2023 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Authority: This program is authorized under Section 307 of the PHS Act (42 U.S.C 242); section 317(k)(1) and (2) of the PHS Act (42 U.S.C. 247b(k)(1) and (2).

Period of Performance: 7/1/2023 through 6/30/2028.

Dated: February 15, 2023.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–03522 Filed 2–17–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0343]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with current good manufacturing practice (CGMP) for blood and blood components, including information collection recommendations found in Agency guidance related to reducing the risk of transfusion-transmitted infection (TTI).

DATES: Either electronic or written comments on the collection of information must be submitted by April 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–N–0343 for ''Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

OMB Control Number 0910–0116—Revision

The FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulatory oversight of the U.S. blood supply. FDA issues and enforces requirements for blood collection and for the manufacturing of blood products, including both blood components intended for transfusion or for further manufacturing use. To implement applicable statutory provisions, regulations have been codified at 21 CFR part 606—Current Good Manufacturing Practice for Blood and Blood Components; 21 CFR part 610—General Biological Products Standards; 21 CFR part 630—Requirements for Blood and Blood Components Intended For Transfusion or For Further Manufacturing Use; and 21 CFR part 640—Additional Standards for Human Blood and Blood Products. The regulations establish quality standard requirements applicable to blood and blood products including information collection provisions.

CBER works closely with other parts of the Department of Health and Human Services to identify and respond to potential threats to blood safety and to monitor the availability of the blood supply. FDA has progressively strengthened the overlapping safeguards that help to ensure donor health and the safety of the blood supply for recipients of blood and blood products. For example:

- Blood donors answer donor history questions to identify risk factors that could indicate possible infection with a relevant-transfusion transmitted infection.
- FDA requires blood establishments to maintain a record of deferred donors to prevent collections ineligible donors.
- Blood donations are tested for several relevant transfusion-transmitted infections, include HIV, hepatitis B virus, and hepatitis C virus.

FDA also inspects blood establishments and monitors reports of errors, accidents, and adverse events associated with blood donation or transfusion.

Description of Respondents: Respondents to the collection of information are establishments that collect blood and blood components intended for transfusion or further manufacturing use.

For operational efficiency, we are revising the information collection to account for burden that may be attributable to recommendations found in associated FDA guidance documents, as listed below. FDA regulations in § 630.3(h) (21 CFR 630.3(h)) set forth a list of relevant transfusion-transmitted infections (RTTIs) (§ 630.3(h)(1)) and the conditions under which a TTI would meet the definition of an RTTI (§ 630.3(h)(2)). We have developed the following guidance documents, consistent with our Good Guidance Practice regulations in 21 CFR 10.115, that provide for comment at any time. The guidance documents include recommendations specific to certain RTTI or TTI regarding the collection of blood and blood components and discuss corresponding recordkeeping and/or notification activities.

Guidances Recommending Notification Based on Reactive Test Results

The following guidance documents provide recommendations for consignee and physician notification relating to donations that test reactive for RTTIs:

- Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (November 2009);
- Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; Guidance for Industry (December 2017);
- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry (May 2019); and
- Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV–I/II); Guidance for Industry (February 2020).

Guidances Recommending Notification Based on Post Donation Information Regarding a Risk Factor

The following guidance documents provide recommendations for consignee and physician notification under circumstances where a blood establishment may receive information following collection that reveals the donor had a risk factor for a RTTI or TTI at the time of collection and should have been deferred for the risk factor:

- Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry (January 2017);
- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products—Guidance for Industry (August 2020);
- 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 (May 2022); and
- Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry (December 2022).

These guidance documents are available for download from our website at *https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances.*

We believe such notifications are rare and that these notification practices would be part of the usual and customary business practice for blood establishments and consignees in addressing the RTTIs or TTIs under the regulations. We also believe respondents would have already developed standard operating procedures for notifying consignees and the recipient's physician of record regarding distributed blood components potentially at risk for a RTTI or TTI. However, to account for burden among respondents that may be attributable to this activity we allot one response and 1 hour annually. As additional guidance is developed by FDA addressing other RTTIs under § 630.3(h)(2), we will modify the information collection accordingly.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03515 Filed 2–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with medical device premarket notification (510(k)).

DATES: Either electronic or written comments on the collection of information must be submitted by April 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2013–N–0804 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification Procedures.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

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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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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