4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1391]

Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is opening a public docket to solicit input and comments from stakeholders interested in informing strategic priorities for the Office of Women's Health (OWH). This will help the Agency ensure that important health concerns are carefully considered in establishing OWH's scientific, educational, and outreach priorities.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that untimely comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2020-N-1391 for "Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), 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.

- 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." FDA 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 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 the 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, September18, 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.

FOR FURTHER INFORMATION CONTACT: Lisa Lineberger, Food and Drug Administration, Office of the Commissioner, Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2333, Silver Spring, MD 20993, 301-796-8751, lisa.lineberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's OWH was established by Congressional mandate in 1994 as part of the Office of the Commissioner. The mission of the OWH is to:

- provide leadership and policy direction for the Agency related to women's health and coordinate efforts to establish and advance a women's health agenda for the Agency.
- promote the inclusion of women in clinical trials, the implementation of guidelines concerning the representation of women in clinical trials, and the incorporation of sex and gender considerations into clinical trial data analysis.
- identify and monitor the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission.
- serve as the Agency's liaison with other agencies, industry, professional associations, and advocacy groups with regards to the health of women.

OWH achieves its mission through the foundational principle that sex as a biological variable should be factored into research design, analysis, reporting, and education. To this end, OWH supports FDA's regulatory mission by funding and engaging in intramural and extramural scientific research and collaborating with stakeholders on educational and outreach projects. More information on OWH research and educational activities is available at https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research.

OWH recognizes the unique role FDA can play in protecting and promoting women's health and the value of considering input from consumers, health professionals, and other stakeholders as it works toward this goal. Therefore, FDA is issuing this *Federal Register* notice to open Docket No. FDA-2020-N-1391 for the public to submit comments. FDA will take the suggestions and information submitted to the docket into consideration when developing OWH scientific, educational, and outreach priorities.

II. Issues for Consideration

To maximize FDA OWH's ability to promote, protect, and advance the health of women, we are seeking input on research priorities driven by data gaps and areas of unmet need; topics for education among consumers, health professionals, and other stakeholders; and outreach to women, especially underserved and diverse populations. We are also interested in proposed methods for acting on these priorities, such as collaborations and partnerships. In particular, OWH requests comments on:

- efforts to encourage analysis and detection of potential sex and gender differences in the safety, efficacy, and use of FDA-regulated products.

- efforts to anticipate, meet, and respond to existing and emerging issues related to women's health and FDA-regulated products.
- direct outreach to diverse groups of women to promote access to relevant information about FDA-regulated products, encourage participation in clinical trials, and maintain dialogue about critical women's health topics.
- coordination and collaboration with other Federal Agencies and external stakeholders to support research and programming on women's health topics.
- identification of regulatory decisions that can benefit from participation of women across the lifespan (e.g., reproductive-age women, pregnant women, post-menopausal women, and elderly women) and women with certain health conditions.
- generation of research and programming topics, interests, and areas of focus that predominantly affect women and/or would benefit from sex- and gender-related analyses.

Dated: July 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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