DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1482]

Cannabidiol and Other Cannabinoids: Sex and Gender Differences in Use and Responses; Public Meeting

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 ''CBD and Other Cannabinoids: Sex and Gender Differences in Use and Responses.'' The purpose of the public meeting is to discuss potential sex (biological) and gender (psychosocial) differences in use and responses to cannabidiol (CBD) and other cannabinoids. Researchers, educators, clinicians, and patients may benefit from attending this multidisciplinary scientific conference on CBD and other cannabinoids. Presentations will address patient and healthcare provider perspectives on CBD and other cannabinoid use, sex differences in the effects of CBD and other cannabinoids, use of CBD and other cannabinoids in pregnancy, and government agency perspectives on CBD research and evaluation.

DATES: The public meeting will be held on November 19, 2020, from 9 a.m. to 4 p.m. Eastern Time and will take place virtually by webcast only. Registration to attend the meeting and other information can be found at *https://www.fda.gov/science-research/womens-health-research/scientific-conference-cbd-and-other-cannabinoids-sex-and-gender-differences-use-and-responses.* See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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

FDA is responsible for protecting the public health by assuring the safety and efficacy of FDA-regulated products. Although CBD is widely available and marketed as a component of products including drugs, food, dietary supplements, cosmetics, and animal health products, FDA has only approved one CBD product—a prescription drug to treat two rare, severe forms of epilepsy. There is very limited available information about CBD, including about its effects on the body.

FDA recognizes the significant public interest in cannabis and cannabis-derived compounds, particularly CBD. However, there are many unanswered questions about the science, safety, and quality of products containing CBD. The Agency is working on answering these questions through ongoing efforts including feedback from a FDA hearing and information and data gathering through a public docket. This public meeting will provide further insight into the scientific evidence suggesting the presence or absence of sex and gender differences in use and responses to CBD and other cannabinoids. Conditions for which CBD is often marketed, such as chronic pain, anxiety, depression, and sleep disturbances, are more prevalent in women than men. Therefore, consideration of issues pertaining to the safety of CBD products may be particularly important to address in women. In addition, use of CBD and other cannabinoids during pregnancy is an important public health concern that will be highlighted at this meeting.

II. Topics for Discussion at the Public Meeting

This public meeting will include presentations and panel discussions by experts in the fields of cannabinoid research, education, and clinical care about potential biological (sex) and psychosocial (gender) differences in the use and effects of CBD and other cannabinoids. Each panel discussion will include a Q&A session to respond to questions from attendees.

We will make the agenda and materials for the public meeting available online by November 12, 2020, at *https://www.fda.gov/science-research/womens-health-research/scientific-conference-cbd-and-other-cannabinoids-sex-and-gender-differences-use-and-responses.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://collaboration.fda.gov/owh-cbd-meeting/event/registration.html.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register online by November 16, 2020, 5 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Lisa Lineberger at 301–796–8751 or *OWHmeetings@fda.hhs.gov* no later than November 9, 2020.

Streaming webcast of the public meeting: The webcast for this meeting will be available to registrants. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* 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.

Dated: September 15, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1640]

Draft Guidance for Cannabidiol; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry, entitled ''Draft Guidance for Cannabidiol.'' The draft guidance, when finalized, will provide product-specific recommendations on, among other things, the information and data needed to demonstrate bioequivalence (BE) to support abbreviated new drug applications (ANDAs) for cannabidiol oral solution.

DATES: Submit either electronic or written comments on the draft guidance by November 23, 2020 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 as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.