affected Public:* Individuals or households, Private sector (business or other for-profit and not-for-profit institutions), and State, local or Tribal Government; *Number of Respondents:* 609; *Total Annual Responses:* 13,742,805; *Total Annual Hours:* 1,682,411. (For policy questions regarding this collection contact Amy Gentile at 410–786–3499.)

Dated: March 1, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–04645 Filed 3–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two 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 Bio-Rad Laboratories for the BioPlex 2200 SARS–CoV–2 IgG, and Quotient Suisse SA for the MosaiQ COVID–19 Antibody Magazine. 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 Authorizations are revoked as of January 11, 2022.

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 July 1, 2021, FDA issued an EUA to Bio-Rad Laboratories for the BioPlex 2200 SARS–CoV–2 IgG, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on October 28, 2021 (86 FR 59738), as required by section 564(h)(1) of the FD&C Act. On September 25, 2020, FDA issued an EUA to Quotient Suisse SA for the MosaiQ COVID–19 Antibody Magazine, 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

In a request received by FDA on December 20, 2021, Bio-Rad Laboratories requested revocation of, and on January 11, 2022, FDA revoked, the Authorization for the BioPlex 2200 SARS–CoV–2 IgG. Because Bio-Rad Laboratories notified FDA that Bio-Rad Laboratories has not commercialized the authorized product in the United States and requested FDA revoke the BioPlex 2200 SARS–CoV–2 IgG, 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 December 22, 2021, Quotient Suisse SA requested termination of, and on January 11, 2022, FDA revoked, the Authorization for the MosaiQ COVID–19 Antibody Magazine. Because Quotient Suisse SA notified FDA that Quotient Suisse SA has decided not to continue to commercially support the product and requested FDA terminate the MosaiQ COVID–19 Antibody Magazine, 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 EUA of Bio-Rad Laboratories for the BioPlex 2200 SARS–CoV–2 IgG and of Quotient Suisse SA for the MosaiQ COVID–19 Antibody Magazine. 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 11, 2022

Linda Staswick
Regulatory Affairs Project Manager
Bio-Rad Laboratories
4000 Alfred Nobel Dr.
Hercules, CA 94547

Re: Revocation of EUA202689

Dear Linda Staswick:

This letter is in response to a request from Bio-Rad Laboratories, received December 20, 2021, that the U.S. Food and Drug Administration (FDA) revoke the BioPlex 2200 SARS-CoV-2 IgG – EUA202689 issued on July 1, 2021 and revised September 23, 2021. The BioPlex 2200 SARS-CoV-2 IgG Panel has not been commercialized by Bio-Rad in the U.S.

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 Bio-Rad has notified FDA that Bio-Rad has not commercialized the authorized product in the U.S. and requested FDA revoke the BioPlex 2200 SARS-CoV-2 IgG – EUA202689, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202689 for the BioPlex 2200 SARS-CoV-2 IgG, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BioPlex 2200 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/

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

U.S. FOOD & DRUG ADMINISTRATION

January 11, 2022

Michael Campbell
Head of Regulatory Affairs & Quality
Quotient Suisse SA
Route de Crassier 13
Eysins, VD 1262
Switzerland

Re: Revocation of EUA201083

Dear Michael Campbell:

This letter is in response to a request from Quotient Suisse SA, received December 22, 2021, that the U.S. Food and Drug Administration (FDA) terminate the MosaiQ COVID-19 Antibody Magazine – EUA201083 issued on September 25, 2020 and amended April 27, 2021 and September 23, 2021. Quotient Suisse SA decided not to continue to commercially support the MosaiQ COVID-19 Antibody Magazine.

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 Quotient Suisse SA has notified FDA that Quotient Suisse SA has decided not to continue to commercially support the product and requested FDA terminate the MosaiQ COVID-19 Antibody Magazine – EUA201083, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201083 for the MosaiQ COVID-19 Antibody Magazine, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MosaiQ COVID-19 Antibody Magazine 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: February 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04635 Filed 3–3–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1825 and FDA–2020–D–1136]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented