support disaster survivors during response missions. ACF is requesting immediate approval for this information collection but also requesting comments to inform any updates prior to requesting an extension of approval within six months.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice. These comments will be considered prior to requesting an extension of approval.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be submitted by emailing *infocollection@acf.hhs.gov.* Identify all by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OHSEPR's case managers would use this collection during an intake assessment to identify a disaster survivor's unmet needs and to work with the survivor to develop a case management plan based on the survivor's responses. ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing, as authorized under 44 U.S.C. 3507 (subsection j). The information collected is essential to the mission of the agency and an unanticipated event occurred that could reasonably result in public harm if normal PRA clearance procedures are followed. ACF is requesting expedited processing to ensure that the agency is operationally ready to support disaster survivors in Hawai'i who were impacted by the wildfires that began August 8, 2023, on Maui County. A request for review under normal procedures will be submitted within 180 days of the approval for this request.

Respondents: Disaster Survivors.

ANNUAL BURDEN ESTIMATES

Data collection	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Disaster Human Services Case Management Intake Assessment—Survivor	9,000	1	1.5	13,500
Case Management Plan—Case Manager	180	50	1	9,000
Resource Referral Form—Case Manager	180	50	1	9,000
Case Record Notes—Case Manager	180	50	1	9,000
Survivor Satisfaction Survey—Survivor	9,000	1	.25	2,250
Estimated Total Annual Burden Hours				42,750

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication. Comments will be considered and any necessary updates to materials made prior to, and responses provided in, the submission to OMB that will follow this public comment period.

Authority: The Disaster Human Services Case Management Program is authorized through appropriations language under the Children and Families Services account. It is operated by the ACF Office of Human Services Emergency Preparedness and Response, which is the lead in HHS for human service preparation for, response to, and recovery from, natural disasters.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–22294 Filed 10–4–23; 8:45 am]

BILLING CODE 4184–PC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4182]

Revocation of Eleven Authorizations of Emergency Use of In Vitro Diagnostic Device 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 Luminostics, Inc., for the Clip COVID Rapid Antigen Test; NeuMoDx Molecular, Inc., a QIAGEN Company, for the NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay; LGC, Biosearch Technologies for the SARS–CoV–2 Real-Time and End-Point RT–PCR Test; LGC, Biosearch Technologies, for the Biosearch Technologies SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test; Becton, Dickinson and Co. for the BD Veritor At-Home COVID–19 Test; Verily Life Sciences for the Verily COVID–19 RT–PCR Test; Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)–PCR Diagnostic Assay (Version 3); Xtrava Health for the SPERA COVID–19 Ag Test; Exact Sciences Laboratories for the COVID–Flu Multiplex Assay; Exact Sciences Laboratories for the SARS–CoV–2 (N gene detection) Test; and dba SpectronRx for the Hymon SARS–CoV–2 Test Kit. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holders. The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the Luminostics, Inc.'s, Clip COVID Rapid Antigen Test is revoked as of May 5, 2023. The Authorization for the NeuMoDx Molecular, Inc., a QIAGEN Company, for the NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay is revoked as of May 24, 2023. The Authorization for the LGC, Biosearch Technologies for the SARS–CoV–2 Real-

Time and End-Point RT–PCR Test is revoked as of June 1, 2023. The Authorization for the LGC, Biosearch Technologies, for the Biosearch Technologies SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test is revoked as of June 1, 2023. The Authorization for the Becton, Dickinson and Co.'s BD Veritor At-Home COVID–19 Test is revoked as of June 15, 2023. The Authorization for the Verily Life Sciences' Verily COVID–19 RT–PCR Test is revoked as of June 21, 2023. The Authorization for the Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) is revoked as of July 3, 2023. The Authorization for the Xtrava Health's SPERA COVID–19 Ag Test is revoked as of August 3, 2023. The Authorization for the Exact Sciences Laboratories' COVID–Flu Multiplex Assay is revoked as of August 18, 2023. The Authorization for the Exact Sciences Laboratories' SARS–CoV–2 (N gene detection) Test is revoked as of August 18, 2023. The Authorization for the dba SpectronRx's Hymon SARS–CoV–2 Test Kit is revoked as of August 23, 2023.

