4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1825]

Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Investigational COVID-19 Convalescent Plasma." The guidance document provides recommendations to healthcare providers and investigators on the use of investigational convalescent plasma for the treatment of the Coronavirus Disease 2019 (COVID-19) during the public health emergency. The guidance announced in this notice supersedes the guidance of the same title dated April 2020 and updated in May 2020. The guidance includes a discussion to facilitate the availability of investigational convalescent plasma when blood establishments, hospitals, and healthcare providers collect plasma that does not meet the Conditions of Authorization of the Emergency Use Authorization (EUA). The guidance also provides recommendations for healthcare providers who wish to administer and study convalescent plasma under an investigational new drug (IND) application.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2020-D-1825 for "Investigational COVID-19 Convalescent Plasma." 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: Shruti Modi, 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 guidance entitled "Investigational COVID-19 Convalescent Plasma." The guidance provides recommendations to healthcare providers and investigators on the use of investigational convalescent plasma for the treatment of COVID-19 during the public health emergency. The guidance announced in this notice supersedes the guidance of the same title dated April 2020 and updated in May 2020, and provides recommendations and additional information related to the August 23, 2020, EUA for COVID-

19 convalescent plasma for the treatment of hospitalized patients with COVID-19.[1] Accordingly, FDA is replacing the May 2020 guidance to provide recommendations to healthcare providers for administering COVID-19 convalescent plasma under the EUA. The new guidance also provides recommendations to blood establishments on collection of COVID-19 convalescent plasma under the EUA, including on donor eligibility and qualification, testing plasma for anti-SARS-CoV2 antibodies, and labeling.

In addition, the guidance describes FDA's interim compliance and enforcement policy regarding the IND requirements for the use of investigational convalescent plasma. Following issuance of the EUA for COVID-19 convalescent plasma on August 23, 2020, FDA has received numerous inquiries from blood establishments and healthcare providers regarding investigational convalescent plasma that was collected prior to the EUA and that remains in inventory. FDA understands that investigational convalescent plasma collected prior to the EUA may not meet the Conditions of Authorization set forth in the EUA. FDA also understands that it will take time for blood establishments to develop the necessary operating procedures to manufacture COVID-19 convalescent plasma pursuant to the Conditions of Authorization in the EUA. In addition, the Agency is aware that enrollment into the National Expanded Access Treatment Protocol sponsored by the Mayo Clinical was discontinued as of August 28, 2020.

Considering these issues and recognizing the immediate need for convalescent plasma to treat hospitalized patients with COVID-19, the guidance explains that FDA intends to exercise enforcement discretion with respect to the IND requirements for the collection, shipment, and administration of investigational convalescent plasma for a period of 90 days following the issuance of the guidance document provided certain circumstances are present. The guidance

[1] Emergency Use Authorization for COVID-19 Convalescent Plasma available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

outlines these circumstances and explains that during this period of enforcement discretion and beyond, FDA will continue to work with any investigators who wish to submit INDs for the study of investigational convalescent plasma and that ongoing clinical trials of investigational convalescent plasma should not be amended because of this enforcement discretion policy. The guidance also provides recommendations for healthcare providers who wish to administer and study convalescent plasma under an IND.

In light of this public health emergency, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

In the *Federal Register* of May 26, 2020 (85 FR 31513), FDA announced the availability of a guidance of the same title. Elsewhere in this issue of the *Federal Register*, FDA is announcing the withdrawal of the guidance of the same title that was announced on May 26, 2020.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on investigational COVID-19 convalescent plasma. 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 part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR 606.121 and 21 CFR part 630 have been approved under OMB control number 0910-0116; and the collections of information in Form FDA 3926 have been approved under OMB control number 0910-0814.

III. Electronic Access

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

Dated: September 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-20800 Filed: 9/18/2020 8:45 am; Publication Date: 9/21/2020]