specific to autologous or allogeneic CAR T cell products are noted in the guidance. The guidance also provides recommendations for analytical comparability studies for CAR T cell products. While the guidance specifically focuses on CAR T cell products, some of the information and recommendations provided may also be applicable to other genetically modified lymphocyte products, such as CAR Natural Killer cells or T cell receptor modified T cells.

In the **Federal Register** of March 16, 2022 (87 FR 14893), FDA announced the availability of the draft guidance of the same title dated March 2022. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifying the scope, focusing on treatment for oncology indications, and the recommendations for CAR T cells manufactured using cellular starting material from patients who have received CAR T cells previously, potency for CAR T cells that express multiple transgene elements, stability studies, and clinical monitoring. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated March 2022.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another human gene therapy final guidance entitled ''Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0130; 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; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 1271 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.*

Date: January 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01789 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3561]

Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for Food and Drug Administration-Regulated 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 guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' The purpose of this guidance is to provide FDA's expectations for, and recommendations on, use of a standardized approach for collecting and reporting race and ethnicity data in submissions including information collected and reported from clinical studies and clinical trials for FDA-regulated medical products. Using standard terminology for race and ethnicity helps ensure that data are collected and reported consistently in submissions to FDA. This draft guidance revises the final guidance for industry and FDA staff entitled ''Collection of Race and Ethnicity Data in Clinical Trials'' issued on October 26, 2016.

DATES: Submit either electronic or written comments on the draft guidance by April 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–2016–D–3561 for ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' 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; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: 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, 301–796–2500; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7256, Silver Spring, MD 20993, 240–402–7911; or Office of Minority Health and Health Equity, *healthequity@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' FDA's recommended approach is based on the Office of Management and Budget (OMB) Statistical Policy Directive No. 15 (Policy Directive 15) and was developed in accordance with section 4302 of the Affordable Care Act (42 U.S.C. 300kk); the Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status; and the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 Action Plan.[1]

OMB standards for the classification of Federal data on race and ethnicity were developed to provide a common framework for uniformity and consistency in the collection and use of data on race and ethnicity by Federal agencies (Policy Directive 15). This guidance provides recommendations on:

1. Meeting the requirements set forth in the 1998 final rule (63 FR 6854, February 11, 1998) regarding presentation of demographic data in investigational new drug applications and new drug applications (known as the Demographic Rule);

2. Collection of race and ethnicity data in biologics license applications (BLAs) and medical device applications; and

3. Addressing the FDASIA Section 907 Action Plan to improve the completeness and quality of demographic data collection and reporting.

This guidance is also intended to help an applicant preparing a BLA or medical device application, which should be done in accordance with the OMB standards described in the guidance.

In the **Federal Register** of January 27, 2023 (88 FR 5375) OMB announced a formal review of OMB Policy Directive 15 and requested public comments on initial proposals to revise the directive to account for large societal, political, and economic demographic shifts in the United States over the 25 years since its publication. FDA intends to update this guidance as appropriate if OMB revises Policy Directive 15.

This guidance revises the final guidance for industry and FDA staff entitled ''Collection of Race and Ethnicity Data in Clinical Trials'' issued in October 2016. When finalized, this guidance will replace the October 2016 guidance. Changes from the 2016 version include broadening the draft guidance to include non-interventional (observational) clinical studies in addition to the interventional clinical trials discussed in the 2016 guidance. Other changes include a revised title and editorial changes for clarity, as well as updated references and contact information for FDA.

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 ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated 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 new 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB Control Number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB Control Number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB Control Number 0910–0338; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB Control Number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB Control Number 0910–0078; the

[1] *https://www.fda.gov/media/89307/download.*

collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB Control Number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB Control Number 0910–0332; the collections of information in 21 CFR part 860, subpart D, have been approved under OMB Control Number 0910–0844; and the collections of information in 42 CFR part 11 have been approved under OMB Control Number 0925–0586.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.*

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01782 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0398]

Human Gene Therapy Products Incorporating Human Genome Editing; 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 final guidance entitled ''Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry.'' The guidance document provides recommendations to sponsors developing human gene therapy products incorporating genome editing (GE) of human somatic cells. Specifically, the guidance provides recommendations regarding information that should be provided in an investigational new drug (IND) application to assess the safety and quality of the investigational GE product, including information on product design, product manufacturing and testing, nonclinical safety assessment, and clinical trial design. The guidance announced in this notice finalizes the draft guidance of the same title dated March 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on January 30, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2021–D–0398 for ''Human Gene Therapy Products Incorporating Human Genome Editing.'' 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 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 guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See