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]

BILLING CODE 4164–01–P

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.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by March 10, 2025.

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–3334 for ''Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway.'' 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tamy Kim, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2206, Silver Spring, MD 20993–0002, 301–796–1125, or James Myers, 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, or Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926 or 301–796–2500.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 have been required to conduct confirmatory studies postapproval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In the Consolidated Appropriations Act, 2023 (CAA), Congress amended section 506(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)), to provide additional authorities to help ensure timely completion of such trials, including that FDA ''may require, as appropriate, a study or studies to be underway prior to approval, or within a specified time period after the date of approval, of the applicable product. This draft guidance, when finalized, will describe FDA's interpretation of the term ''underway'' and policies for implementing this requirement, including factors FDA intends to consider when determining whether a confirmatory trial is underway prior to an accelerated approval action.

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 ''Accelerated Approval and Considerations for Determining Whether a Required Post-Marketing Clinical Trial is Underway.'' 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

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway

OMB Control Number 0910–0001—Revision

As noted, section 506 of the FD&C Act was modified by section 3210 of the CAA, which granted FDA additional authorities with additional obligations regarding the accelerated approval pathway. Among other revisions, section 3210 of the CAA provides statutory authority to help ensure timely completion of confirmatory trials of accelerated approval products, including that FDA may require as appropriate, a confirmatory study or studies to be underway prior to approval or within a specified time period after the date of approval of the product. The CAA also requires sponsors to submit postmarketing reports to FDA on the progress of required confirmatory trials approximately every 180 days. This draft guidance describes FDA's policies for implementing this statutory authority. FDA will use the reports to monitor the progress of confirmatory trials and take action, if necessary. The information is needed to support FDA's efforts to protect the health of users of drugs approved under accelerated approval. We are requesting approval to revise the statutory authority reference in approved OMB control numbers 0910–0001 and 0910–0338 to include section 3210 of the CAA.

Description of Respondents: Respondents to this information collection are sponsors of human drug and biological products.

Burden Estimate: We reviewed the statutory authority granted by section 3210 of the CAA as well as our existing statutory authority and regulations. Section 506B of the FD&C Act (21 U.S.C. 356b), and implementing regulations in §§ 312.20, 314.81 and 601.70 (21 CFR 312.20, 314.81 and 601.70), provide for the submission of postmarket study reports, requiring sponsors of approved drugs and biological products to report to FDA on the progress of their postmarketing study commitments, including reports on required studies, clinical trials, and agreed upon commitments.

We tentatively conclude that the change in our statutory authority adds no further information collection requirements and imposes no further burden beyond what is already required in our statutes and regulations and included in the approved ICRs for reporting the status of postmarketing study commitments.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 50 and 56 for protection of human subjects and institutional review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 for submission of investigational new drug applications, conduction of clinical trials and good clinical practice, meetings for design and implementation of drug development plans, and reports of data for confirmatory trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in §§ 312.20, 314.81 and 601.70 for submission of postmarketing reports including accelerated approval clinical benefit studies have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338. The collections of information in 21 CFR parts 601 and 610 for submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information for expedited pathways for development programs of drugs and biologics for serious conditions have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31527 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–2402]

Considerations for Including Tissue Biopsies in Clinical Trials; Draft Guidance for Industry, Investigators, Institutions, and Institutional Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) and the Office for Human Research Protections (OHRP) are announcing the availability of a draft guidance for industry, clinical investigators, institutions, and institutional review boards (IRBs) entitled ''Considerations for Including Tissue Biopsies in Clinical Trials.'' This guidance provides recommendations regarding considerations for tissue biopsies that may be conducted in adults and in children as part of clinical trials evaluating investigational medical products and/or that are conducted or