format (*i.e.,* in-person, virtual (video conference), teleconference, or written response only). This guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings.

This draft guidance for industry revises and replaces the draft guidance of the same name issued on June 5, 2018 (83 FR 26060). This revision includes:

- Changes to the data expectations in Biosimilar Initial Advisory meeting requests
- Addition of Biological Product Development (BPD) Type 2a meeting
- Changes to when the meeting background package is submitted for BPD Type 4 meeting
- Changes to the description of the available meeting formats
- Addition of an option for a request for clarification

FDA also made certain clarifying and editorial changes. Editorial changes were made primarily for clarification.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.''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 312 regarding sponsor requests to FDA related to the submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in section 351(a) of the PHS Act and part 601 (21 CFR part 601) relating to the submission of a BLA have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and part 601 relating to the submission of biosimilar applications and biosimilar user fee applications have been approved under OMB control number 0910–0718.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2629]

Postmarketing Approaches To Obtain Data on Under-Represented Populations in Clinical Trials; 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 ''Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials.'' The purpose of this draft guidance is to describe FDA requirements and provide recommendations for obtaining safety and effectiveness information on drug and biological products, when appropriate, in the postmarketing setting in historically under-represented patient populations in clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 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–2022–D–2629 for ''Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials.'' 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; or 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 Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, 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: Nicole Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Silver Spring, MD 20993–0002, 240–402–0210; or Anne Taylor, 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, *Anne.Taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials.'' The purpose of this draft guidance is to describe FDA requirements and provide recommendations for obtaining safety and effectiveness information on drug and biological products, when appropriate, in the postmarketing setting in historically underrepresented patient populations in clinical trials. FDA regulations require sponsors to present information from premarket clinical trials on the safety and effectiveness of drugs in terms of gender, age, and racial subgroups. These clinical trials should include patient populations that are historically underrepresented in clinical research, including but not limited to, populations based on race, ethnicity, sex, age, geographic location, gender identity, socioeconomic status, disability, pregnancy status, lactation status, and co-morbidity. Obtaining information early in development can be advantageous in that information may help inform subsequent clinical trials and ultimately result in more efficient, informative, and successful drug development. However, if despite the sponsor's best efforts, these populations are not adequately represented in premarket clinical trials or if the data suggests there may be serious safety concerns in these populations, it may be appropriate to collect such data in the postmarketing setting. Reviews of clinical trial data indicate that there is often underrepresentation of patient populations, based on race, ethnicity, sex, or age. The draft guidance discusses mechanisms by which FDA can require or request information on safety and effectiveness be collected in the postmarketing setting; design and statistical considerations for subpopulation analyses; and postmarketing approaches to obtain information on the benefit-risk profile in underrepresented clinical trial populations.

Underrepresentation in clinical trials remains a significant issue despite the Agency's efforts to encourage sponsors and investigators to improve representation of historically under-represented patient populations. We welcome further dialogue in other settings or collaborative efforts to explore methods to enhance representation in clinical trials.

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 ''Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials.'' 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 parts 50 and 56 have been approved under OMB control number 0910–0130; 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 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 pertaining to submission of a biologics license application (BLA) under section 351(k) of the Public Health Service Act 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/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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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