blood donors who are residents of a non-endemic country and who travel to malaria-endemic areas. In addition, the guidance provides notice of an alternative procedure to permit the collection of blood and blood components from such donors without a deferral period, provided the blood components are pathogen-reduced using an FDA-approved pathogen reduction device, effective against *Plasmodium falciparum,* according to manufacturer's instructions for use. The revised recommendations are based on the current epidemiological data on malaria, the risk of transfusion-transmitted malaria and the availability of FDA-approved devices. FDA expects implementation of these revised recommendations will not be associated with any adverse effect on the safety of the blood supply. Furthermore, early implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing Coronavirus Disease 2019 (COVID–19) public health emergency.

The guidance announced in this notice supersedes the guidance entitled ''Recommendations for Donor Questioning, Deferral, Reentry, and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry'' dated August 2013 and updated August 2014.

In light of the COVID–19 public health emergency, FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(3) 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))). FDA expects 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(g)(2)). The guidance represents the current thinking of FDA on ''Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.'' 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

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338; 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116; and the collections of information for consignee and transfusion recipient physician notification have been approved under OMB control number 0910–0681.

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, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders,* or *https://www.regulations.gov.*

Dated: June 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13066 Filed 6–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1893]

Patient-Focused Drug Development: Collecting Comprehensive and Representative Input; Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; 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 final guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' This guidance is the first of a series of four methodological guidance documents that FDA committed to develop to address in a stepwise manner how to collect and submit information from patients and caregivers for medical product development and regulatory decision making. This guidance finalizes the draft guidance of the same title issued on June 13, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on June 17, 2020.

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–2018–D–1893 for ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 240–402–6525, Fax: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov* or Stephen Ripley, 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, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' This guidance (Guidance 1) is the first of a series of four guidance documents that FDA committed to develop to address in a stepwise manner how stakeholders (patients, researchers, medical product developers, and others) can collect and submit information on the patient experience for medical product development and regulatory decision making. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform medical product development and regulatory decision making. The purpose of Guidance 1 is to present methods for collecting information on the patient experience that is representative of the intended population to inform the development and evaluation of medical products throughout the medical product lifecycle. In addition, this document discusses methods on how to operationalize and standardize the collection, analysis, and dissemination of patient experience data. Guidance 1 also includes a glossary of terms that will be used in one or more of the series of four guidance documents.

From the outset, FDA recognized that developing this guidance would benefit from public input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders. On December 18, 2017, FDA conducted a public workshop to discuss this topic. FDA considered stakeholder input from the workshop and associated public docket when drafting this guidance (FDA–2017–N–5896).

This guidance finalizes the draft guidance entitled ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input,'' issued on June 13, 2018 (83 FR 27618). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include removing most of the section and appendix on methods for collecting and analyzing patient experience data since that information will be covered in later guidances in the series. In addition, editorial changes were made to improve clarity.

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 ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' 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

This guidance refers to collections of information from ''individuals under treatment or clinical examination in connection with research,'' which are not subject to review by the Office of Management and Budget under 5 CFR 1320.3(h)(5). This guidance also refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Electronic Access

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

Dated: June 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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