questions regarding this collection contact Robert Giles at 667–290–8626.)

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–22370 Filed 11–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5942]

Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus; 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 Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' The guidance document provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for hepatitis B virus (HBV) to reduce the risk of transfusion-transmitted HBV. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. The guidance announced in this notice finalizes the draft guidance titled ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen'' (July 2025 Draft Guidance). The guidance also supersedes the documents titled ''Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)'' (December 1987 Memorandum), ''FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)'' (September 1991 Memorandum), ''Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes'' (November 2007 Final Guidance), ''Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)'' (May 2010 Final Guidance), ''Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection'' (November 2011 Final Guidance), and ''Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus'' (October 2012 Final Guidance). The guidance supersedes the recommendations specific to HBV in ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T-Lymphotropic Virus Type I (HTLV–I)'' (July 1996 Memorandum).

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 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–5942 for ''Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' 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 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 draft guidance document.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document titled ''Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' The guidance provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for HBV to reduce adequately and appropriately the risk of transfusion-transmitted HBV. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. Specifically, the guidance provides recommendations on donation testing, donor deferral and requalification of deferred donors. The guidance also provides recommendations for product management, retrieval and quarantine.

In the **Federal Register** of July 16, 2025 (90 FR 32013), FDA announced the availability of the draft guidance titled ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen'' dated July 2025. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the recommendations in the draft guidance dated July 16, 2025.

As such, the guidance recommends the discontinuation of testing certain donations for HBsAg and conforming changes for donor requalification and labeling. Namely, we recommend that when donations are tested for HBV deoxyribonucleic acid (DNA) by nucleic acid tests (NAT) and for anti-HBc using screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions, testing for HBsAg is not necessary to reduce adequately and appropriately the risk of transmission of HBV. For Source Plasma donations, we continue to recommend that testing for HBsAg and HBV DNA by NAT is necessary to reduce adequately and appropriately the risk of transmission of HBV.

In addition, the guidance consolidates FDA's recommendations for testing blood and blood components for HBV that have been issued previously in various memoranda and guidance documents. In consolidating the previous recommendations, minor changes were made to reflect advances in the tests used to screen blood donation for HBV and for consistency and alignment with current practices. As such, this final guidance supersedes the prior memoranda and guidance documents containing recommendations on donation testing, donor deferral and requalification of deferred donors, and blood product management, retrieval and quarantine related to HBV listed in the Summary above.

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 Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' 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 collection 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 601.12 pertaining to licensed blood establishments reporting changes to an approved biologics license application have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 610, 630, and 606 pertaining to current good manufacturing practices for blood, blood components, donor notification, and requirements for donor testing have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4299]

Potency Assurance for Cellular and Gene Therapy Products; 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 ''Potency Assurance for Cellular and Gene Therapy Products.'' The guidance document provides recommendations to help assure the potency of human cellular therapy or gene therapy (CGT) products at all stages of the product lifecycle. FDA is recommending a comprehensive approach to potency assurance of CGT products that is grounded in quality risk management. For investigational products, we describe how to progressively implement a strategy for potency assurance during product development and provide additional considerations to help assure the potency of products that are undergoing rapid clinical development. For licensed products, we describe requirements for potency assurance, including testing required for lot release assays. The guidance announced in this notice finalizes the draft guidance of the same title issued on December 28, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: