eligible States, territories, and Tribes in response to the consequences of major disasters and emergencies declared pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) occurring in 2023 and 2024.

OCC will be requesting information from eligible Child Care and Development Fund (CCDF) Lead Agencies who are interested in receiving these funds. The information requested includes the relevant major disaster or emergency declaration; a detailed description of the affected area; a detailed description of the impact on children, families, staff, and child care services; a description of each proposed activity; information on previous expenses incurred related to the disaster or emergency; and the total amount of funds requested. OCC will use the information received to inform decisions about distribution of funds.

Respondents: State, territory, and Tribal Lead Agencies.

Annual Burden Estimates

Respondents would provide one response to this request and information. The following burden estimates reflect the total estimated burden, which is expected within the first year of approval.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
ACF–OCC–CCDF–PI–2025–X (Disaster Supplemental Funds for Child Care—2023 and 2024 major disasters and emergencies)	70	1	80	5,600

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

In addition, The Department solicits public comment on whether OCC should, in advance of receiving Lead Agency applications for funding, establish funding ranges for the size of grants based on certain factors, and if so, what those ranges and factors should be.

Authority: Public Law 118–158.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–01221 Filed 1–16–25; 8:45 am]

BILLING CODE 4184–87–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0121]

Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public workshop entitled ''Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development.'' The purpose of this workshop is to discuss the current state of the science for development and testing of certain cellular therapies and tissue-based products. In particular, FDA is convening this public workshop with relevant stakeholders to discuss best practices on generating scientific data necessary to further facilitate the development of cellular therapies, including stem cell products.

DATES: The public workshop will be held virtually on February 25, 2025, from 8:30 a.m. to 5 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by March 18, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be virtual.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 18, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2025–N–0121 for ''Cell Therapies and

Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development; Public Workshop; Request for Comments.'' 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: Victoria Wagman, 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's Center for Biologics Evaluation and Research (CBER) protects and enhances the public health by ensuring the safety, purity, potency, and effectiveness of biological products, including vaccines, allergenics, blood and blood products, and cellular and gene therapies for the prevention, treatment, or cure of human diseases or conditions. CBER's Office of Therapeutic Products (OTP) regulates, among others, regenerative medicine products, including human cells, tissues, and cellular and tissue-based products (HCT/Ps) intended to treat or cure diseases or medical conditions. The purpose of this workshop is to discuss the current state of the science for development and testing of certain cellular therapies and tissue-based products. In particular, FDA is convening this public workshop with relevant stakeholders to discuss best practices on generating scientific data necessary to further facilitate the development of cellular therapies, including stem cell products. Within 6 months after the meeting, FDA will issue a transcript of the meeting. This workshop will fulfill the requirement under the Food and Drug Omnibus Reform Act of 2022, section 3205.

II. Topics for Discussion at the Public Workshop

The workshop will include presentations and panel discussions with experts from research and academic institutions to identify and discuss scientific considerations, opportunities, and challenges to help inform the development of cellular therapies and tissue-based products. Topics discussed during the workshop include:

1. The current state of the science for tissue and cell-derived therapies and explore what challenges remain as the field continues to mature.
2. Nonclinical work to assess the safety of cell therapy products in support of product development.
3. Considerations for characterization of cell therapy products to help ensure manufacturing quality during product development and through commercialization.
4. Clinical considerations and future directions for locally-administered cell therapies under investigation for niche indications
5. Considerations for a revised risk-based HCT/P framework

During the workshop, attendees will be able to submit questions to the speakers and panelists for consideration during the panel discussions.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website to register: *https://www.fda.gov/news-events/otp-events-meetings-and-workshops/cell-therapies-and-tissue-based-products-public-workshop-generating-scientific-evidence-facilitate.* Please provide complete contact information for each attendee, including name, affiliation, and email.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by February 25, 2025, at 8:30 a.m. Eastern Time. Early registration is recommended. Registrants will receive confirmation when they have registered for the event.

If you need special accommodations due to a disability, please Claire Simon (*Claire.Simon@fda.hhs.gov*) no later than January 24, 2025.

No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. Registration is available on FDA.gov: *https://www.fda.gov/news-events/otp-events-meetings-and-workshops/cell-therapies-and-tissue-based-products-public-workshop-generating-scientific-evidence-facilitate.* A recording will be available on *https://www.fda.gov/news-events/otp-events-meetings-and-workshops/cell-therapies-and-tissue-based-products-public-workshop-generating-scientific-evidence-facilitate.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov/news-events/otp-events-meetings-and-workshops/cell-therapies-and-tissue-based-products-public-workshop-generating-scientific-evidence-facilitate.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01200 Filed 1–16–25; 8:45 am]

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