An Acceptable Circular of Information for the Use of Human Blood and Blood Components

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Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit one set of either electronic or written comments on this guidance at anytime. Submit electronic comments to https://www.regulations.gov. Submit written comments to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with docket number FDA-2002-D-0223.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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Contains Nonbinding Recommendations

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

We, the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research, are recognizing as acceptable for use by you, manufacturers of blood and blood components intended for transfusion, the document entitled "Circular of Information for the Use of Human Blood and Blood Components," dated June 2024 (June 2024 Circular). The June 2024 Circular provides specific labeling instructions for the administration and use of blood and blood components intended for transfusion. We believe that the June 2024 Circular will assist you in complying with labeling requirements under 21 CFR 606.122. The requirements under 21 CFR 606.122 specify that a circular of information must be available for distribution with blood and blood components intended for transfusion. Section 606.122 further specifies the information that is required in the circular of information. This guidance supersedes the guidance of the same title updated March 2022.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA's guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The June 2024 Circular was prepared jointly by the Association for the Advancement of Blood and Biotherapies (AABB), the American Red Cross (ARC), America's Blood Centers (ABC), and the Armed Services Blood Program (ASBP). The Circular is periodically updated to address changes in regulations, technology, testing, and product indications.

III. FDA REVIEW AND CONCLUSION

We have reviewed the June 2024 Circular and find it acceptable for use in the labeling of blood and blood components intended for transfusion under 21 CFR 606.122. A link to the June 2024 Circular is found in section V. of this guidance.

The blood components in the June 2024 Circular marked with the symbol "Ω" are blood components for which FDA has not received data to demonstrate that they meet requirements for safety, purity and potency. Therefore, these blood components are not licensed for distribution in interstate commerce under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

Any subsequent modifications to the June 2024 Circular are not covered by this guidance.

IV. IMPLEMENTATION

Licensed manufacturers must report the implementation of the June 2024 Circular to FDA under 21 CFR 601.12 as follows:

1. If the June 2024 Circular is implemented without modification and in its entirety, the change is considered to be minor. You must report such changes to FDA in your annual report, consistent with 21 CFR 601.12(f)(3) and noting the date the process was implemented.

2. If the June 2024 Circular is implemented with modification, the change is considered to be major. You must report such changes as a Prior Approval Supplement, consistent with 21 CFR 601.12(f)(1), unless a lower reporting category is recommended by FDA in guidance (see 21 CFR 601.12 (a)(3)).

Unlicensed blood establishments are not required to report this change to FDA.

V. SUPPLEMENTARY INFORMATION

The June 2024 Circular can be accessed on the AABB website at: http://www.aabb.org/tm/coi/.

If you have questions regarding the June 2024 Circular, contact AABB by phone at 301-907-6977 or by email at regulatory@aabb.org to the attention of the Director, Regulatory Affairs.