the persons as legitimate subjects in the CDAD clinical trial, when in fact they were not. Mr. Montalvo Villa was primarily responsible for completing the patients' informed consent form and falsifying their signatures to make it appear as though the patients consented to participate in the clinical trial when they had not. In addition, Mr. Montalvo Villa along with his co-conspirators submitted his own stool and blood samples to make it appear as if they came from study participants.

Furthermore, Mr. Montalvo Villa was one of only two individuals who inputted CDAD clinical trial data in the Almac Clinical Technology Integrated Response Technology database (Almac database). The information in the Almac database was the foundation for all subsequent subject CDAD clinical trial data. Mr. Montalvo Villa repeatedly entered false and fabricated subject screening and randomization information in the Almac database.

After an on-site audit by the Sponsor of AMB, the Sponsor notified the FDA in writing of potential scientific misconduct by AMB. Mr. Montalvo Villa wrote AMB's response letter, which contained false information, for the Principal Investigator's signature. Mr. Montalvo Villa told the Principal Investigator that she would lose her medical license if she did not sign the letter. In addition, an FDA regulatory investigator conducted an official on-site inspection of AMB for the CDAD clinical trial that began on February 20, 2018. On the first day of the inspection, Mr. Montalvo Villa told the FDA investigator that during the CDAD clinical trial he was present when his co-conspirator, the Principal Investigator, had obtained all the informed consents from the trial subjects. Mr. Montalvo Villa also told the regulatory investigator that copies of the informed consent were given to the subjects and that he was the most responsible person at AMB.

Mr. Montalvo Villa received $100,634.84 in proceeds for the CDAD clinical trial. AMB received over $277,000 for the CDAD clinical trial.

FDA sent Mr. Montalvo Villa, by certified mail, on August 12, 2024, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Mr. Montalvo Villa was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. The proposal informed Mr. Montalvo Villa of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Montalvo Villa received the proposal and notice of opportunity for a hearing on August 20, 2024. Mr. Montalvo Villa failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Division of Field Enforcement Director, finds that Mr. Miguel Angel Montalvo Villa has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product.

As a result of the foregoing finding, Mr. Montalvo Villa is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Montalvo Villa during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Montalvo Villa provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Montalvo Villa during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27093 Filed 11–19–24; 8:45 am]

BILLING CODE 4164–01–P

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 Cue Health, Inc., for the Cue COVID–19 Test, and Cue COVID–19 Test for Home and Over The Counter (OTC) Use. 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 Authorizations for the Cue Health, Inc.'s Cue COVID–19 Test, and Cue COVID–19 Test for Home and Over The Counter (OTC) Use are effective as of October 9, 2024.

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 10, 2020, FDA issued the Authorization to Cue Health, Inc., for the Cue 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 March 5, 2021, FDA issued the Authorization to Cue Health, Inc., for the Cue COVID–19 Test for Home and Over The Counter (OTC) Use, 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 September 9, 2024, Cue Health, Inc., requested the revocation of, and on October 9, 2024, FDA revoked, the Authorization for the Cue Health, Inc.'s Cue COVID–19 Test. Because Cue Health, Inc., notified FDA that they ceased manufacturing, shipping, and distributing the Cue COVID–19 Test and requested FDA revoke the Cue COVID–19 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 September 9, 2024, Cue Health, Inc., requested the revocation of, and on October 9, 2024, FDA revoked, the Authorization for Cue Health, Inc.'s Cue COVID–19 Test for Home and Over The Counter (OTC) Use. Because Cue Health, Inc., notified FDA that they have ceased manufacturing, shipping, and distributing the Cue COVID–19 Test for Home and Over The Counter (OTC) Use and requested FDA revoke the Cue COVID–19 Test for Home and Over The Counter (OTC) Use, 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 Cue Health, Inc.'s Cue COVID–19 Test, and Cue COVID–19 Test for Home and Over The Counter (OTC) Use. 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

U.S. FOOD & DRUG ADMINISTRATION

October 9, 2024

Chanda Owens
Cue Health Inc.
4890 Carroll Canyon Road, Suite 100
San Diego, CA 92121
Re: Revocation of EUA200248

Dear Chanda Owens:

This letter is in response to the request from Cue Health Inc., in a letter dated September 9, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cue COVID-19 Test issued on June 10, 2020, amended on August 20, 2020, reissued on March 26, 2021, and then amended on March 1, 2022, March 9, 2022, and March 8, 2023. Cue Health Inc. indicated that they have ceased manufacture, shipping and distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter any remaining viable Cue COVID-19 Test cartridges in distribution in the United States cannot be used due to the disabling of the Cue Health Mobile Application (Cue Health App) required to run the test.

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 Cue Health Inc. has requested that FDA revoke the EUA for the Cue COVID-19 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200248 for the Cue COVID-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cue 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//

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

October 9, 2024

Chanda Owens
Cue Health Inc.
4890 Carroll Canyon Road, Suite 100
San Diego, CA 92121
Re: Revocation of EUA210180

Dear Chanda Owens:

This letter is in response to the request from Cue Health Inc., in a letter dated September 9, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cue COVID-19 Test for Home and Over The Counter (OTC) Use issued on March 5, 2021, and amended on September 23, 2021, February 9, 2022, January 21, 2022 and August 24, 2022. Cue Health Inc. indicated that they have ceased manufacture, shipping and distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter any remaining viable Cue COVID-19 Test for Home and Over The Counter (OTC) Use cartridges in distribution in the United States cannot be used due to the disabling of the Cue Health Mobile Application (Cue Health App) required to run the test.

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 Cue Health Inc. has requested that FDA revoke the EUA for the Cue COVID-19 Test for Home and Over The Counter (OTC) Use, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210180 for the Cue COVID-19 Test for Home and Over The Counter (OTC) Use, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cue COVID-19 Test for Home and Over The Counter (OTC) Use 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: November 14, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27094 Filed 11–19–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; 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 additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific