

21 CFR part; guidance; or FDA form	Topic	OMB control No.
860, subpart D ..... “Administrative Procedures for CLIA Categorization” and “Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices”.	De Novo classification process ..... CLIA Administrative Procedures; CLIA Waivers .....	0910–0844 0910–0607
800, 801, 809, and 830 .....	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56 .....	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: December 26, 2024.  
**Kimberlee Trzeciak,**  
*Deputy Commissioner for Policy, Legislation, and International Affairs.*  
 [FR Doc. 2024–31522 Filed 1–6–25; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2024–D–3863]

**Recommendations To Reduce the Risk of Transmission of Mycobacterium Tuberculosis by Human Cells, Tissues, and Cellular and Tissue-Based Products; 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 final guidance for immediate implementation entitled “Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).” FDA is issuing this guidance to assist establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), with recommendations for screening donors for evidence of, and risk factors for, infection with *Mycobacterium tuberculosis* (Mtb), the organism that causes tuberculosis. The guidance also recommends additional steps that HCT/P establishments should take to reduce risk of transmission of Mtb until such time as appropriate FDA-licensed, approved, or cleared donor screening tests are available for use to test donors for Mtb infection. The guidance identifies Mtb as a relevant communicable disease agent or disease (RCDAD) and supplements the

recommendations contained in other donor eligibility guidance documents for donors of HCT/Ps. This guidance is being issued to address the urgent public health need to reduce the risk of transmission of Mtb by HCT/Ps.

**DATES:** The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

**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–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).” 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 § 10.115(g)(5) (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. 3128, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that 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:**

Jessica Gillum, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a final guidance for immediate implementation entitled "Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." FDA is issuing this guidance to provide establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for screening for evidence of, and risk factors for, infection with Mtb, the organism that causes tuberculosis. The guidance also recommends additional steps that HCT/P establishments should take to reduce risk of transmission of Mtb until such time as appropriate FDA-licensed, approved, or cleared donor screening tests are available for use to test donors for Mtb infection.

In addition, this guidance identifies Mtb as an RCDAD as defined in 21 CFR 1271.3(r)(2) and supplements the recommendations contained in other donor eligibility guidance documents for donors of HCT/Ps.

In 2021 and 2023, multistate outbreaks of Mtb in the United States were linked to transplantation of bone allograft products and resulted in significant morbidity and mortality. Because Mtb transmission can occur from HCT/P donors with unrecognized and undiagnosed tuberculosis infection, these circumstances demand heightened awareness when screening donors of HCT/Ps.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because of the urgent public health need to provide recommendations to industry to reduce the risk of transmission of Mtb by HCT/Ps. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another immediately in effect 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)" with recommendations to reduce the risk of transmission of disease agents associated with sepsis, including mycobacterial agents such as Mtb, which can be a cause of sepsis.

The guidance represents the current thinking of FDA on "Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." 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 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 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 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>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

**Kimberlee Trzeciak,**

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

[FR Doc. 2024-31544 Filed 1-6-25; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2024-D-3334]

**Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway; Draft 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 draft guidance for industry entitled "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway." For drugs granted accelerated approval, sponsors conduct confirmatory studies that must be completed postapproval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. This draft guidance describes FDA's interpretation of the term "underway" and discusses policies for implementing this requirement, including factors FDA intends to consider when determining whether a confirmatory trial is underway prior to accelerated approval.