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This guidance finalizes the draft guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products'' issued on August 11, 2023 (88 FR 54622). FDA considered comments received on the draft guidance as the guidance was finalized.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.

[FR Doc. 2025–13682 Filed 7–18–25; 8:45 am]

BILLING CODE 4164–01–P

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

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–D–1797 for ''E21 Inclusion of Pregnant and Breastfeeding Women 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 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. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling Center for Biologics Evaluation and Research 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:

Regarding the guidance: Leyla Sahin, Center for Drug Evaluation and Research, Food and Drug Administration, *Leyla.Sahin@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911; or Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2333, Silver Spring, MD 20993–0002, 301–796–9440.

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–348–1967, *Brooke.DalSanto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

The recommendations found in this draft guidance are the product of the Efficacy Working Group of the ICH. Comments about this draft will be

considered by FDA and the Efficacy Expert Working Group.

The draft guidance outlines strategies and considerations for developing and implementing clinical studies that include pregnant or breastfeeding women. This draft guidance includes approaches to plan, collect data, evaluate outcomes, and monitor safety of pregnant and breastfeeding women participating in clinical trials safely and ethically. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials. The draft guidance also emphasizes reduction of burden on pregnant and breastfeeding women participating in these trials.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''E21 Inclusion of Pregnant and Breastfeeding Women 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 11 relating to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects, informed consent, and institutional review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 58 relating to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR 201.56 and 201.57 relating to the content and format requirements of labeling for prescription drug products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 310.305 and 314.80 relating to submission of adverse drug experience reports have been approved under OMB control number 0910–0230. The collections of information in 21 CFR part 312 relating to the investigational new drug application pathway, which includes clinical trials, clinical trial design, benefit-risk planning, and submission of IND safety reports and reports of serious and unexpected adverse events have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the content and format of investigational new drugs applications, regulatory requirements relating to postmarketing study commitments, and risk evaluation and mitigation strategies relating to benefit-risk assessments, have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, 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,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: July 15, 2025

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13680 Filed 7–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: September 4–5, 2025.

Open: September 04, 2025, 1:00 p.m. to 5:00 p.m.

Agenda: staff reports on divisional, programmatical, and special activities.

Address: National Institutes of Health, Neuroscience Center, Rooms 1135/45/55, 6001 Executive Boulevard, Rockville, MD 20852, In Person and Virtual Meeting.

Closed: September 05, 2025, 9:00 a.m. to 9:40 a.m.

Agenda: To review and evaluate BSC Report.

Address: National Institutes of Health, Neuroscience Center, Rooms 1135/45/55, 6001 Executive Boulevard, Rockville, MD 20852, In Person and Virtual Meeting.

Closed: September 05, 2025, 10:00 a.m. to 1:05 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, Rooms 1135/45/55, 6001 Executive Boulevard, Rockville, MD 20852, In Person and Virtual Meeting.

Contact Person: Rebecca Wagenaar-Miller, Ph.D., Director, Division of Extramural Activities, NIDCD/NIH, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 496–8693, *rebecca.wagenaar-miller@nih.gov*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nidcd.nih.gov/about/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)