4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-5942]

Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled "Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry." The draft guidance document provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood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 surface antigen (HBsAg) to reduce the risk of transfusion-transmitted hepatitis B virus (HBV). The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. The draft guidance, when finalized, is intended to supersede the recommendations regarding testing of all blood donations for HBsAg in the guidance document entitled "Guidance for Industry: 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" dated October 2012 (October 2012 Guidance). The guidance, when finalized, will also supersede information on the same topic that is in the document entitled "Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)" dated December 1987 (December 1987 Memorandum).

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to

ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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-2024-D-5942 for "Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; 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. 3103, 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: 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 draft document entitled "Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry." The draft guidance provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for HBsAg 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. Specifically, the guidance recommends that when the donations are tested for HBV Deoxyribonucleic acid (DNA) by nucleic acid tests (NAT) and for antibody to hepatitis B core antigen (anti-HBc) using screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions, testing for hepatitis B surface antigen (HBsAg) is not necessary to reduce adequately and appropriately the risk of transmission of HBV. Because Source Plasma donations are not tested for anti-HBc, the draft guidance

recommends the continued testing of Source Plasma donations for HBsAg. The draft guidance, when finalized, is intended to supersede the recommendations with respect to blood donations that are tested for HBV NAT and anti-HBc in the October 2012 Guidance and the information on the same topic in the December 1987 Memorandum. Upon finalization of the new recommendations set forth in this draft guidance, we intend to consolidate all FDA recommendations for testing blood and blood components for HBV to issue one guidance that includes finalized recommendations for testing donations to reduce the risk of transfusion transmission of hepatitis B. Except for conforming changes needed to reflect the new recommendations in this draft guidance, we do not intend to revise existing recommendations for HBV donation testing, quarantine and disposition of reactive units, donor deferral and requalification.

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 the current thinking of FDA on "Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen." 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.

As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M-25-20, and in particular, on any costs or cost savings.

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 have been approved under OMB control number 0910-0338 and the collections of

information in 21 CFR parts 610 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 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: July 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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