Meeting Procedures

The Presiding Officers will prepare a schedule for persons wishing to testify and establish the order of presentation. To ensure an opportunity for all interested commenters to present their views, the Presiding Officers may limit the time for providing oral comments and may establish other procedures related to the conduct of the public meeting as appropriate. For instance, each person may be permitted up to three minutes to testify. In order to verify the identity of persons scheduled to testify at the virtual public meeting, individuals who register to testify will be required to join a virtual waiting room in advance of the public meeting, where they must present a valid, government-issued photo identification using the video conference feature. Individuals who register to testify will be contacted by email to schedule their identity verification sessions. The Presiding Officers may extend the end time of the meeting beyond 7:00 p.m. EDT, if additional time is needed to accommodate demonstrated public interest.

Reasonable Accommodations

Persons who wish to request reasonable accommodations should submit a request through the online registration website at *https://www.federalreserve.gov/foia/bank-of-montreal-bank-of-the-west-application-materials.htm,* or by calling Jason Bouleris, Program Analyst in the OCC's Community Affairs Division, at (202) 649–6382. Requests should be made no later than 12:00 p.m. EDT on June 23, 2022. Requests submitted after this time may not be possible to accommodate. Requests should include a detailed description of the accommodation needed and a way for agency staff to contact the requester if more information is needed regarding the request.

Extension of the Comment Period

The Board is extending the comment period on the Holding Company Application, and the OCC is extending the comment period on the Bank Application, through 5:00 p.m. EDT on July 19, 2022.

Written comments regarding the Holding Company Application may be submitted to the Federal Reserve Bank of Chicago, Colette A. Fried, Assistant Vice President, 230 South LaSalle Street, Chicago, Illinois 60604, or electronically to *comments.applications@chi.frb.org;* or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001. In general, all written comments will be made available on the Board's website at *https://www.federalreserve.gov/foia/bank-of-montreal-bank-of-the-west-application-materials.htm* as submitted, and will not be edited to remove any confidential, contact, or other identifying information.

Written comments on the Bank Application may be submitted to Jason Almonte, Director for Large Bank Licensing at *LargeBanks@occ.treas.gov* or at 340 Madison Avenue, Fifth Floor, New York, New York 10173. Written comments will be made available on OCC's website at *https://www.occ.gov/topics/charters-and-licensing/public-comment/business-combination-or-merger-applications-comments.html.* In general, the OCC will publish each comment without change, including any business or personal information, name and address, email addresses, and phone numbers. Comments received, including attachments and other supporting material, are part of the public record and subject to public disclosure. Do not enclose any information in a comment or supporting material that is confidential or inappropriate for public disclosure.

Privacy Note

The Board will make the public record of the Holding Company Application, including all comments received, the written copy of a person's oral testimony at the public meeting (if a written copy is provided to the agencies), and the transcript of the public meeting, available on the Board's public website at: *https://www.federalreserve.gov/foia/bank-of-montreal-bank-of-the-west-application-materials.htm.* The OCC will make the public record of the Bank Application, including all comments received, the written copy of a person's oral testimony at the public meeting (if a written copy is provided to the agencies), and the transcript of the public meeting, available on the OCC's public website at: *https://occ.gov/topics/charters-and-licensing/public-comment/business-combination-or-merger-applications-comments.html.* Persons submitting comments and/or testimony are reminded to include only information that they wish to make available to the public.

Michael J. Hsu,

Acting Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2022–11070 Filed 5–23–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0307]

Recommendations To Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components.'' The guidance document provides blood establishments that collect blood and blood components with recommendations intended to reduce the possible risk of transmission of Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD) by blood and blood components. The recommendations in the guidance apply to the collection of Whole Blood and blood components intended for transfusion or for use in further manufacturing, including Source Plasma. The guidance removes the recommendations to defer indefinitely blood donors for geographic risk of possible exposure to bovine spongiform encephalopathy for time spent in the United Kingdom (U.K.) from 1980 to 1996 and for time spent in France and Ireland from 1980 to 2001, and receipt of a blood transfusion in the U.K., France, and Ireland from 1980 to the present. The guidance also provides recommendations for requalification of individuals previously deferred for these geographic risk factors, provided they meet all other eligibility requirements. The guidance announced in this notice supersedes the guidance

of the same title dated April 2020 and updated August 2020 (2020 guidance).

DATES: The Agency is soliciting public comment, but is implementing this guidance immediately, because the Agency has determined that prior public participation is not feasible or appropriate. 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–2012–D–0307 for ''Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components.'' 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: Tami Belouin, 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 document entitled ''Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components.'' The guidance document provides blood establishments that collect blood and blood components with recommendations intended to reduce the possible risk of transmission of Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD) by blood and blood components. The recommendations in the guidance apply to the collection of Whole Blood and blood components intended for transfusion or for use in further manufacturing, including Source Plasma. The guidance removes the recommendations in the 2020 guidance to defer indefinitely blood donors for: (1) Geographic risk of possible exposure to bovine spongiform encephalopathy for time spent in the U.K. from 1980 to 1996 and for time spent in France and Ireland from 1980 to 2001, and (2) receipt of a blood transfusion in the U.K., France, and Ireland from 1980 to present. The guidance also provides recommendations for requalification of individuals previously deferred for these geographic risk factors, provided they meet all other eligibility requirements. The guidance announced in this notice supersedes the final guidance of the same title dated April 2020 and updated August 2020. In the **Federal Register** of June 17, 2020 (85 FR 36593), FDA announced the availability of the final guidance of the same title dated April 2020. The guidance was updated in August 2020.

The recommendations on reducing the possible risk of transmission of CJD are unchanged from the 2020 guidance. The guidance changes the geographic deferral recommendations for vCJD risk based on new information in the risk assessments published by U.K.'s Advisory Committee on the Safety of Blood, Tissues and Organs and

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