Medicines and Healthcare Products Regulatory Agency. These risk assessment models, which FDA has independently evaluated, demonstrate that, in the U.K., the current risk of vCJD transmission by blood and blood components would expose transfusion recipients to no or minimal additional risk of vCJD in the future, and, for blood components that are leukocyte reduced, the possible risk is even further reduced. FDA has determined that the recommendations will simplify the donor screening process and increase the number of eligible donors while maintaining the safety of blood and blood components.

FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)) without initially seeking prior comment, because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because the revised recommendations present a less burdensome policy for reducing the risk of transmission of CJD and vCJD by blood and blood components that is consistent with public health, and we expect that the revised recommendations will increase the availability of blood and blood components while maintaining the safety of blood and blood components.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components.'' 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 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 610 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

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

Dated: May 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11119 Filed 5–23–22; 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 Authorization of Emergency Use of an 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 Authorization (EUA) (the Authorization) issued to Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard (Broad Institute) for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay is revoked as of May 5, 2022.

ADDRESSES: Submit a written request for a single copy of the revocation 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

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 July 8, 2020, FDA issued an EUA to the Broad Institute for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic 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 updates to the Authorization 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 Request

In a request received by FDA on April 4, 2022, Broad Institute requested revocation of, and on May 5, 2022, FDA revoked, the Authorization for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. Because the Broad Institute notified FDA that it has decided to discontinue use of the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay and requested FDA revoke the EUA for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic 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 revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Broad Institute for the CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. The revocation in its entirety follows and provides 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

May 5, 2022

Chuck Kolifrath
Associate Director, Regulatory Affairs, Genomics Platform
Broad Institute of MIT and Harvard
320 Charles Street
Cambridge, MA 02141
Re: Revocation of EUA200147

Dear Mr. Kolifrath:

This letter is in response to the request from Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard ("Broad Institute of MIT and Harvard") received on April 4, 2022, 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 issued on July 8, 2020, re-issued on October 23, 2020, December 18, 2020, and June 10, 2021, and amended on August 30, 2020, and September 23, 2021. The Broad Institute of MIT and Harvard indicated that it is no longer conducting testing under this 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 the Broad Institute of MIT and Harvard has notified FDA that it has decided to discontinue use of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay and requested FDA revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200147 for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, 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 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

Cc: Niall J. Lennon, Ph.D., Institute Scientist and Sr. Director, Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard

Dated: May 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11122 Filed 5–23–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2002–D–0362]

Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; 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 entitled ''Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry.'' The draft guidance document addresses certain regulatory requirements for determining donor eligibility that apply to blood establishments that collect blood and blood components for transfusion or for further manufacturing use, including Source Plasma. In a final rule dated May 22, 2015, FDA amended the regulations applicable to blood establishments for determining donor eligibility and testing blood and blood components. The revised requirements were implemented in order to assure the safety of the blood supply and to protect donor health.

DATES: The announcement of the guidance is published in the **Federal Register** on May 24, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0362 for ''Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to 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 the office in processing your requests. The 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: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry.'' The draft guidance document addresses certain regulatory requirements for determining donor eligibility that apply to blood establishments that collection blood components for transfusion or for further manufacturing use, including Source Plasma. In the final rule dated May 22, 2015 (80 FR 29841) entitled ''Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use,'' FDA amended the regulations applicable to blood establishments for determining donor eligibility and testing blood and