ADDRESSES: Submit a written request 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 December 7, 2020, FDA issued the Authorization to Luminostics, Inc., for the for the Clip COVID Rapid Antigen Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On March 25, 2021, FDA issued the Authorization to NeuMoDx Molecular, Inc., a QIAGEN Company, for the NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay, 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. On April 15, 2021, FDA issued the Authorization to LGC, Biosearch Technologies for the SARS–CoV–2 Real-Time and End-Point RT–PCR Test. Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040), subject to the terms of the Authorization. On August 24, 2021, FDA issued the Authorization to Becton, Dickinson and Co. for the BD Veritor At-Home COVID–19 Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on October 28, 2021 (86 FR 59740), as required by section 564(h)(1) of the FD&C Act. On April 26, 2022, FDA issued the Authorization to LGC, Biosearch Technologies, for the Biosearch Technologies SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 22, 2022 (87 FR 43877), as required by section 564(h)(1) of the FD&C Act. On September 8, 2020, FDA issued the Authorization to Verily Life Sciences for the Verily COVID–19 RT–PCR 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 Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), 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. On October 12, 2021, FDA issued the Authorization to Xtrava Health for the SPERA COVID–19 Ag Test, 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 16198), as required by section 564(h)(1) of the FD&C Act. On July 1, 2021, FDA issued the Authorization to Exact Sciences Laboratories for the COVID–Flu Multiplex Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on October 28, 2021 (86 FR 59740), as required by section 564(h)(1) of the FD&C Act. On March 31, 2020, FDA issued the Authorization to Exact Sciences Laboratories for the SARS–CoV–2 (N gene detection) 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 May 22, 2020, FDA issued the Authorization to dba SpectronRx for the Hymon SARS–CoV–2 Test 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.

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. Authorization Revocation Requests

In a request received by FDA on May 2, 2023, Luminostics, Inc. requested the withdrawal of, and on May 5, 2023, FDA revoked, the Authorization for the Luminostics, Inc.'s Clip COVID Rapid Antigen Test. Because Luminostics, Inc. notified FDA that there are no viable Clip COVID Rapid Antigen Test reagents remaining in distribution in the United States and requested FDA withdraw the Luminostics, Inc.'s Clip COVID Rapid Antigen 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 May 11, 2023, NeuMoDx Molecular, Inc., a QIAGEN Company requested revocation

