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#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 17, 2014, FDA published final guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Standardized Study Data” (eStudy Data guidance), posted on FDA’s Study Data Standards Resources web page at <https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k-1(a)) for study data contained in new drug applications, abbreviated new drug applications, biologics license applications, and investigational new drug applications submitted to CDER or the Center for Biologics Evaluation and Research by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify any new standard version updates that will be added to the Catalog and will specify when support for the new standard begins or ends, and when the requirement to submit data using the new standard begins or ends. FDA will begin supporting SDTM v1.8 and SENDIG-AR v1.0 on March 15, 2020, and such Animal Rule<sup>1</sup> submissions will be required to use the new standard effective March 15, 2022.

Dated: March 5, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-04898 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-2019-N-1482]

#### Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Reopening of the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

<sup>1</sup> The Animal Rule refers to FDA’s regulations for the approval of new drugs and biological products when human efficacy studies are not ethical or feasible (see 21 CFR 314.600-650 for drugs and 21 CFR 601.90-95 for biologics).

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is reopening the comment period for the notice that appeared in the **Federal Register** of April 3, 2019, and extending it indefinitely. The notice announced 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, it notified the public that FDA was establishing a docket for public comment on this hearing and that the docket would close on July 2, 2019. On June 20, 2019, a notice that appeared in the **Federal Register** extended the comment period to July 16, 2019. To provide a public and transparent way for stakeholders to provide new and emerging information to us in real time as it becomes available, we are reopening the comment period and extending it indefinitely to allow interested parties to continue to comment. We are particularly interested in data that may help to address uncertainties and data gaps related to the safety of cannabidiol (CBD).

**DATES:** FDA is reopening the comment period and extending it indefinitely on the notice published in the **Federal Register** of April 3, 2019 (84 FR 12969).

**ADDRESSES:** You may submit either electronic or written 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-2019-N-1482 for “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds.” Received comments 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.” We will review this copy, including the claimed confidential information, in our 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.

**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.*

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## 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,