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.

[FR Doc. 2020–21023 Filed 9–22–20; 8:45 am]

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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.

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–D–1640 for ''Draft Guidance for Cannabidiol.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office 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.'' 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.

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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Mara Miller, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993–0002, 301–796–0683.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a draft guidance on a generic cannabidiol oral solution.

FDA initially approved new drug application 210365 for EPIDIOLEX (cannabidiol) in September 2018. We are now issuing draft guidance for industry on BE recommendations for generic cannabidiol oral solution (''Draft Guidance for Cannabidiol'').

The 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 the information and data to demonstrate BE to support ANDAs for cannabidiol oral solution. 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. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20968 Filed 9–22–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: The Council on Graduate Medical Education (COGME) meeting scheduled on Tuesday, December 8, 2020, and Wednesday, December 9,