regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product BYFAVO (remimazolam). BYFAVO is indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. Subsequent to this approval, the USPTO received a patent term restoration application for BYFAVO (U.S. Patent No. 9,827,251) from Acacia Pharma Limited, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 14, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BYFAVO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BYFAVO is 4,482 days. Of this time, 3,931 days occurred during the testing phase of the regulatory review period, while 551 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 1, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 1, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 5, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for BYFAVO (NDA 212295) was initially submitted on April 5, 2019.

3. *The date the application was approved:* October 6, 2020. FDA has verified the applicant's claim that NDA 212295 was approved on October 6, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 796 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01220 Filed 1–23–23; 8:45 am]

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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; 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 final guidance for industry entitled ''Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research.'' This guidance outlines FDA's current thinking on several topics relevant to the development of cannabis and cannabis-derived human drugs, including the source of cannabis for clinical research; general quality considerations for developing human drugs that contain cannabis and cannabis-derived compounds; and calculation of percent delta-9 tetrahydrocannabinol (THC) in botanical raw materials, intermediates, drug substances, and drug products to determine their control status. This guidance is being issued to support clinical research for development of cannabis and cannabis-derived human drugs. This guidance finalizes the draft guidance of the same title issued on July 22, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on January 24, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–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-2015-09-18/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Zuk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6684, Silver Spring, MD 20993–0002, 240–402–9133; or Cassandra Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4150, Silver Spring, MD 20993–0002, 240–402–5290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research.'' This guidance outlines FDA's current thinking on several topics relevant to the development of human drugs containing cannabis and cannabis-derived compounds, including the source of cannabis for clinical research; general quality considerations for developing human drugs that contain cannabis and cannabis-derived compounds; and calculation of percent delta-9 THC in botanical raw materials, intermediates, drug substances, and drug products to determine their status as a controlled substance. This guidance is being issued to support clinical research for development of human drugs containing cannabis and cannabis-derived compounds.

Cannabis and cannabis-derived compounds (*i.e.,* compounds that occur naturally in the *Cannabis sativa L* plant) have been the subject of interest from consumers, industry, researchers, the public, and regulators. The Agriculture Improvement Act of 2018 (Pub. L. 115–334) (often called the 2018 Farm Bill) changed certain Federal authorities relating to the production of cannabis and cannabis-derived compounds. Among other things, the 2018 Farm Bill removed hemp, defined as cannabis and derivatives or extracts of cannabis having not more than 0.3 percent delta-9 THC by dry weight, 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 and section 351 of the Public Health Service Act (42 U.S.C. 262). Accordingly, consistent 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. 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 is a controlled substance (*i.e.,* it 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 does not enforce the CSA or other laws within DEA's jurisdiction.

Many sponsors initiating clinical research for drugs containing cannabis and cannabis-derived compounds may be unclear regarding, or unfamiliar with, applicable drug quality expectations. Early interaction with FDA may prevent clinical hold issues and aid sponsors in developing a complete investigational new drug (IND) application.

In general, drugs containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as drugs containing any other substance. Drugs intended for human use are evaluated by FDA's Center for Drug Evaluation and

Research [1] to help 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.

The recommendations in this guidance are intended to address the legal definitions and regulatory controls related to cannabis, and to address certain questions raised about drugs containing cannabis. The guidance also introduces key FDA regulatory concepts to stakeholders who may be less familiar with FDA or our authorities than other drug developers.

This guidance finalizes the draft guidance entitled ''Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research'' issued on July 22, 2020 (85 FR 44305). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarifying sources of cannabis for clinical research (including Schedule I sources), adding resources that explain expectations for INDs in various stages of drug development, and providing guidance on quality considerations for INDs. The final guidance also lists applicable U.S. Pharmacopeia chapters on quality testing, including the assessment of leachables from packaging and delivery systems. Further, the guidance addresses the calculation of delta-9 THC content, which is relevant to determine control status for cannabis and cannabis-derived compounds. In addition, editorial changes were made to improve clarity, including better explaining FDA's authority to regulate human drugs and renaming subsection III.C to emphasize that this section relates to control status considerations under the CSA.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections 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 for this guidance. The previously approved 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. The collections of information pertaining to 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 guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01286 Filed 1–23–23; 8:45 am]

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[1] FDA's Center for Biologics Evaluation and Research also has regulatory responsibilities with respect to the review of human drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0691]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on March 22, 2023, from 10 a.m. to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0691. Please note that late, untimely filed comments will not be considered. The docket will close on March 21, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 21, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before March 8, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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'').