Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 21, 2023.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 25, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910–0116—Revision

This information collection helps support FDA implementation of statutory and regulatory requirements that govern current good manufacturing practice (CGMP) for blood and blood components. We have issued regulations in parts 606, 610, 630, and 640 (21 CFR parts 606, 610, 630, and 640) setting forth applicable standards and procedures that include associated reporting, recordkeeping, and disclosure requirements. Respondents to the collection of information are licensed and registered-only establishments that collect blood and blood components intended for transfusion or further manufacturing use. We provide information on our website at *https://www.fda.gov/vaccines-blood-biologics/blood-blood-products* regarding CGMP for blood and blood products, including available Agency resources.

We are revising the information collection to support implementation of annual reporting to FDA of the release of unsuitable blood donations from establishments that intend for their activities to fall under the compliance policy set forth in the draft guidance for industry entitled ''Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements'' (May 2022). The draft guidance describes FDA's compliance policy for certain regulations. Blood establishments that collect blood and blood components, including Source Plasma, must comply with requirements in § 630.30 regarding donation suitability. However, 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 for such an establishment's filing of annual reports on the release of unsuitable donations to FDA. Specifically, under this policy, when finalized, when the donation is otherwise suitable under § 630.30(a), FDA does not intend to take regulatory action if blood establishments release donations for transfusion or further manufacture when the review of records, required after donation under § 630.30(a)(2), identifies the donation as unsuitable because of inadvertent failure to follow procedures to ensure that the donation would not adversely affect the health of the donor, namely for:

- blood pressure (§ 630.10(f)(2));
- pulse (§ 630.10(f)(4));
- weight (§ 630.10(f)(5));
- donation frequency for Whole Blood and Red Blood Cells collected by apheresis (§ 630.15(a)(1));
- pregnancy (§ 630.10(e)(2)(v)); and
- red blood cell loss for plasma collected by plasmapheresis (§ 630.15(b)(6)).

The draft guidance sets forth that FDA intends to apply the compliance policy provided blood establishments that elect to release unsuitable units as described in the guidance report the release of unsuitable donations to FDA annually. The draft guidance document is available for download at *https://www.fda.gov/media/158608/download.* We issued the guidance document consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We intend on finalizing the guidance document upon OMB approval of the attendant information collection. When finalized, the guidance will supersede the guidance entitled, ''Alternative Procedures for Blood and Blood Components During the COVID–19 Public Health Emergency; Guidance for Industry,'' dated April 2020.

As explained in section III.A of the guidance, licensed and registered-only blood establishments must maintain records as required under § 606.160; investigate the error that resulted in the collection of an unsuitable donation under § 630.30(a)(2); and submit a report to FDA annually if they intend for their activities to fall under this

compliance policy. The report should describe the number and type of donations released under these conditions. The report should also describe the corrective actions taken to prevent recurrence of errors and to ensure compliance with the applicable regulations. The final guidance will clarify that the report may be submitted in summary format.

The submission of these reports will allow us to monitor error rates associated with the collection of unsuitable units and work with establishments to implement corrective actions, if necessary. We expect that this compliance policy 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. If, based upon the available scientific evidence, the risk to the safety of the blood supply or the risk to donors' health significantly changes, FDA may revise this compliance policy as warranted.

In the **Federal Register** of May 24, 2022 (87 FR 31440), we published a 60-day notice requesting public comment on the proposed collection of information. We received six comment letters, each of which contained multiple comments, in response to the notice. Some comments were not responsive to the four information collection topics solicited.

(Comment 1) With regard to the statement in the draft guidance that ''licensed and registered-only blood establishments must maintain records as required under 21 CFR 606.160; investigate the error that resulted in the collection of an unsuitable donation under 21 CFR 630.30(a)(2); and submit a report to FDA annually if they intend for their activities to fall under this compliance policy,'' one comment asked that we clarify whether post-donation information (PDI) related to blood pressure, pulse, weight, and red blood cell loss would need to be investigated and reported to us in the report on an annual basis.

(Response 1) PDI is information received by the blood establishment after donation from the donor or another source that is out of the control of the establishments. We do not consider the receipt of PDI to be an error that must be reported to FDA on an annual basis as described in the guidance. However, the blood establishment's measurement of a donor's blood pressure, pulse or red blood cell loss are in the control of the establishment, and errors in such measurement would not be identified through PDI.

We have considered the comment and have determined that the comment does not present information that would warrant changes to the guidance document at this time.

(Comment 2) Another comment requested that the annual report not include corrective actions taken for each error because this would represent duplication of information already available to FDA via its inspection compliance program. The comment noted that each establishment has a defined deviation management and corrective action program and each error related to donor eligibility determination is investigated. The comment further noted that FDA should not request this report because the information can be reviewed during FDA's inspection compliance program.

(Response 2) We disagree that including a summary of corrective actions on the annual report would represent duplication of information. Establishments may submit the information already developed as part of their deviation management and corrective action program. A new investigation does not need to be completed and new documentation does not need to be created. Receiving annual information about the corrective actions taken will allow us to better assess the robustness of the establishment's GMP system in a timely manner. We also note that blood establishments may elect not to use the enforcement discretion provided in the guidance to release certain unsuitable blood components, and therefore, would not submit a report to FDA.

Comments are being considered as the guidance is being finalized. We are clarifying in the final guidance that the annual report about the corrective actions taken may be submitted in summary format. This change in wording did not affect our estimate of the burden.

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

We estimate the burden of the information collection 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 of released unsuitable units—Licensed blood collection establishments/section III.A	50	1	50	4	200
Annual report of released unsuitable units—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 on our experience with similar information collections and a review of similar reporting data.

Dated: August 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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