



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2024-D-3067; FDA-2024-D-3863]

**Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products;**

**Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* by Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidances for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is withdrawing two final guidances entitled “Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” and “Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” and reissuing them as draft guidances.

**DATES:** Submit either electronic or written comments on the draft guidances by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on the draft guidances before it begins work on the final version of the guidances.

**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-3067 for "Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" or the Docket No. FDA-2024-D-3863 for "Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based

Products (HCT/Ps),” as appropriate. 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 guidances to the Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive labels to assist that office in processing your requests. The guidances 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 documents.

**FOR FURTHER INFORMATION CONTACT:** Irma Sison, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-8190.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing the availability of two draft guidances, “Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” and “Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).” These draft guidance documents were originally published as final guidance in the *Federal Register* on January 7, 2025 (90 FR 1141; 90 FR 1170). Both guidances recommended that establishments making donor eligibility determinations (establishments) implement the recommendations in the guidances “as soon as feasible, but not later than 4 weeks after the guidance issue date.” On February 3, 2025, FDA subsequently announced the availability of revised versions of these guidances that recommended implementation of the guidance recommendations on a longer timeframe, by May 4, 2025 (90 FR 8802).

FDA is withdrawing the final guidances “Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular

and Tissue-Based Products (HCT/Ps)” and “Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” and reissuing them as draft guidances.

The draft guidance entitled “Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” provides establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of disease agents associated with sepsis for donors of human cells, tissues, and cellular and tissue-based products. This guidance, when finalized, will supersede information regarding sepsis included in the guidance “Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry,” dated August 2007 (August 2007 HCT/P DE Guidance), by updating recommendations for making a donor eligibility determination when screening a donor for clinical evidence of sepsis and clinical signs to consider. The August 2007 HCT/P DE guidance identified sepsis as a relevant communicable disease agent or disease under 21 CFR 1271.3(r)(2).

The draft guidance entitled “Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” assists establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products, with recommendations for screening donors for evidence of, and risk factors for, infection with Mtb, the organism that causes tuberculosis.

FDA is issuing these draft guidances consistent with our good guidance practices regulation (21 CFR 10.115). FDA has received comments on the now-withdrawn final guidances issued in January 2025, and the Agency has made certain revisions that have been incorporated into the new draft guidances in response to those comments. The Agency will continue to consider those comments, as well as any comments received on these draft

guidances, as we consider next steps. These draft guidances, when finalized, will represent the current thinking of FDA on “Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” and “Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)”. These guidances do not establish any rights for any person and are 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 these guidance documents contain no collection of information, they do 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 1271 relating to HCT/Ps, including establishing and maintaining records, investigation and reporting of adverse actions and documentation of methods used in facilities related to HCT/Ps, which includes but is not limited to donor screening, donor testing, and labeling have been approved under OMB control number 0910-0543.

## III. Electronic Access

Persons with access to the internet may obtain the guidances 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: April 29, 2025.  
**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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