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Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Draft Guidance for Industry.''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 The draft guidance document provides manufacturers of CGT products and TEMPs with recommendations regarding assuring the safety, quality, and identity of materials of human and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The draft guidance, when finalized, is intended to supplement the following two final guidances: ''Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy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]

BILLING CODE 4164–01–P

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-*

and-processes-advisory-committees-06132024.

FDA is establishing a public docket for this listening session. You may submit comments as follows. Please note that late, untimely filed comments may not be considered. Electronic comments must be submitted on or before August 13, 2024. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. EDT on August 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–1809 for ''Listening Session: Optimizing FDA's Use of and Processes for Advisory Committees.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Jill Wasserman, Stakeholder Engagement Staff, Office of External Affairs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5367, Silver Spring, MD 20993, 240–623–6945, (this is not a toll-free number), email: *ACfeedback@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Advisory committees comprised of external advisors support FDA's mission of protecting and promoting the public health by providing us with independent advice on scientific, technical, and policy matters. FDA makes the final decisions on any matters considered by an advisory committee.

Committees are either mandated by statute or established at FDA's discretion. Advisory committees must meet the requirements set forth in the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). General procedures for FDA advisory committees are included in FDA's regulations at 21 CFR part 14.

The products that FDA regulates can impact the daily lives of the American public, and advisory committee are an important part of FDA's regulatory processes. While the Agency hears frequently from certain groups about advisory committees, we are interested in more broadly hearing from all parties interested in the advisory committee process and how advisory committees inform FDA's decisions. We are hosting this virtual public meeting to give an open and transparent platform for feedback on advisory committees.

II. Topics for Comment at the Public Meeting

We have listed the specific topics on which FDA is seeking input below. Input may be provided orally, during the virtual public meeting on June 13, 2024, or via written comments to the docket referenced above. In all cases, FDA encourages respondents to provide the specific rationale and basis for their comments, including any available supporting data and information. Respondents need not address all topics listed. Please identify your answers as responses to a specific topic.

A. Topic 1: Composition of Advisory Committees

1. The membership of a committee, which is set by each committee's charter, typically varies depending on the focus of the committee and topics for particular meetings. In some cases, the composition of a particular committee may be set by law.[1] To the extent there is flexibility in determining the composition of a committee or the expertise present at particular meetings:

a. What are the categories of expertise, viewpoints, or voices that are particularly important for representation on advisory committees?

[1] *E.g.,* 21 U.S.C. 387q (detailing requirements for composition of the Tobacco Products Scientific Advisory Committee).

b. What are the categories of expertise, viewpoints, or voices that may not be relevant given the topic or product type that is the focus of the committee?

2. Are there ways that FDA can better ensure that a variety of diverse perspectives and experiences are incorporated into advisory committee meetings, and if so, how?

3. In some cases, there is a legal requirement to include a consumer or patient representative on advisory committees. In other cases, the charter of an advisory committee may allow for there to be a consumer or patient representative who is a voting member of the committee. Consumers and patients may also participate in the open public hearing or submit written comments to the docket for a particular advisory committee meeting. Are there ways that FDA can better incorporate the consumer or patient voice into advisory committee meetings, and if so, how?

B. Topic 2: Service on an Advisory Committee as a Special Government Employee (SGE)

4. Service on an advisory committee as an SGE gives individuals an opportunity to provide advice and recommendations on decisions that are often critical to protecting public health, but we understand that administrative burdens (*e.g.,* amount of onboarding paperwork and processing time) are sometimes a deterrent to SGE service. FDA is exploring ways to streamline the administrative requirements on SGEs for initial hiring and meeting preparation. While FDA must remain in compliance with federal laws around federal service, how might we mitigate administrative barriers to service for SGEs?

5. How can FDA otherwise improve the experience of advisory committee members?

C. Topic 3: Public Perception and Understanding of Advisory Committees

6. What do you perceive to be the public's awareness and understanding of the role of FDA advisory committees?

7. What steps can FDA take to improve public awareness and understanding of advisory committees and their role in providing advice and recommendations for FDA to consider in its decision-making?

8. How can FDA better communicate with the public about advisory committee meetings?

9. FDA's regulatory decisions are often, but not always, aligned with advisory committee recommendations. What steps can FDA take to clarify for the public that its regulatory decisions take the committee's recommendation into account, but that the committee's recommendations are only one of several factors considered?

10. There appears to be a persistent misconception that advisory committee votes are the final decision of the Agency on the matter considered by the committee. Is there a way that FDA could adjust the processes for discussion and/or voting that would improve public understanding of how FDA receives external advice through the exchange of information at advisory committee meetings, and the ultimate import of the advisory committee's discussion?

III. Participating in the Public Meeting

Registration: To register for the free public meeting, please visit the following website: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-meeting-optimizing-fdas-use-and-processes-advisory-committees-06132024.* Non-speaking attendees may register any time before or during the listening session. Individuals who wish to make presentations at the public meeting must register by the deadline described below.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in making an oral presentation at this public meeting must register by 3 p.m. EDT on May 13, 2024. Early registration is recommended. FDA may limit the number of participants from each organization due to technology constraints on the total number of participants. Registrants will receive confirmation when they have been accepted.

Information on requests for special accommodations due to a disability will be provided during registration.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the listening session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the deadline to register to make an oral presentation, we will determine the amount of time allotted to each presenter (which we expect to be approximately 5 minutes), the approximate time each oral presentation is to begin, and will select and notify participants by June 3, 2024. All requests to make oral presentations must be received by May 13, 2024, at 3 p.m. EDT. If selected for presentation, any presentation materials must be emailed to *ACfeedback@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) no later than June 7, 2024. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09014 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 30, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0249. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed