

Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS–10415 Generic Clearance for the Collection Customer Satisfaction Surveys

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Generic Clearance for the Collection Customer Satisfaction Surveys; *Use:* This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency’s programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Collecting voluntary customer feedback is the least burdensome, most effective way for the Agency to determine whether or not its public websites are useful to and used by its customers. Generic clearance is needed to ensure that the Agency can continuously improve its websites through regular surveys developed from these pre-defined questions. Surveying the Agency websites on a regular, ongoing basis will help ensure that users have an effective, efficient, and satisfying experience on any of the websites, maximizing the impact of the information and resulting in optimum benefit for the public. The surveys will ensure that this communication channel meets customer and partner priorities, builds the Agency’s brands, and contributes to the Agency’s health and human services impact goals. *Form Number:* CMS–10415 (OMB control number: 0938–1185); *Frequency:* Occasionally; *Affected Public:* Individuals and Households, Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments; *Number of Respondents:* 1,000,000; *Total Annual Responses:* 1,000,000; *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact John Booth at 410–786–6577.)

Dated: February 25, 2019.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–03638 Filed 2–28–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0767]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Dronabinol (*delta*-9-tetrahydrocannabinol) and its Stereoisomers; Cannabis, Cannabis Resin, Extracts and Tinctures; Cannabidiol Preparations; and Pharmaceutical Preparations of Cannabis; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is providing interested persons with the opportunity to submit comments about the World Health Organization (WHO) recommendations to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States’ position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, March 18–22, 2019. This notice is issued under the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments on the notice by March 14, 2019. The short time period for the submission of comments is needed to ensure that the U.S. Department of Health and Human Services (HHS) may, in a timely fashion, carry out the required action and be responsive to the United Nations.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 14, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 14, 2019. Comments received by mail/hand delivery/courier

(for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-0767 for "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Cannabis and Cannabis Resin; Dronabinol (*delta*-9-tetrahydrocannabinol); Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol); Extracts and Tinctures of Cannabis; Cannabidiol Preparations; Preparations Produced Either by Chemical Synthesis or as Preparation of Cannabis; Request for

Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." 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.gpo.gov/fdsys/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: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 5150, Silver Spring, MD 20993-0002, 301-796-3156, james.hunter@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (1971 Psychotropic Convention). Section 201(d)(2)(B) of the CSA (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the 1971 Psychotropic Convention that the CND proposes to decide whether to add a drug or other substance to one of the schedules of the 1971 Psychotropic Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received notification from the Secretary-General of the United Nations (the Secretary-General) regarding two substances to be considered for deleting from the 1971 Psychotropic Convention. This notification reflects the recommendation from the 41st WHO Expert Committee for Drug Dependence (ECDD), which met in November 2018. In the **Federal Register** of October 10, 2018 (83 FR 50938), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

The United States is also a party to the 1961 Single Convention on Narcotic Drugs (1961 Single Convention). The Secretary of State has received a notification from the Secretary-General regarding several substances to be considered for changes in control under this convention. The CSA does not require HHS to publish a summary of such information in the **Federal Register**. Nevertheless, to provide interested and affected persons an

opportunity to submit comments regarding the WHO recommendations for narcotic drugs, the notification regarding these substances is also included in this **Federal Register** notice. The comments will be shared with other relevant Agencies to assist the Secretary of State in formulating the position of the United States on the control of these substances. The HHS recommendations are not binding on the representative of the United States in discussions and negotiations relating to the proposal regarding control of substances under the 1961 Single Convention.

II. United Nations Notification

The formal notification from the United Nations that identifies the drug substances and explains the basis for the recommendations is reproduced as follows (non-relevant text removed):

Reference: NAR/CL.3/2019
WHO/ECDD41; 1961C-Art.3, 1971C-Art.2 CU 2019/36/DTA/SGB (A)

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that on 28 January 2019, he received a notification from the Director-General of the World Health Organization (WHO), pursuant to article 3, paragraphs 1, 3, 5, and 6 of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (1961 Convention), and article 2, paragraphs 1, 4, and 6 of the Convention on Psychotropic Substances of 1971 (1971 Convention), with the following recommendations regarding the review of cannabis and cannabis-related substances as follows:

—Cannabis and cannabis resin

To be deleted from Schedule IV of the 1961 Convention.

—Dronabinol (*delta*-9-tetrahydrocannabinol)

To be added to Schedule I of the 1961 Convention.

To be deleted from Schedule II of the 1971 Convention, subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the 1961 Convention.

—Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol)

To be added to Schedule I of the 1961 Convention subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the 1961 Convention.

