4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0109]

Revocation of Four 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 Mammoth Biosciences, Inc. for the SARS-CoV-2 DETECTR Reagent Kit and DETECTR BOOST SARS-CoV-2 Reagent Kit, to the University of Arizona Genetics Core for Clinical Services for the COVID-19 ELISA pan-Ig Antibody Test, and to ChromaCode, Inc. for the HDPCR SARS-CoV-2 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 Authorizations for the SARS-CoV-2 DETECTR Reagent Kit and DETECTR BOOST SARS-CoV-2 Reagent Kit are revoked as of December 15, 2022. The Authorization for the COVID-19 ELISA pan-Ig Antibody Test is revoked as of December 16, 2022. The Authorization for the HDPCR SARS-CoV-2 Assay is revoked as of January 3, 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 August 31, 2020, FDA issued an EUA to Mammoth Biosciences, Inc. for the SARS-CoV-2 DETECTR Reagent Kit, 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 January 21, 2022, FDA issued an EUA to Mammoth Biosciences, Inc. for the DETECTR BOOST SARS-CoV-2 Reagent Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on March 22, 2022 (87 FR 16196), as required by section 564(h)(1) of the FD&C Act. On August 31, 2020, FDA issued an EUA to the University of Arizona Genetics Core for Clinical Services for the COVID-19 ELISA pan-Ig Antibody 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 June 9, 2020, FDA issued an EUA to ChromaCode, Inc. for the HDPCR 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 November 20, 2020 (85 FR 74346), 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 October 20, 2022, FDA received requests from Mammoth Biosciences, Inc. for the withdrawal of, and on December 15, 2022, FDA revoked, the Authorizations for the SARS-CoV-2 DETECTR Reagent Kit and DETECTR BOOST SARS-CoV-2 Reagent Kit. Because Mammoth Biosciences, Inc. requested FDA withdraw the EUAs for the SARS-CoV-2 DETECTR Reagent Kit and DETECTR BOOST SARS-CoV-2 Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke these Authorizations. On December 14, 2022, FDA received a request from the University of Arizona Genetics Core for Clinical Services for the withdrawal of, and on December 16, 2022, FDA revoked, the Authorization for the COVID-19 ELISA pan-Ig Antibody Test. Because the University of Arizona Genetics Core for Clinical Services requested FDA withdraw the EUA for the COVID-19 ELISA pan-Ig Antibody Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On December 2, 2022, FDA received a request from ChromaCode, Inc., for the revocation of, and on January 3, 2023, FDA revoked, the Authorization for the HDPCR SARS-CoV-2 Assay. Because ChromaCode, Inc. requested FDA revoke the EUA for the HDPCR SARS-CoV-2 Assay, 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 Mammoth Biosciences, Inc.'s SARS-CoV-2 DETECTR Reagent Kit and DETECTR BOOST SARS-CoV-2 Reagent Kit, the University of Arizona Genetics Core for Clinical Services's COVID-19 ELISA pan-Ig Antibody Test, and ChromaCode, Inc.'s HDPCR 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.

December 15, 2022

Janice Chen, PhD
Co-Founder & CTO
Mammoth Biosciences, Inc.
1000 Marina Blvd., Suite 600
Brisbane, CA 94005

Re: Revocation of EUA202365

Dear Dr. Chen:

This letter is in response to the request from Mammoth Biosciences, Inc., received via email on October 20, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 DETECTR Reagent Kit issued on August 31, 2020, and amended on July 7, 2021, and September 23, 2021. Mammoth Biosciences, Inc. indicated that there is no longer a viable market for this SARS-CoV-2 reagent kit and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there will no longer be any SARS-CoV-2 DETECTR Reagent Kits 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 Mammoth Biosciences, Inc. has requested FDA withdraw the EUA for the SARS-CoV-2 DETECTR Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202365 for the SARS-CoV-2 DETECTR Reagent Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 DETECTR Reagent Kit 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

Cc: Timothy Patno, Mammoth Biosciences, Inc.

U.S. FOOD & DRUG ADMINISTRATION

December 15, 2022

Janice Chen, PhD
Co-Founder & CTO
Mammoth Biosciences, Inc.
1000 Marina Blvd., Suite 600
Brisbane, CA 94005

Re: Revocation of EUA210625

Dear Dr. Chen:

This letter is in response to the request from Mammoth Biosciences, Inc., received via email on October 20, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the DETECTR BOOST SARS-CoV-2 Reagent Kit issued on January 21, 2022. Mammoth Biosciences, Inc. indicated that there is no longer a viable market for this SARS-CoV-2 reagent kit and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there will no longer be any DETECTR BOOST SARS-CoV-2 Reagent Kits 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 Mammoth Biosciences, Inc. has requested FDA withdraw the EUA for the DETECTR BOOST SARS-CoV-2 Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210625 for the DETECTR BOOST SARS-CoV-2 Reagent Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 DETECTR Reagent Kit 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

Cc: Timothy Patno, Mammoth Biosciences, Inc.

U.S. FOOD & DRUG ADMINISTRATION

December 16, 2022

Taylor Edwards, MSc, Ph.D.
Associate Staff Scientist, Clinical Laboratory Manager
University of Arizona Genetics Core for Clinical Services
Keating Bioresearch Building
1657 E. Helen Street Room 111H
Tucson, AZ 85721

Re: Revocation of EUA201116

Dear Dr. Edwards:

This letter is in response to the request from the University of Arizona Genetics Core for Clinical Services, received via email on December 14, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the COVID-19 ELISA pan-Ig Antibody Test issued on August 31, 2020, and amended September 23, 2021. The University of Arizona Genetics Core for Clinical Services indicated that they are no longer offering this as a clinical test service, and it has been removed from their activity menu.

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 the University of Arizona Genetics Core for Clinical Services has requested FDA withdraw the EUA for the COVID-19 ELISA pan-Ig Antibody Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201116 for the COVID-19 ELISA pan-Ig Antibody Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the COVID-19 ELISA pan-Ig Antibody 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/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

January 3, 2023

Vincent Jacquemin
Associate Director of Quality
ChromaCode Inc.
2330 Faraday Avenue Suite 100
Carlsbad, CA 92008

Re: Revocation of EUA200707

Dear Mr. Jacquemin:

This letter is in response to the request from ChromaCode Inc., received via email on December 2, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the HDPCR SARS-CoV-2 Assay issued on June 9, 2020, amended on September 12, 2020, and September 23, 2021, and reissued on February 14, 2022. ChromaCode Inc. indicated that they are discontinuing the HDPCR SARS-CoV-2 Assay and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable HDPCR SARS-CoV-2 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 ChromaCode Inc. has requested FDA revoke the EUA for the HDPCR SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200707 for the HDPCR SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the HDPCR 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/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Dated: January 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-02074 Filed: 1/31/2023 8:45 am; Publication Date: 2/1/2023]