DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2732]

Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Guidance for Industry; 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 titled ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.'' The guidance document provides recommendations on the development of blood collection, processing, and storage systems (*e.g.,* blood bags with anticoagulant and additive solutions, empty bags for platelet pooling) intended for the manufacture of blood and blood components for transfusion using the buffy coat (BC) method and on regulatory submissions to FDA for such products. This guidance is intended for manufacturers of blood collection, processing, and storage systems. The guidance announced in this notice finalizes the draft guidance of the same title dated October 18, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on September 17, 2026.

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–2024–D–2732 for ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.'' 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 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. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance titled ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.'' This guidance provides recommendations on the development of blood collection, processing, and storage systems (*e.g.,* blood bags with anticoagulant and additive solutions, empty bags for platelet pooling) intended for the manufacture of blood and blood components for transfusion using the BC method and on regulatory submissions to FDA for such products. This guidance is intended for manufacturers of blood collection, processing, and storage systems.

Blood and blood components must be prepared in a manner consistent with

the instructions provided by the manufacturer (21 CFR 606.65(e)), including the directions provided in the instructions for use of the approved or cleared collection, processing, and storage system. To prepare blood components using the BC method, blood establishments must use blood collection, processing and storage systems approved or cleared for such use.

This guidance provides recommendations to manufacturers who wish to obtain FDA approval or clearance to market blood collection, processing, and storage systems intended for the manufacture of blood components for transfusion using the BC method. With the availability of such FDA-approved or cleared systems, blood establishments in the United States would have the option of manufacturing Whole Blood-derived blood components using the BC method and licensed blood establishments could submit Biologics License Application (BLA) supplements to FDA.

In the **Federal Register** of October 18, 2024, (89 FR 83886), FDA announced the availability of the draft guidance of the same title dated October 18, 2024. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to comments received, FDA made several clarifying edits. For example, FDA made clarifying revisions regarding timeframes for overnight ambient temperature holds, use of additive solutions that are currently not approved by FDA, and efforts to transition to systems that do not contain di(2-ethylhexyl) phthalate (DEHP). In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 18, 2024.

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 ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.'' 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

While this guidance contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312.47 relating to the submission of investigational new drug applications and related meetings, including pre-IND meetings, ''pre-NDA'' stages, and pre-new drug application meetings, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314.102 relating to submission of new drug marketing applications, as well as related meetings between sponsors or applicants and FDA or other communication with appropriate FDA officials to obtain advice and other information necessary to support submissions, and to discuss appropriate regulatory pathways, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 807, subpart E relating to the submission of a premarket notification ((510(k)) for a medical device have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 812 relating to the submission of Investigational Device Exemption applications have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814 relating to the submission of a premarket approval application (PMA) have been approved under OMB control number 0910–0231.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *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.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19080 Filed 9–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at: *samhsapra@samhsa.hhs.gov.*

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Survey on Drug Use and Health (OMB No. 0930–0110)

The National Survey on Drug Use and Health (NDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older within the 50 states and the District of Columbia. Consistent with NSDUH designs since 1991, the 2027 NSDUH will include residents of noninstitutional group quarters (*e.g.,* shelters, rooming houses, dormitories) and civilians residing on military bases. Excluded from the NSDUH are people without fixed household address (*e.g.,* homeless people not in shelters) and residents of institutional group quarters, such as jails and hospitals.

The 2027 sampling frame will exclude U.S. territories. Although data collection pilots were conducted to assess operational feasibility in Puerto Rico (2023–2025) and in the U.S. Virgin Islands (2024), SAMHSA determined that additional testing and discussions with other statistical agencies are needed before expanding full-scale