DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1079]

Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research.” This draft guidance outlines FDA’s current thinking on several topics relevant to the development of cannabis and cannabis-derived products: The source of cannabis and cannabis-derived compounds; quality considerations for developing drugs that contain cannabis and cannabis-derived compounds; and calculation of percent delta-9 tetrahydrocannabinol (THC) in botanical raw materials, extracts, and finished products. This draft guidance has been developed to help support clinical research into development of cannabis and cannabis-derived products.

DATES: Submit either electronic or written comments on the draft guidance by September 21, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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 on any guidance at any time as follows:

- 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 comment, you should clearly indicate in the comment that you are not waiving your right to request confidential treatment of such information if it is submitted as “confidential.”

- Submit electronic comments in the following way:
  - 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035; or Cindee Hogan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2181.

SUPPLEMENTARY INFORMATION: FDA is announcing support for the use in regulatory submissions the current version of the IEEE BioCompute standard (available at https://standards.ieee.org/standard/) and an update to include this standard in the FDA Data Standards Catalog for the submission of HTS data in NDAs, ANDAs, BLAs, and INDs to CBER, CDER, and CFSAN.

Scientific workflows have emerged as a model for representing and managing complex scientific computations. The BioCompute standard facilitates the exchange of HTS bioinformatics workflows (i.e., computations and analyses) between various organizations by specifying the information needed to understand and organize bioinformatic analyses. Currently, the range of bioinformatics tools and associated parameters of those tools makes it difficult to describe, exchange, and assess the reproducibility of a complex analysis in a standardized format.

The BioCompute standard represents a distillation of the bioinformatics workflows, describing the mechanisms for each step on the pipeline. The pipeline steps are organized into groups of conceptually related information or domains, which provides the ability to describe the full extent of the analysis, the purpose of the experiment, and any other relevant information. BioCompute tracks the flow of data from the beginning to the end of the bioinformatics pipeline, making transformations apparent at each step. In this way, an analysis formatted according to the BioCompute standard provides the manifest (metadata) for the HTS data files.


Lauren K. Roth,

Associate Commissioner for Policy.

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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–1079 for “Cannabis and
Cannabis-Derived Compounds: Quality
Considerations for Clinical Research.”

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, 240–402–7500.

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-

**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,
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 document.

FOR FURTHER INFORMATION CONTACT:
Amy Muhlberg, Center for Drug
Evaluation and Research, Food
and Drug Administration, Bldg. 51, Rm.
3117, 10903 New Hampshire Ave.,
Silver Spring, MD 20993–0002, 240–
402–6901 or Cassandra Taylor, Center
for Drug Evaluation and Research, Food
and Drug Administration, Bldg. 51, Rm.
4150, 10903 New Hampshire Ave.,
Silver Spring, MD 20993–0002, 240–
402–5290.

**SUPPLEMENTARY INFORMATION:**

1. **Background**

FDA is announcing the availability of
a draft guidance for industry entitled
“Cannabis and Cannabis-Derived
Compounds: Quality Considerations for
Clinical Research.”

This draft guidance outlines FDA’s
current thinking on several topics
relevant to the development of drugs
containing cannabis and cannabis-
derived compounds: (1) The source of
cannabis and cannabis-derived
compounds for clinical research; (2)
general quality considerations for
developing drugs that contain cannabis
and cannabis-derived compounds; and
(3) calculation of percent delta-9 THC in
botanical raw materials, extracts, and
finished products. This draft guidance
has been developed to help support
clinical research into development of
drugs containing cannabis and
cannabis-derived compounds.

Cannabis and cannabis-derived
compounds have been the subject of
interest from consumers, industry,
researchers, the public, and regulators.
The Agriculture Improvement Act of
2018, Public Law 115–334 (the 2018
Farm Bill), changed certain federal
authorities relating to the production
and marketing of cannabis and
cannabis-derived compounds. Among
other things, the 2018 Farm Bill
removed hemp from Schedule I controls
in the Controlled Substances Act (CSA).
The 2018 Farm Bill also explicitly
preserved FDA’s authority to regulate
products containing cannabis or
cannabis-derived compounds under the
Federal Food, Drug, and Cosmetic Act
(FD&C Act) and section 351 of the
Public Health Service Act (PHS Act) (42
U.S.C. 262). In doing so, Congress
recognized FDA’s important public
health role with respect to all the
products it regulates. Accordingly,
consistently with the 2018 Farm Bill,
drugs that contain cannabis and
cannabis-derived compounds are
subject to the same authorities and
requirements as FDA-regulated products
containing any other substance,
regardless of whether the products fall
within the definition of hemp under the
2018 Farm Bill.

The Drug Enforcement Administration
(DEA) is the lead Federal agency for regulating controlled
substances. FDA does not enforce the
CSA or other laws within DEA’s
jurisdiction. Activities related to
growing and manufacturing cannabis for
use as an investigational drug for
research must comply with CSA and DEA
requirements if the cannabis
exceeds the threshold of 0.3 percent
delta-9 THC by dry weight. Sponsors
and investigators are encouraged to
contact DEA with questions regarding
Schedule I cannabis or the CSA.

