

March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP).

Section 1312(e) of the Affordable Care Act and 45 CFR 155.220(a)(1) expands the role of agents/brokers by permitting them to enroll qualified individuals or small employers/employees in qualified health plans (QHPs) through the Exchanges and assist individuals in applying for Advance Premium Tax Credits (APTCs) and Cost Sharing Reductions (CSRs). To participate as facilitators to enrollment, agents/brokers must register with the FFE, complete a training course covering eligibility and enrollment criteria for assisting in QHP enrollment, and sign agreements that formalize their understanding and commitment to adhere to the rules of the program. This requirement is specific to the FFE and does not automatically apply to State-based Exchanges (SBEs). *Form Number:* CMS–10464 (OMB control number: 0938–1204); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 100,000; *Number of Responses:* 100,000; *Total Annual Hours:* 12,000. (For questions regarding this collection, contact Madeline Pellish at 301–492–4390).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; 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 for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of proposed biosimilar, including interchangeable biosimilar, products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This guidance finalizes the draft guidance of the same title issued on August 11, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on July 21, 2025.

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–2018–D–1922 for “Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act 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 this 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Mustafa Ünlü, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993, 301–796–3396; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of proposed biosimilar, including interchangeable biosimilar, products regulated by CDER or CBER. This guidance does not apply to meetings associated with the development of products intended for submission in, or review of, new drug applications or abbreviated new drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355), biologics license applications under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)), or submissions for devices under the FD&C Act. For the purposes of this guidance, a formal meeting includes any meeting that is requested by a sponsor or applicant following the procedures provided in this guidance and includes meetings conducted in any 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 guidance finalizes the draft guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products” issued on August 11, 2023 (88 FR 54622). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification that

requesting a Biosimilar Initial Advisory meeting is not a requirement prior to joining the Biosimilar Biological Product Development program, additional description of in-person meetings and core attendees, and a description regarding the maximum number of questions that should be submitted within a single meeting request. In addition, editorial changes were made to improve clarity.

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 “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. 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 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(k) of the PHS Act and 21 CFR 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 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: July 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–1797]

E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; International Council for Harmonisation; 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 “E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials.” The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide general principles on the conduct of clinical trials that include pregnant and breastfeeding women to inform evidence-based decisions on safe and effective use of medicinal products by these populations. The draft guidance includes approaches to generating data that support informed decision-making on the safety, dosing, and efficacy of medicinal products during pregnancy and breastfeeding. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials, while reducing burden and harm on these participants.

DATES: Submit either electronic or written comments on the draft guidance by September 19, 2025 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