0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Lei K. Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4724, Silver Spring, MD 20993–0002, 301–796–1635, *Leik.Zhang@fda.hhs.gov.*

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms.'' The draft guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each ICH guideline, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

On December 20, 2022, the ICH Assembly endorsed the draft guideline entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Multidisciplinary Expert Working Group (M13) of ICH. Comments about this draft will be considered by FDA and the M13 Expert Working Group.

The draft guidance describes the scientific and technical aspects of study design and data analysis to support BE assessment for orally administered immediate-release solid oral dosage forms such as tablets, capsules, and granules/powders for oral suspension. The draft guidance is intended to provide globally harmonized scientific recommendations for conducting BE studies during both development and postapproval phases that can increase the efficiency of drug development and accelerate the availability of safe and effective orally administered immediate-release solid oral dosage forms.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 314.94 for content and format for BE studies submitted under abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information for the implementation of improved quality and integrity of the study data approaches pertaining to good clinical practice have been approved under OMB control number 0910–0843.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: January 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02106 Filed 1–31–23; 8:45 am]

BILLING CODE 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.

BILLING CODE 4164–01–P

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 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.

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

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 1–31–23; 8:45 am]

BILLING CODE 4164–01–C