fellowship data in real time; moreover, data cleaning and manipulation do not need to be done outside the system, which will increase the security of these data. These increased functionalities will facilitate the enhanced use of administrative data collections for program improvement and evidence building activities across CDC and other federal agencies. The update to the software platform will also make it easier for additional fellowships to opt in to use FMS, expanding the benefits of the system to a broader set of CDC programs. Finally, the platform change should also enhance user experience. This Revision does not propose substantive changes to the nature or extent of information collected from respondents, and will allow all respondents—fellowship applicants, public health agencies hosting fellowship participants, and fellowship alumni—the continued use of FMS for submission of electronic data with increased efficiency and reduced burdens.

The burden table reflects OMB-approved changes since 2020 and anticipated growth in fellowships from 2022 onward. CDC requests approval for an estimated total of 14,914 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Fellowship applicants	FMS Fellowship Application Information Collection Instrument.	5146	1	87/60	7,462
Reference Letter Writers	FMS Fellowship Application Information Collection Instrument.	6842	1	15/60	1,711
Public Health Agency or Organization Staff.	FMS Host Site Information Collection Instrument.	960	1	75/60	1,200
Public Health Agency or Organization Staff.	FMS Activity Tracking Information Collection Instrument.	555	2	30/60	555
Fellowship Alumni	FMS Alumni Tracking Information Collection Instrument.	6463	1	37/60	3,986
Total					14,914

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–05302 Filed 3–11–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0959]

Determination That MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Technetium Tc-99m Succimer Kit, Injectable, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Michelle Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240 402–0374, *Michelle.Weiner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, is the subject of NDA N017944, held by GE Healthcare, and initially approved on May 18, 1982. MPI DMSA KIDNEY REAGENT is indicated to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders. MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps, & McNamara, P.C. submitted a citizen petition dated August 27, 2021 (Docket No. FDA–

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