To be deleted from Schedule I of the 1971 Convention, subject to the CND's adoption of the recommendation to add

tetrahydrocannabinol to Schedule I of the 1961 Convention on Narcotic Drugs.

—Extracts and tinctures

To be deleted from Schedule I of the 1961 Convention.

—Cannabidiol preparations

To give effect to the recommendation of the fortieth meeting of the ECDD that preparations considered to be pure cannabidiol (CBD) should not be scheduled within the International Drug Control Conventions by adding a footnote to the entry for cannabis and cannabis resin in Schedule I of the 1961 Convention to read, "*Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.*"

Preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health.

To be added to Schedule III of the 1961 Convention.

In accordance with the provisions of article 3, paragraph 2 of the 1961 Convention, and article 2, paragraph 2 of the 1971 Convention, the Secretary-General hereby transmits the notification as annex I to the present note. The relevant extract from the report of the 41st meeting of the WHO Expert Committee on Drug Dependence is hereby transmitted as annex II. For time reasons, this notification and its annexes I and II are transmitted in English only. The notification will be transmitted in French and Spanish as soon as it becomes available.

Also in accordance with the same provisions, the notification from WHO will be brought to the attention of the 62nd session of the Commission on Narcotic Drugs (from 14 to 22 March 2019) in document E/CN.7/2019/12, which will be made available on the website of the 62nd session of the CND: http://www.unodc.org/unodc/en/commissions/CND/session/62_Session_2019/session-62-of-the-commission-on-narcotic-drugs.html.

To assist the Commission in reaching a decision, it would be appreciated if the Government could communicate any comments it considers relevant to the recommendations made by WHO regarding changes in the scope of control of cannabis and cannabis-related substances under the 1961 Convention, namely:

—Cannabis and cannabis resin

—Dronabinol (*delta*-9-tetrahydrocannabinol)

—Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol)

—Extracts and tinctures

—Cannabidiol preparations;

—Preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health; as well any economic, social, legal, administrative or other factors that it considers relevant to the recommendations made by WHO regarding changes in the scope of control of cannabis and cannabis-related substances under the 1971 Convention, namely:

—Dronabinol (*delta*-9-tetrahydrocannabinol)

—Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol)

1 February 2019

Annex I

Letter Addressed to the Secretary-General of the United Nations From the Director-General of the World Health Organization, 24 January 2019

"The forty-first meeting of the WHO Expert Committee on Drug Dependence (ECDD) convened from 12 to 16 November 2018 at WHO headquarters in Geneva. Following recommendations made by the fortieth ECDD in June 2018 regarding the pre-review of cannabis and cannabis-related substances, the forty-first ECDD carried out critical reviews of these substances to determine the most relevant level of international control for cannabis and cannabis-related substances and whether the World Health Organization (WHO) should recommend changes in their level of control.

In addition, the forty-first WHO ECDD reviewed ten New Psychoactive Substances (NPS), five of which are synthetic opioids; and two pain-relieving medicines, pregabalin and tramadol. The recommendations regarding these substances are communicated to you through a separate letter under the same date as this letter.

The review of cannabis and cannabis-related substances was carried out in relation to Resolution 52/5 of the Commission on Narcotic Drugs, in which the Commission stated that it looked forward to an updated report on cannabis by the Expert Committee.

With reference to Article 3, paragraphs 1, 3, 5, and 6 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, and Article 2, paragraphs 1, 4, and 6 of the Convention on Psychotropic Substances (1971), I am pleased to submit recommendations of the forty-first meeting of the ECDD regarding the review of cannabis and cannabis-related substances as follows:

Cannabis and cannabis-related substances

—Cannabis and cannabis resin

To be deleted from Schedule IV of the Single Convention on Narcotic Drugs (1961).

—Dronabinol (*delta*-9-tetrahydrocannabinol)

To be added to Schedule I of the Single Convention on Narcotic Drugs (1961).

To be deleted from Schedule II of the Convention on Psychotropic Substances (1971), subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Single Convention on Narcotic Drugs (1961).

—Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol)

To be added to Schedule I of the Single Convention on Narcotic Drugs (1961), subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Single Convention on Narcotic Drugs (1961).

To be deleted from Schedule I of the Convention on Psychotropic Substances (1971), subject to the CND's adoption of the recommendation to add tetrahydrocannabinol to Schedule I of the Single Convention on Narcotic Drugs (1961).

—Extracts and tinctures

To be deleted from Schedule I of the Single Convention on Narcotic Drugs (1961).

