2021–P–0959), under 21 CFR 10.30, requesting that the Agency determine whether MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MPI DMSA KIDNEY REAGENT ((Technetium Tc-99m Succimer Kit), Injectable, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to MPI DMSA KIDNEY REAGENT ((Technetium Tc-99m Succimer Kit), Injectable, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05324 Filed 3–11–22; 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 LifeHope Labs for the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel, and Omnipathology Solutions Medical Corporation for the Omni COVID–19 Assay by RT–PCR. 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 Authorization for the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel is revoked as of February 7, 2022. The Authorization for the Omni COVID–19 Assay by RT–PCR is revoked as of February 14, 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 June 29, 2020, FDA issued an EUA to LifeHope Labs for the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel, 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 17, 2020, FDA issued an EUA to Omnipathology Solutions Medical Corporation for the Omni COVID–19 Assay by RT–PCR, 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 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 January 6, 2022, LifeHope Labs requested discontinuation of, and on February 7, 2022, FDA revoked, the Authorization for the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel. Because LifeHope Labs notified FDA that it is no longer using the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel and requested FDA discontinue the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In requests received by FDA on February 7, 2022, and February 9, 2022, Omnipathology Solutions Medical Corporation requested revocation of, and on February 14, 2022, FDA revoked, the Authorization for the Omni COVID–19 Assay by RT–PCR. Because Omnipathology Solutions Medical Corporation notified FDA that it is no longer using the Omni COVID–19 Assay by RT–PCR and requested FDA revoke the EUA for the Omni COVID–19 Assay by RT–PCR, 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 LifeHope Labs for the LifeHope 2019-nCoV Real-Time RT–PCR Diagnostic Panel and of Omnipathology Solutions Medical Corporation for the Omni COVID–19 Assay by RT–PCR. 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

February 7, 2022

Beth Hoover
Associate Director
LifeHope Labs
5009 Roswell Road
Sandy Springs, GA 30342
Re: Revocation of EUA200796

Dear Beth Hoover:

This letter is in response to a request from LifeHope Labs received via email on January 6, 2022, that the U.S. Food and Drug Administration (FDA) discontinue the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel for which an EUA was issued on June 29, 2020 and revised on September 23, 2021. LifeHope Labs confirmed that it is no longer using the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel, having transitioned to another FDA EUA-authorized 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 LifeHope Labs has notified FDA that it is no longer using the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel and requested FDA discontinue the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200796 for the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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

February 14, 2022

Mohammad Kamal, MD
Omnipathology Solutions Medical Corporation
11 West Del Mar Blvd. Suite 203
Pasadena, CA 91105
Re: Revocation of EUA200170

Dear Dr. Kamal:

This letter is in response to requests from Omnipathology Solutions Medical Corporation received via email on February 7, 2022 and February 9, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the COVID-19 Assay by RT-PCR issued on June 17, 2020 and amended on December 28, 2020 and September 23, 2021. Omnipathology Solutions Medical Corporation confirmed that due to discontinuation of the commercial primer and probe products used in the Omni COVID-19 Assay by RT-PCR it has decided to discontinue use of this test but continue to offer COVID-19 testing using another FDA EUA-authorized 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 Omnipathology Solutions Medical Corporation has notified FDA that it is no longer using the Omni COVID-19 Assay by RT-PCR and requested FDA revoke the EUA for the Omni COVID-19 Assay by RT-PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200170 for the Omni COVID-19 Assay by RT-PCR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Omni COVID-19 Assay by RT-PCR 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: March 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05310 Filed 3–11–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics

AGENCY: Centers for Disease Control and Prevention.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: *https://ncvhs.hhs.gov/meetings/full-committee-meeting-10/.*

Name: National Committee on Vital and Health Statistics (NCVHS), Meeting of the full Committee.

DATES: The meeting will be held Wednesday, March 30, 2022: 11:00 a.m.–3:00 p.m. EST.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to *vgh4@cdc.gov;* or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the