of, and on May 24, 2023, FDA revoked, the Authorization for the NeuMoDx Molecular, Inc., a QIAGEN Company's, NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay. Because NeuMoDx Molecular, Inc., a QIAGEN Company, notified FDA that it has decided to discontinue distribution of the NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay in the United States and requested FDA voluntary revocation of the EUA for the NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay, 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 May 1, 2023, LGC, Biosearch Technologies requested revocation of, and on June 1, 2023, FDA revoked, the Authorization for the LGC Biosearch Technologies' SARS–CoV–2 Real-Time and End-Point RT–PCR Test. Because LGC, Biosearch Technologies notified FDA that it is no longer marketing the SARS–CoV–2 Real-Time and End-Point RT–PCR Test and requested FDA revoke the EUA for the LGC Biosearch Technologies SARS–CoV–2 Real-Time and End-Point RT–PCR 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 May 1, 2023, LGC, Biosearch Technologies requested revocation of, and on June 1, 2023, FDA revoked, the Authorization for the LGC Biosearch Technologies' SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test. Because LGC, Biosearch Technologies notified FDA that it is no longer marketing the SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test and requested FDA revoke the EUA for the LGC Biosearch Technologies SARS–CoV–2 ultra-high-throughput End-Point RT–PCR 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 May 30, 2023, Becton, Dickinson and Co. requested withdrawal of, and on June 15, 2023, FDA revoked, the Authorization for the Becton, Dickinson and Co.'s BD Veritor At-Home COVID–19 Test. Because Becton, Dickinson and Co. notified FDA that it has discontinued the sale of BD Veritor At-Home COVID–19 Test and requested FDA withdraw the EUA for the Becton, Dickinson and Co.'s BD Veritor At-Home 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 June 13, 2023, Verily Life Sciences requested withdrawal of, and on June 21, 2023, FDA revoked, the Authorization for the Verily Life Sciences' Verily COVID–19 RT–PCR Test. Because Verily Life Sciences notified FDA that it is no longer distributing the Verily COVID–19 Nasal Swab Kits (authorized as part of the Verily COVID–19 RT–PCR Test) or offering testing services at the Verily Life Sciences' laboratory using the Verily COVID–19 RT–PCR Test and requested FDA withdraw the EUA for the Verily Life Sciences' Verily COVID–19 RT–PCR 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 June 14, 2023, Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard, requested voluntary revocation of, and on July 3, 2023, FDA revoked, the Authorization for the CRSP, LLC at the Broad Institute of MIT and Harvard's CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)–PCR Diagnostic Assay (Version 3). Because CRSP, LLC at the Broad Institute of MIT and Harvard notified FDA that it is no longer distributing the CRSP Self-swab Kits (authorized as part of the CRSP SARS–CoV–2 Real-time RT–PCR Diagnostic Assay (Version 3)) or offering testing services at the CRSP, LLC at the Broad Institute of MIT and Harvard laboratory using the CRSP SARS–CoV–2 Real-time RT–PCR Diagnostic Assay (Version 3), and requested FDA revoke the EUA for the CRSP, LLC at the Broad Institute of MIT and Harvard's CRSP SARS–CoV–2 Real-time RT–PCR Diagnostic Assay (Version 3), 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 July 18, 2023, Xtrava Health requested the withdrawal of, and on August 3, 2023, FDA revoked, the Authorization for the Xtrava Health's SPERA COVID–19 Ag Test. Because Xtrava Health notified FDA that there are no SPERA COVID–19 Ag Test reagents in distribution in the United States and requested FDA withdraw the Xtrava Health's, SPERA COVID–19 Ag 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 August 1, 2023, Exact Sciences Laboratories requested the withdrawal of, and on August 18, 2023, FDA revoked, the Authorization for the Exact Sciences Laboratories' COVID-Flu Multiplex Assay. Because Exact Sciences Laboratories notified FDA that they have discontinued use of the COVID-Flu Multiplex Assay at Exact Sciences Laboratories and requested FDA withdraw the Exact Sciences Laboratories' COVID-Flu Multiplex Assay, 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 August 1, 2023, Exact Sciences Laboratories requested the withdrawal of, and on August 18, 2023, FDA revoked, the Authorization for the Exact Sciences Laboratories' SARS–CoV–2 (N gene detection) Test. Because Exact Sciences Laboratories notified FDA that they have discontinued use of the SARS–CoV–2 (N gene detection) Test at Exact Sciences Laboratories and requested FDA withdraw the Exact Sciences Laboratories' SARS–CoV–2 (N gene detection) 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 March 24, 2023, dba SpectronRx requested the withdrawal of, and on August 23, 2023, FDA revoked, the Authorization for the dba SpectronRx's Hymon SARS–CoV–2 Test Kit. Because dba SpectronRx notified FDA that they are discontinuing the distribution of the Hymon SARS–CoV–2 Test Kit and requested FDA withdraw the dba SpectronRx for the Hymon SARS–CoV–2 Test Kit, 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 Luminostics, Inc.'s, Clip COVID Rapid Antigen Test, NeuMoDx Molecular, Inc., a QIAGEN Company's, NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay, LGC Biosearch Technologies' SARS–CoV–2 Real-Time and End-Point RT–PCR Test, LGC Biosearch Technologies' SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test, Becton, Dickinson and Co.'s BD Veritor At-Home COVID–19 Test, Verily Life Sciences' Verily COVID–19 RT–PCR Test, Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard's CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)–PCR Diagnostic Assay (Version 3), Xtrava Health's SPERA COVID–19 Ag Test, Exact Sciences Laboratories' COVID-Flu Multiplex Assay, Exact Sciences

Laboratories' SARS–CoV–2 (N gene detection) Test, and dba SpectronRx's Hymon SARS–CoV–2 Test Kit. These 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

May 5, 2023

Bala Raja Ph.D.
President and CEO
Luminostics, Inc.
48389 Fremont Blvd, Suite 112,
Fremont, CA, 94538

Re: Revocation of EUA202907

Dear Dr. Raja:

This letter is in response to the request from Luminostics, Inc., in a letter received May 2, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Clip COVID Rapid Antigen Test issued on December 7, 2020, reissued March 4, 2022, and revised on September 23, 2021, and November 1, 2022. FDA understands that as of the date of this letter there are no viable Clip COVID Rapid Antigen Test 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 Luminostics, Inc. has requested FDA withdraw the EUA for the Clip COVID Rapid Antigen Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202907 for the Clip COVID Rapid Antigen Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Clip COVID Rapid Antigen 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