FDA held a public hearing 1 on May
31, 2019, to obtain scientific data and
information about the safety,
manufacturing, product quality,
marketing, labeling, and sale of products
containing cannabis or cannabis-derived
compounds. The hearing was attended
by more than 600 participants in person
and over 2,300 joining remotely.
Presentations by over 100 speakers
represented a broad and diverse array of
stakeholders. Nearly 4,500 comments
were submitted to the docket associated
with the hearing, and the docket’s
closing date was extended to

1 “Scientific Data and Information About
Products Containing Cannabis or Cannabis-Derived
Compounds”; https://www.fda.gov/news-events/
fda-meetings-conferences-and-workshops/scientific-
data-and-information-about-products-containing-
cannabis-or-cannabis-derived-compounds.
accommodate greater participation. FDA developed this draft guidance in part to respond to issues and questions raised in the discussion at that hearing and in many of the public comments received. Although the hearing was not exclusively about cannabidiol (CBD), this compound was a key discussion topic. FDA and many stakeholders have concerns about marketed products that contain CBD, including concerns about potential contamination and inaccurate or misleading labeling. FDA would like to reiterate that EPIDIOLEX® (cannabidiol) is the sole FDA-approved product derived from an extract of the cannabis plant.

Many sponsors initiating clinical research for drugs containing cannabis and cannabis-derived compounds may be unclear regarding, or unfamiliar with, applicability drug quality expectations. In general, drugs containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as drugs containing any other substances intended for human use are evaluated by FDA’s Center for Drug Evaluation and Research (CDER) to ensure that drugs marketed in the United States are safe and effective for their intended uses and will be manufactured in a manner that ensures quality. CDER has published extensive regulations and guidance documents regarding the drug development and review process. In addition, FDA’s website contains useful explanations regarding drug research and development. Finally, CDER’s Small Business and Industry Assistance helps small pharmaceutical businesses and industry navigate the wealth of information that FDA offers, and assists in understanding the regulation of human drug products.

FDA’s support of drug development extends to drugs containing cannabidiol and other compounds found in cannabis. One important element is encouraging drug developers to meet with FDA early in their development programs—ideally, before submitting an Investigational New Drug (IND) application. The pre-IND meeting is an opportunity to obtain FDA input on research plans and required content for an IND submission. The pre-IND meeting can be valuable in planning a drug development program, especially if sponsors’ questions are not fully answered by guidelines and other information provided by FDA. Early interactions with FDA staff through a pre-IND meeting can answer sponsors’ questions related to a specific drug development program and provide information that will assist them in preparing complete IND applications. Efficient use of FDA resources can lead to more efficient drug development.

The FDA web page “FDA and Cannabis: Research and Drug Approval Process” (available at https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process) provides the basic roadmap for conducting clinical research at FDA using cannabis and cannabis-derived compounds. The resources on this page may be helpful to those interested in better understanding FDA processes for conducting clinical trials using cannabis and cannabis-derived compounds.

Calculating the amount of a substance in a botanical raw material by dry weight is a standard procedure. However, the calculation of dry weight for an extract or solid oral dosage form is less familiar to many stakeholders than the standard calculation for botanical raw materials. Therefore, the draft guidance recommends calculating delta-9 THC by dry weight in intermediates and drug products by removing the water content, including water contained in excipients. We invite comment from the public on this recommended approach. In addition, FDA invites public comment on the appropriate manufacturing controls over materials that cross under the 0.3 percent delta-9 THC by dry weight threshold during the production of a drug that contains cannabis or cannabis derived compounds.

This 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 “Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research.” 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 (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. However, the draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 for submission and approval of applications for investigational drugs and new drugs have been approved under OMB control numbers 0910–0014 and 0910–0001 respectively; and current Good Manufacturing Practices for Finished Pharmaceuticals as outlined in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs or https://www.regulations.gov.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.
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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Supplemental Award, Initiated by the Maternal and Child Health Bureau, to the University of Mississippi Medical Center for the Early Childhood Developmental Health System: Implementation in a High Need State Cooperative Agreement

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

ACTION: Notice of a Supplemental Award.

SUMMARY: HRSA announces the award of a supplemental for $3,500,000 to the University of Mississippi Medical Center for the Early Childhood Developmental Health System: Implementation in a High Need State program. The supplement will add another year of funding to the current recipient, during the period of September 30, 2020–September 29, 2021, to continue a study focused on improving child health through a statewide system of early childhood developmental screenings and interventions.

FOR FURTHER INFORMATION CONTACT: Dina Lieser, Division of Home Visiting and Early Childhood Systems, HRSA, 26 Federal Plaza, Room 3337, New York,