been approved under OMB control number 0910–0543.

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Persons with access to the internet may obtain the draft guidance at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: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09287 Filed 4–29–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1244]

Considerations for the Use of Human- and Animal-Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Draft Guidance for Industry; Availability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 document entitled ''Considerations for the Use of Human- and Animal-Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Draft Guidance for Industry.'' The draft guidance document provides manufacturers of cellular and gene therapy (CGT) and tissue-engineered medical products (TEMPs) with recommendations regarding assuring the safety, quality, and identity of materials of human and animal origin used in the manufacture of these products. In addition, recommendations are provided regarding the chemistry, manufacturing, and control (CMC) information submitted in an investigational new drug application (IND) relating to the use of human- and animal-derived materials.

DATES: Submit either electronic or written comments on the draft guidance by July 29, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–1244 for ''Considerations for the Use of Human- and Animal-Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; 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. 3128, 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, 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 draft document entitled ''Considerations for the Use of Human- and Animal-Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Draft Guidance for Industry.'' The use of human- and animal-derived materials to manufacture CGT products and TEMPs raises several key issues to consider, including transmission of adventitious agents, material lot-to-lot consistency, and material identity, as well as general material qualification considerations. The draft guidance document provides manufacturers of CGT products and TEMPs with recommendations regarding assuring the safety, quality, and identity of materials of human and animal origin used in the manufacture of these products. In addition, recommendations are provided regarding the CMC information submitted in an IND relating to the use of human- and animal-derived materials.

Human- and animal-derived materials may be used directly during manufacturing of a drug substance and a drug product. In addition, human- and animal-derived materials may be used in the manufacture of reagents or substrates used in manufacturing, such as cell banks, viral stocks, antibodies, and other proteins. Some common examples of human- and animal-derived materials include human or animal blood, antibodies produced in sera from animal hybridoma cells, and cytokines produced in insect cell lines.

Use of human- and animal-derived materials during product manufacturing may increase risks of infectious disease transmission, and raises potential safety concerns, such as the possible introduction of adventitious agents or other impurities into CGT products and TEMPs. Human- and animal-derived materials can also contribute to product variability by affecting the reproducibility of the manufacturing process or the quality of the final product.

The draft guidance, when finalized, is intended to supplement the following two final guidances: ''Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Guidance for Industry'' dated January 2020, and ''Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs)'' dated April 2008.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another human gene therapy final guidance document entitled ''Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft Guidance for Industry.''

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 ''Considerations for the Use of Human- and Animal-Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products.'' 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 312 pertaining to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 211 pertaining to current good manufacturing practice for finished pharmaceuticals have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 610, 630, and 640 pertaining to current good manufacturing practice for blood and blood components have been approved under OMB control number 0910–0116. The collections of information in 21 CFR part 1271 pertaining to human cells, tissues, and cellular and tissue-based products have been approved under OMB control number 0910–0543. The collections of information in FDA's guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants'' have been approved under OMB control number 0910–0001. The collections of information in FDA's guidance entitled, ''PHS Guideline on Infectious Disease Issues in Xenotransplantation'' have been approved under OMB control number 0910–0456.

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: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09286 Filed 4–29–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1809]

Listening Session: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled ''Listening Session: Optimizing FDA's Use of and Processes for Advisory Committees.'' The purpose of the listening session is to solicit feedback on the Agency's use of and processes for its advisory committee system.

DATES: The virtual listening session will be held on June 13, 2024, from 9 a.m. to 4 p.m. Eastern Daylight Time (EDT) or until after the last public commenter has spoken, whichever occurs first. Submit requests to make oral presentations at the listening session by 3 p.m. EDT, May 13, 2024. Electronic or written comments on this listening session must be submitted to the docket by August 13, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Additional details, such as registration information, are available at: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-meeting-optimizing-fdas-use-*