DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2436]

Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry; Availability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of a draft document entitled ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry.'' The management of manufacturing changes presents many challenges for human cellular therapy or gene therapy (CGT) products due to the complexity of these products. The draft guidance provides sponsors of Investigational New Drug Applications (INDs) and applicants of Biologics License Applications (BLAs) for CGT products, with recommendations regarding product comparability and the management of manufacturing changes for investigational and licensed CGT products. The purpose of this draft guidance is to provide FDA's current thinking on management and reporting of manufacturing changes for CGT products based on a life-cycle approach, and comparability studies to assess the effect of manufacturing changes on product quality.

DATES: Submit either electronic or written comments on the draft guidance by September 12, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2023–D–2436 for ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy 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: Phillip Kurs, 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 ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry.'' The management of manufacturing changes presents many challenges for human CGT products due to the complexity of these products. The draft guidance provides sponsors of INDs and applicants who intend to submit or currently hold BLAs for CGT products, with recommendations on product comparability and the management of manufacturing changes for investigational and licensed CGT products, considering the unique challenges that apply to these products.

While existing guidances provide general principles and recommendations regarding comparability studies and management of manufacturing changes for biological products, they generally do not address specific CGT product challenges. The purpose of this draft guidance is to provide FDA's current thinking on: (1) management and reporting of manufacturing changes for CGT products based on a life-cycle approach and (2) comparability studies to assess the effect of manufacturing changes on CGT product quality.

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 ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR 601.2 and 601.12 have been approved under OMB control number 0910–0338.

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: July 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6395]

Request for Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for applications.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the FDA's Patient Affairs Staff, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner at FDA, and is hosted by CTTI. Through the PEC, the patient community and FDA Staff are able to discuss an array of topics related to increasing meaningful patient engagement with diverse populations in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patient, caregiver and patient advocate perspectives are incorporated into general medical product development and regulatory processes.

DATES: Applications can be submitted starting at 11:59 p.m. Eastern Time on July 14, 2023. This announcement is open to receive a maximum of 75 applications. Applications will be accepted until 11:59 p.m. Eastern Time on August 14, 2023 or until 75 applications are received, whichever happens first.

ADDRESSES: All applications should be submitted to FDA's Patient Affairs Staff in OCPP. The preferred application method is via the online submission system provided by CTTI, available at *https://duke.qualtrics.com/jfe/form/SV_6L8l7z4YfyCHFVY.* For those applicants unable to submit an application electronically, please call FDA's Patient Affairs Staff at 301–796–8460 to arrange for mail or delivery service submission. Only complete applications, as described under section IV of this document, will be considered.

FOR FURTHER INFORMATION CONTACT: Wendy Slavit, Office of the Commissioner, Office of Clinical Policy and Programs, Patient Affairs Staff, Food and Drug Administration, 301–796–8460, *PatientEngagementCollaborative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The CTTI is a public-private partnership cofounded by FDA and Duke University whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of diverse patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The PEC is an ongoing, collaborative forum in which the patient community and FDA Staff discuss an array of topics related to increasing patient engagement in medical product development and regulatory discussions at FDA. The PEC is a joint endeavor between FDA and CTTI. The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization, and membership will not constitute employment by either organization.

The Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), section 1137, entitled ''Patient Participation in Medical Product Discussions,'' added section 569C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c). This provision directs the Secretary of Health and Human Services to ''develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions.'' On November 4, 2014, FDA issued a **Federal Register** notice establishing a docket (FDA–2014–N–1698) for public commenters to submit information related to FDA's implementation of this provision. Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers. After considering the comments, FDA formed the PEC in 2018 to discuss a variety of