May 24, 2023

Eveline Arnold, Ph.D.
Director, Regulatory Affairs
Clinical, Medical, and Regulatory Affairs (CMRA)
NeuMoDx Molecular, Inc., a QIAGEN Company
1250 Eisenhower Place
Ann Arbor, MI 48108

Re: Revocation of EUA202947

Dear Dr. Arnold:

This letter is in response to QIAGEN's request on behalf of NeuMoDx Molecular, Inc., a QIAGEN Company, in an email received May 11, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay issued on March 25, 2021, and revised on September 23, 2021. QIAGEN has decided to discontinue distribution of the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay in the United States and requested voluntary revocation of the EUA.

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 QIAGEN, on behalf of NeuMoDx Molecular, Inc., has requested FDA revoke the EUA for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202947 for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 1, 2023

Ray Bandziulis, Ph.D.
Director of Regulatory Affairs
LGC, Biosearch Technologies
2905 Parameter Street
Middleton, WI 53562

Re: Revocation of EUA203030

Dear Dr. Bandziulis:

This letter is in response to the request from LGC, Biosearch Technologies, in an email received May 1, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test issued on April 15, 2021, and revised on September 23, 2021 and May 3, 2022. LGC, Biosearch Technologies indicated that they are no longer marketing the authorized product and requested that the EUA be revoked. FDA understands that, as of the date of this letter, there are no viable Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test 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 LGC, Biosearch Technologies has requested that FDA revoke the EUA for Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA203030 for the Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 1, 2023

Ray Bandziulis, Ph.D.
Director of Regulatory Affairs
LGC, Biosearch Technologies
2905 Parameter Street
Middleton, WI 53562

Re: Revocation of EUA210561

Dear Dr. Bandziulis:

This letter is in response to the request from LGC, Biosearch Technologies, in an email received May 1, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test issued on April 26, 2022. LGC, Biosearch Technologies indicated that they are no longer marketing the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter customers will discontinue use of the Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test reagents.

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 LGC, Biosearch Technologies has requested FDA revoke the EUA for Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210561 for the Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 15, 2023

Amanda Ker,
Regulatory Specialist
Becton, Dickinson and Co.
7 Loveton Circle
Sparks, MD 21152

Re: Revocation of EUA210417

Dear Amanda Ker:

This letter is in response to the request from Becton, Dickinson and Co ("BD"), in an email received May 30, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD Veritor At-Home COVID-19 Test issued on August 24, 2021, reissued on November 22, 2021 and revised on August 4, 2022, November 1, 2022 and February 21, 2023. BD indicated that they discontinued the sale the authorized product and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there are no viable BD Veritor At-Home COVID-19 Test 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 BD has requested FDA withdraw the EUA for the BD Veritor At-Home 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 EUA210417 for the BD Veritor At-Home COVID-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BD Veritor At-Home 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 21, 2023

Aarthi Srinivasan
Regulatory Affairs
Verily Life Sciences
269 E Grand Ave.
South San Francisco, CA 94080

Re: Revocation of EUA202054

Dear Aarthi Srinivasan:

This letter is in response to the request from Verily Life Sciences, in an email received June 13, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Verily COVID-19 RT-PCR Test issued on September 8, 2020, reissued on December 18, 2020, March 30, 2021, and November 8, 2021, and revised on September 23, 2021 and November 15, 2022. Verily Life Sciences indicated that they are no longer distributing the Verily COVID-19 Nasal Swab Kits (authorized as part of the Verily COVID-19 RT-PCR Test) or offering testing services at the Verily Life Sciences laboratory using the Verily COVID-19 RT-PCR Test and requested that the EUA be withdrawn.

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 Verily Life Sciences has requested FDA withdraw the EUA for the Verily COVID-19 RT-PCR Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202054 for the Verily COVID-19 RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Verily COVID-19 RT-PCR 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

July 3, 2023

Charles Kolifrath
Associate Director, Regulatory Affairs, Genomics Platform
Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard
320 Charles Street
Cambridge, MA 02141

Re: Revocation of EUA210089

Dear Charles Kolifrath:

This letter is in response to the request from Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard, in an email received June 14, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) issued on March 5, 2021, reissued on May 13, 2021, and June 3, 2022, and revised on September 23, 2021. In addition, on June 15, 2021, FDA included the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) under Exhibit 1 of the April 20, 2021, pooling and serial testing amendment. Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard indicated that as of the date of this letter they are no longer distributing the CRSP Self-swab Kits (authorized as part of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3)) or offering testing services at the Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard laboratory using the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) and requested voluntary revocation of the EUA.

