

of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These 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 section 910(c)(1)(A)(i) of the FD&C Act have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673; the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684; the collections of information in section 904(a)(3) of the FD&C Act have been approved under OMB control number 0910–0732, and the collections of information in 21 CFR part 1114 have been approved under OMB control number 0910–0879.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/guidance-related-tobacco-products>, or <https://www.regulations.gov>.

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31541 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5591]

Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Evaluation of Sex-Specific and Gender-Specific Data in

Medical Device Clinical Studies.” This document provides guidance on the study and evaluation of sex- and/or gender-specific data in clinical investigations or research involving one or more subjects to determine the safety or effectiveness of a device. The purpose of this guidance is to encourage science-driven consideration of sex and/or gender, as appropriate for both the scientific question being addressed and the intended use of the device, when designing medical device clinical studies and reporting data from such studies in accordance with legal requirements. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 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–2023–D–5591 for “Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies.” 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies” to 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 request.

FOR FURTHER INFORMATION CONTACT: Terri Cornelison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5516, Silver Spring, MD 20993-0002, 301-796-5682; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Recognition of the importance of sex- and gender-specific considerations has been steadily growing in areas such as medical technology design and development, including clinical study design, and assessing product performance throughout the total product life cycle and other medical device-related matters. Sex and gender are key considerations in the development and performance of medical devices. Although there has been steady growth in the recognition of sex- and gender-considerations in medical technology design and development, it is important to understand that this was not always the case. Historically, females and/or women have been under-represented in or excluded from many clinical studies. This has led to a lack of information available for females and/or women and their health care providers regarding the

benefits and risks of many medical devices. Further, individuals with intersex traits and those with differences in sex development may have not been properly included within clinical studies. In addition, historically, as gender was often conflated with sex or otherwise not properly reported in clinical studies, there is a lack of data regarding the underrepresentation of nonbinary, transgender, fluid gender identities and other gender identities.

Given these historical concerns and the growing recognition of the importance of sex- and gender-specific considerations in medical technology design and development, it is important that a medical device be developed and evaluated with study participants that represent the demographic, clinical, and disease characteristics of the intended population. The purpose of this draft guidance is to encourage science-driven consideration of sex and/or gender. Upon finalization, this document will update the policy reflected in the existing guidance entitled “Evaluation of Sex-Specific Data in Medical Device Clinical Studies” by addressing both sex- and gender-specific data and will replace the existing guidance. As such, the recommendations within the guidance have been updated to help sponsors consider sex- and/or gender-specific data, as appropriate for the scientific questions being addressed and the intended use of the device, when designing medical device clinical studies and reporting data from such studies in accordance with legal requirements. The guidance provides recommendations for sponsors to consider sex- and/or gender-specific data throughout the clinical study process. This includes updated recommendations for clinical study design, study participant enrollment, data collection and analysis, and reporting of study information for sex-specific data, gender-specific data, or both, according to the scientific question at hand.

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 “Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies.” 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00001727 and complete title to identify the guidance you are requesting.

III. 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 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
860, subpart D	De Novo classification process ..	0910-0844
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions	0910-0756
800, 801, and 809	Medical Device Labeling Regulations.	0910-0485
822	Postmarket Surveillance of Medical Devices.	0910-0449

21 CFR Part or guidance	Topic	OMB control No.
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910-0130

Dated: December 26, 2024.

Kimberlee Trzeciak,
Deputy Commissioner for Policy, Legislation,
and International Affairs.

[FR Doc. 2024-31526 Filed 1-6-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0553]

Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act; Guidance for FDA Staff and Interested Parties; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for FDA staff and interested parties entitled “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.” This guidance document provides our current thinking on the approach we generally intend to take when we evaluate the public health importance of a food allergen other than one of the major food allergens (*i.e.*, milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybean, and sesame) listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on FDA 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-N-0553 for “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.” 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.” We will review this copy, including the claimed confidential information, in our

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 Division of Chemical Contaminants, Office of Post-Market Assessment, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Stefano Luccioli, Office of Post-Market Assessment, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1283; or Alexandra Beliveau, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: