FDA has considered the request and is extending the comment period for the proposed rule for 90 days, until September 6, 2022. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments.

Dated: May 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11116 Filed 5–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 630 and 640

[Docket No. FDA–2022–D–0588]

Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability, draft compliance policy.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Draft Guidance for Industry.'' The draft guidance document addresses certain requirements that apply to blood establishments that collect blood and blood components, including Source Plasma. Specifically, the draft guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain requirements in the biologics regulations regarding donation suitability, donor eligibility, and quarantine hold for Source Plasma. FDA expects that the compliance policy described in the draft guidance will increase the availability of blood and blood components, including Source Plasma, while maintaining the health of blood donors and the safety of blood and blood components.

DATES: Submit either electronic or written comments on the draft guidance by July 25, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by July 25, 2022.

ADDRESSES: You may submit comments on any guidance 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–0588 for ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; 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 draft 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Phillip Kurs, 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.

With regard to the proposed collection of information: 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:

I. Background

FDA is announcing the availability of a draft document entitled ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements.'' The draft guidance document addresses certain requirements that apply to blood establishments that collect blood and blood components, including Source Plasma. Specifically, the draft guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain requirements in title 21 of the Code of Federal Regulations § 630.30 (21 CFR 630.30) regarding donation suitability; 21 CFR 630.10(c)(2) regarding donor eligibility; and 21 CFR 640.69(f) regarding quarantine hold for Source Plasma.

To address the urgent and immediate need for blood and blood components during the Coronavirus Disease 2019 (COVID–19) public health emergency, FDA issued certain exceptions and alternatives to the requirements regarding blood and blood components under 21 CFR 640.120(b) through the guidance entitled, ''Alternative Procedures for Blood and Blood Components During the COVID–19 Public Health Emergency; Guidance for Industry'' dated April 2020 (April 2020 guidance).

Since publication of the April 2020 guidance, FDA has received numerous comments from the blood industry requesting that FDA continue to permit the exceptions and alternatives beyond the public health emergency related to COVID–19 because the changes have increased availability of blood and blood components while maintaining the health of blood donors and safety of blood and blood components. Further, blood establishments have requested that FDA provide our recommendations before the end of the public health emergency to reduce the operational burdens associated with changes in standard operating procedures and blood establishment computer systems. FDA is issuing this guidance after considering the public comments, available data on donor health and the safety and availability of blood and blood components since publication of the April 2020 guidance, and the applicable regulations.

FDA expects that the compliance policy described in this draft guidance will increase the availability of blood and blood components, including Source Plasma, while maintaining the health of blood donors and the safety of blood and blood components.

While the April 2020 guidance is intended to remain in effect only for the duration of the public health emergency (PHE) related to COVID–19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act), the draft guidance ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements,'' when finalized, will remain in effect even after the HHS Secretary declares that this PHE no longer exists or the expiration of the 90-day period beginning on the date the HHS Secretary issues a renewal of the determination that a PHE exists.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on compliance with blood and blood component donation suitability, donor eligibility and Source Plasma quarantine hold requirements. 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

Under the Paperwork Reduction Act of 1995 (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 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.

Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements

OMB Control Number 0910–0116—Revision

As noted, blood establishments that collect blood and blood components, including Source Plasma, must comply with requirements in § 630.30 regarding donation suitability. The draft guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with this requirement and describes proposed procedures in section III.A. under the heading ''Record Maintenance, Investigation and Annual Reporting'' for such an establishment's filing of annual reports on the release of unsuitable donations to FDA. FDA will use the reports to monitor error rates associated with the collection of unsuitable donations and work with establishments to implement corrective actions, if necessary. The information is needed to support FDA's efforts to protect the health of blood donors and the safety of blood and blood components. We are requesting approval to revise the scope of the information collections included in OMB control number 0910–0116 to include the information collection associated with the draft guidance.

Description of Respondents: Licensed and registered-only establishments that collect blood and blood components for transfusion and further manufacturing, and elect to release unsuitable donations pursuant to the compliance policy described in the guidance.

Burden Estimate: FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/draft guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual report—Licensed blood collection establishments/ Section III.A	50	1	50	4	200
Annual report—Registered-only blood establishments/Section III.A	50	1	50	4	200
Total	400				

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the proposed reporting provisions in the guidance on our experience with similar information collections and a review of similar Agency data.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338 and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *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. 2022–11120 Filed 5–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket No. OSHA–2021–0012]

RIN 1218–AD43

Arizona State Plan for Occupational Safety and Health; Proposed Reconsideration and Revocation; Extension of Comment Period; Extension of Hearing Request Period; Extension of Period To Submit Written Testimony; Extension of Period To Submit Notices of Intention To Appear at Public Hearing

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; extension of comment period; extension of period for submitting request for an informal hearing; extension of period to submit written testimony; extension of deadline for submitting notices of intention to appear at public hearing.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is extending the deadlines for submitting comments on the Notice of Proposed Reconsideration and Revocation of Final Approval of the Arizona State Plan for Occupational Safety and Health (Notice), requests for an informal hearing, and submission of written testimony for an additional 40 days to July 5, 2022, and extending the deadline for submitting notices of intention to appear at its informal public hearing for an additional 55 days to July 5, 2022. In its prior Notice announcing this proposed action, OSHA advised the public that any informal public hearing to be held on this matter will begin on August 16, 2022, at 10:00 a.m., ET.

DATES:

Written comments: Written comments on the Notice and requests for a hearing must be submitted electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal, by July 5, 2022.

Informal public hearing: Any interested person may request an informal hearing concerning the proposed revocation. OSHA will hold such a hearing if the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) finds that substantial objections have been filed. The agency will hold such an informal public hearing beginning on August 16, 2022, virtually on WebEx. OSHA expects the hearing to last from 10:00 a.m. to 6:00 p.m., ET; a schedule will be released prior to the start of the hearing. The exact daily schedule may be amended at the discretion of the presiding administrative law judge (ALJ). If necessary, the hearing will continue at the same time on subsequent days.

Notice of intention to appear at the hearing: Interested persons who intend to present testimony or question witnesses at the hearing must submit a notice of their intention to do so by July 5, 2022.

Hearing testimony and documentary evidence: Interested persons who request more than 5 minutes to present testimony, or who intend to submit documentary evidence, at the hearing must submit the full text of their testimony and all documentary evidence by July 5, 2022.

ADDRESSES:

Written comments: You may submit comments and attachments electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions on-line for making electronic submissions.

Informal public hearing: If the agency holds an informal public hearing, the hearing will be held virtually on WebEx. Additional information on how to access the informal hearing will be