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: April Alexandrow, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3147, Silver Spring, MD 20993, 301–796–5363.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 3, 2019, FDA published a notice announcing a public hearing to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. In addition, we notified the public that FDA was establishing a docket for public comment on this hearing. The information from the hearing and comments provided to the docket were solicited to help inform our regulatory oversight of these products and as an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products. We asked that comments be submitted by July 2, 2019.

In response to requests for an extension of the comment period to provide additional time to develop meaningful and thoughtful responses to questions, on June 20, 2019, we published a notice that appeared in the **Federal Register** that extended the comment period for 14 days, until July 16, 2019.

In light of the continued interest and increased research activity in this space, as well as the need for additional scientific data on this topic, we have decided to reopen the comment period and extend it indefinitely to allow interested parties to continue to comment and to provide relevant data to the Agency on this subject. If, in the future, we decide to close the comment period, we will publish a **Federal Register** notice to that effect. This extension will allow stakeholders to continue to provide new and emerging information, in as close to real time as possible, as research in this area evolves.

We are particularly interested in data that may help to address uncertainties and data gaps related to the CBD. Studies that may help to address such uncertainties and data gaps may include, but are not limited to:

- The risk of liver injury from CBD, *e.g.,* clinical studies to evaluate potential liver injury following long-term exposure of CBD in healthy populations and in people who may be more susceptible to CBD-induced liver injury (*e.g.,* due to preexisting liver disease), long-term (chronic), repeated dose studies in an appropriate animal model to determine the most sensitive liver toxicity endpoint, and to establish a no observed effect level (NOAEL), as well as studies to investigate the mechanism of liver injury;
- Toxicities of some of the active metabolites of CBD, *e.g.,* animal toxicology studies of the major human metabolites such as 7–COOH–CBD, as well as pharmacology studies to fully characterize the binding profile and activity of major metabolites of CBD (*e.g.,* 7–OH–CBD, 7–COOH–CBD);
- Impact of CBD on the male reproductive system, *e.g.,* long-term (chronic), repeated dose studies in an appropriate animal model to determine the most sensitive male reproductive toxicity endpoint and to establish a NOAEL, and studies to characterize the mechanism mediating CBD effects on the male reproductive system for the purpose of assessing human relevance;
- Effect of CBD co-administration with other medicines, alcohol, dietary supplements, tobacco products, and herbal products;
- Impact on neurological development, *e.g.,* neurodevelopmental toxicology studies of CBD and 7–COOH–CBD to characterize the long-term functional impact of these compounds on the developing brain; addition of long-term neurodevelopment adverse outcomes in ongoing or future clinical trials of CBD to assess learning, cognition, and behavior;
- Sedative effects of CBD, *e.g.,* studies to characterize the effect on driving performance and ability to operate heavy machinery due to CBD's sedative effects;
- Transdermal penetration and pharmacokinetics of CBD, *e.g.,* methods development for the evaluation and assessment of dermal penetration of CBD;
- Clinical studies (including real world data/evidence) to address safety questions related to long-term sustained or cumulative exposure to CBD, including in vulnerable populations such as children, the elderly, and women who are pregnant or breastfeeding;
- Long-term (chronic) repeated dose toxicity studies in appropriate animal models, evaluating the most relevant toxicological end points (*e.g.,* male reproductive toxicity and liver toxicity), to better characterize the potential long-term effects of CBD, with systematic reporting of relevant parameters including, but not limited to, histopathology, hematology and clinical chemistry analyses, testosterone and other hormone levels, and urinalysis;
- Clinical studies on the effect of different routes of CBD administration (*e.g.,* oral, topical, inhaled) on its safety profile;
- Effect of CBD on pets and food-producing animals, *e.g.,* animal studies that demonstrate the effect of CBD exposure in different target animal species, breeds, or classes, including information on the formation of residues in edible tissues of food-producing animals and safety of chronic exposure;
- Studies to characterize the potential for bioaccumulation of CBD over long-term exposure, *e.g.,* appropriately designed absorption, distribution, metabolism, and elimination studies in appropriate animal models; and
- Effect of CBD on the eye, *e.g.,* studies to determine if CBD is distributed into the eye following various routes of exposure, studies to characterize CBD's potential effect on intraocular pressure, and assessment of potential impacts in potentially sensitive populations such as patients with glaucoma.

Dated: March 5, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04919 Filed 3–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0001]

Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials.'' The meeting will be convened by Duke University's Robert J. Margolis, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting is intended to gather industry, patient, clinician,

researcher, institutional review board, ethicist, professional society and other stakeholder input on the scientific and ethical issues that surround the inclusion of pregnant women in clinical trials for drug development.

DATES: The public meeting will be held on April 16, 2020, from 9 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public meeting will be held at the National Press Club Main Ballroom, 529 14th St. NW, Washington, DC 20045.

FOR FURTHER INFORMATION CONTACT: Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at *ONDPublicMTGSupport@fda.hhs.gov* or 301–796–0621, or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993–0002, Fax: 301–796–9897.

SUPPLEMENTARY INFORMATION:

I. Background

FDA endorses an informed and balanced approach to gathering data informing the safe and effective use of drugs and biological products in pregnancy through judicious inclusion of pregnant women in clinical trials and careful attention to potential fetal risk. Input from this meeting will help provide such information on the development of therapies for pregnancy-specific conditions and for general medical conditions that occur in women of childbearing age and require treatment during pregnancy. This meeting supports the objectives of The Task Force on Research Specific to Pregnant Women and Lactating Women (''Task Force'' or ''PRGLAC'') which was established by section 2041 of the 21st Century Cures Act, Public Law 114–255, to provide advice and guidance on activities related to identifying and addressing gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.[1] Input from this meeting may also help further inform FDA's work toward the finalization of the Agency's draft guidance: Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials (83 FR 15161, April 6, 2018).

[1] *https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf.*

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including industry, clinicians, patients, researchers, institutional review boards, ethicists, professional societies and other stakeholders) to provide input on key topics, including:

- Key areas of unmet needs for therapeutic development or clinical data in obstetrics
- The regulatory, scientific, and ethical considerations and challenges in the enrollment of pregnant women in clinical research

For more information on the meeting topics and discussion questions, visit *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.* FDA will publish a discussion guide outlining background information on the topic areas to this website approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.* 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. Persons interested in attending this public meeting must register. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at *ONDPublicMTGSupport@fda.hhs.gov* or 301–796–0621; or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993–0002, Fax: 301–796–9897.

Persons attending FDA's meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast and archived video footage will be available at the event website. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Persons interested in viewing the live webcast are encouraged to register in advance. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Please register for the webcast by visiting *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.*

Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting.

FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will not be available.

Dated: March 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04990 Filed 3–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Letters of Interest (LOI) for NCI-MATCH Laboratories

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) through its National Clinical Trials Network (NCTN) is developing a successor precision medicine trial to 'NCI-Molecular Analysis for Therapy Choice (NCI-MATCH)' entitled 'NCI-ComboMATCH'. The principal of this intiative is to overcome drug resistance to single-agent therapy by developing genomically-directed targeted agent combinations. All combinations must be