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 Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard has requested voluntary revocation of the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210089 for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

August 3, 2023

Iman Sadreddin
Co-Founder, COO
Xtrava Health
3080 Olcott Street, Suite C201
Santa Clara, CA 95054

Re: Revocation of EUA210544

Dear Mr. Iman Sadreddin:

This letter is in response to the request from Xtrava Health, in an email received July 18, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SPERA COVID-19 Ag Test issued on October 12, 2021, revised on November 1, 2022, and reissued May 22, 2023. FDA understands that as of the date of this letter there are no SPERA COVID-19 Ag Test reagents 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 Xtrava Health has requested that FDA withdraw the EUA for the SPERA COVID-19 Ag Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210544 for the SPERA COVID-19 Ag Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SPERA COVID-19 Ag 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//

_____
Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

August 18, 2023

Thiago Braga
Sr. Regulatory Affairs Specialist
Exact Sciences Laboratories
650 Forward Drive
Madison, WI 53711
Re: Revocation of EUA203022

Dear Thiago Braga:

This letter is in response to the request from Exact Sciences Laboratories, in a letter received via email August 1, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the COVID-Flu Multiplex Assay issued on July 1, 2021, and revised on September 23, 2021, February 14, 2022, and August 2, 2022. Exact Sciences Laboratories indicated that they have discontinued use of the COVID-Flu Multiplex Assay at Exact Sciences Laboratories, located at 650 Forward Drive, Madison, WI 53711, and requested that the EUA be withdrawn.

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 Exact Sciences Laboratories has requested FDA withdraw the EUA for the COVID-Flu Multiplex Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203022 for the COVID-Flu Multiplex Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the COVID-Flu Multiplex 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//

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

August 18, 2023

Thiago Braga
Sr. Regulatory Affairs Specialist
Exact Sciences Laboratories
650 Forward Drive
Madison, WI 53711
Re: Revocation of EUA200367

Dear Thiago Braga:

This letter is in response to the request from Exact Sciences Laboratories, in a letter received via email August 1, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 (N gene detection) Test that was originally authorized under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT Umbrella EUA) on May 22, 2020, and then issued an individual EUA on August 3, 2020, that was revised on August 28, 2020, and September 23, 2021. Exact Sciences Laboratories indicated that they have discontinued use of the SARS-CoV-2 (N gene detection) Test at Exact Sciences Laboratories, located at 650 Forward Drive, Madison, WI 53711 and 145 E. Badger Road Ste. 100, Madison, WI 53713, and requested that the EUA be withdrawn.

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)© of the Act). Because Exact Sciences Laboratories has requested FDA withdraw the EUA for the SARS-CoV-2 (N gene detection) Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200367 for the SARS-CoV-2 (N gene detection) Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 (N gene detection) 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

August 23, 2023

Beth Kraemer, RPh
Director of Quality, Regulatory & Technical Compliance
dba SpectronRx
9550 Zionsville Rd Suite 1
Indianapolis, IN 46268

Re: Revocation of EUA200415

Dear Beth Kraemer:

This letter is in response to the request from dba SpectronRx, received via email on March 24, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Hymon SARS-CoV-2 Test Kit issued on May 22, 2020, and amended on August 11, 2020. dba SpectronRx indicated that they are discontinuing the distribution of the Hymon SARS-CoV-2 Test Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Hymon SARS-CoV-2 Test Kit 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 dba SpectronRx has requested that FDA terminate the EUA for the Hymon SARS-CoV-2 Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200415 for the Hymon SARS-CoV-2 Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Hymon SARS-CoV-2 Test 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: October 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22188 Filed 10–4–23; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1848]

Stimulant Use Disorders: Developing Drugs for Treatment; Draft Guidance 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 a draft guidance for industry entitled ''Stimulant Use Disorders: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of stimulant use disorders. Specifically, this guidance addresses FDA's current recommendations regarding the overall development program and clinical trial designs for the development of drugs to support indications of treatment of moderate to