

your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to-intervene.asp>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP23–536–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP23–536–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail or email at: Matt Everngam, Director, Regulatory Affairs, Eastern Shore Natural Gas Company, 500 Energy Lane, Suite 200, Dover, DE 19901 or by email to meverngam@chpk.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed⁹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹⁰ Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.¹¹ A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Intervention Deadline: 5:00 p.m. Eastern Time on October 6, 2023.

Dated: September 15, 2023.

Kimberly D. Bose,

Secretary.

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⁹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹⁰ 18 CFR 385.214(c)(1).

¹¹ 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0001]

Menopause: Potential Impact on Clinical Pharmacology and Opportunities for Future Research; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Office of Women's Health and Office of Clinical Pharmacology is announcing the following public workshop: "Menopause: Potential Impact on Clinical Pharmacology and Opportunities for Future Research." The purpose of the public workshop is to discuss the current understanding of the impact of menopause on the pharmacokinetics (PK), pharmacodynamics (PD), and exposure-response relationships of FDA-regulated drugs and biologics used by menopausal women for non-menopause-related indications. Researchers, educators, clinicians, and patients may benefit from attending this scientific workshop. Presentations will discuss whether changes in drug absorption, distribution, metabolism, and elimination, if any, could be affected by hormonal changes of menopause (independent of age), or other non-hormonal influences (including age-related renal and hepatic changes). The discussion is further intended to identify the research and data gaps regarding the potential impact of menopause on PK/PD. Speakers will highlight areas with the greatest need for further research and exploration.

DATES: The public workshop will be held virtually on October 11, 2023, from 10 a.m. to 2 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

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

SUPPLEMENTARY INFORMATION:

I. Background

Menopause is often a time of tremendous transition and change for women. The effects of menopause on the PK and PD of drugs are largely unknown. Sex hormone changes during menopause may affect the metabolic pathways of drugs by affecting drug metabolizing enzymes. Hormone changes may also affect other pathways that play an important role for drug disposition and excretion. In addition, many women experience weight gain at menopause. Together, these changes associated with menopausal transition have the potential to affect the PK of medications used for indications not related to menopause. Furthermore, physiologic changes in menopause may result in altered sensitivity to drug response independent of changes in PK. This public workshop will provide insight into identifying the research and data gaps regarding the potential impact of menopause on PK/PD, highlighting areas with the greatest need for further research and exploration.

II. Topics for Discussion at the Public Workshop

This public workshop will include presentations and session discussions by experts in the fields of clinical pharmacology, obstetrics and gynecology, endocrinology, and clinical care. Each session will include a Q&A session to respond to questions from attendees.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://www.fda.gov/consumers/public-meetings-workshops-and-webinars/menopause-potential-impact-clinical-pharmacology-and-opportunities-future-research-10112023>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please contact Lisa Lineberger at OWHmeetings@fda.hhs.gov no later than October 10, 2023.

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20454 Filed 9–20–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0908]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 23, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0016. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Form FDA 3503–21 CFR 70.25, 71.1, and 171.1 and 21 CFR parts 172, 173, 179, and 180 OMB Control Number 0910–0016—Extension.

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) the additive and its use, or intended use, are in conformity with a regulation issued under section 409 that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) is effective. Food Additive Petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA’s regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f). Color Additive Petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the Agency’s regulations (21 CFR 71.1) specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA’s color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, cosmetics, or medical devices be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food, or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.