—Cannabidiol preparations

To give effect to the recommendation of the fortieth meeting of the ECDD that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions by adding a footnote to the entry for cannabis and cannabis resin in Schedule I of the Single Convention on Narcotic Drugs (1961) to read "Preparations containing predominantly cannabidiol and not more than 0.2 percent of *delta*-9-tetrahydrocannabinol are not under international control."

—Preparations produced either by chemical synthesis or as preparation

of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health

To be added to Schedule III of the Single Convention on Narcotic Drugs (1961).

The assessments and findings on which they are based are set out in detail in the forty-first report of the WHO Expert Committee on Drug Dependence. An extract of the report is attached in Annex 1 of this letter.

I am very pleased with the ongoing collaboration between WHO, the United Nations Office on Drugs and Crime (UNODC), and the International Narcotics Control Board (INCB), and in particular, how this collaboration has benefited the work of the WHO Expert Committee on Drug Dependence (including through the participation of UNODC and INCB in the forty-first meeting of the ECDD), and more generally, the implementation of the operational recommendations of the United Nations General Assembly Special Session (UNGASS) 2016."

Annex II

Extract From the Report of the 41st Expert Committee on Drug Dependence

5. Cannabis and Cannabis-Related Substances

5.1 Cannabis and Cannabis Resin

In the 1961 Single Convention on Narcotic Drugs, cannabis and cannabis resin are described, respectively, as the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted and as the separated resin, whether crude or purified, obtained from the cannabis plant. Reference to cannabis below will be taken to also include cannabis resin. Of the many compounds in cannabis, *delta*-9-tetrahydrocannabinol (Δ 9-THC) is the principal psychoactive constituent of cannabis, while CBD is also present but is not psychoactive.

Following consumption of cannabis, the adverse effects experienced include dizziness and impairment of motor control and cognitive function. As a result of the effects on movement and cognition, cannabis use can impair driving. There are particular risks of cannabis use reported for children, such as respiratory depression, tachycardia and coma. The adverse effects of

cannabis consumption are similar to those produced by Δ 9-THC alone.

There are also a number of adverse effects associated with long-term cannabis use, particularly increased risk of mental health disorders such as anxiety, depression, and psychotic illness. Chronic regular cannabis use is particularly problematic for young people because of its effects on the developing brain.

Cannabis can cause physical dependence in people who use the drug daily or near daily. This is evidenced by the onset of cannabis withdrawal symptoms that occur upon abstinence; these symptoms include gastrointestinal disturbance, appetite changes, irritability, restlessness and sleep impairment. Clinical diagnostic guidelines such as DSM-5 and ICD-10 recognize cannabis dependence and other disorders related to cannabis use.

The Committee considered information regarding the therapeutic indications of cannabis and ongoing research into its possible medical applications. A number of countries permit the use of cannabis for the treatment of medical conditions such as chemotherapy-induced nausea and vomiting, pain, sleep disorders, and spasticity associated with multiple sclerosis. The Committee recognized the limited robust scientific evidence on the therapeutic use of cannabis. However, some oral pharmaceutical preparations of cannabis have therapeutic advantages for treatment of conditions such as certain forms of pain and epilepsy. Preparations of cannabis are defined as a mixture, solid, or liquid containing cannabis and are generally subject to the same measures of control as cannabis and cannabis resin as per Article 2.3 of the 1961 Single Convention on Narcotic Drugs.

Cannabis and cannabis resin are included in Schedule I and Schedule IV of the 1961 Single Convention on Narcotic Drugs. Substances that are included in both these Schedules are particularly liable to abuse and to produce ill-effects and have little or no therapeutic use. Other substances that are included in both Schedules I and IV are fentanyl analogues, heroin, and other opioids that are considered especially dangerous. Use of all these substances is associated with a significant risk of death, whereas cannabis use is not associated with such risk.

The evidence presented to the Committee did not indicate that cannabis plant and cannabis resin were particularly liable to produce ill-effects similar to the effects of the other substances in Schedule IV of the 1961

Single Convention on Narcotic Drugs. In addition, preparations of cannabis have shown therapeutic potential for treatment of pain and other medical conditions such as epilepsy and spasticity associated with multiple sclerosis. In line with the above, cannabis and cannabis resin should be scheduled at a level of control that will prevent harm caused by cannabis use and, at the same time, will not act as a barrier to access and to research and development of cannabis-related preparation for medical use.

The Committee concluded that the inclusion of cannabis and cannabis resin in Schedule IV is not consistent with the criteria for a drug to be placed in Schedule IV.

The Committee then considered whether cannabis and cannabis resin were better placed in Schedule I or Schedule II of the 1961 Single Convention on Narcotic Drugs. While the Committee did not consider that cannabis is associated with the same level of risk to health as most of the other drugs that have been placed in Schedule I, it noted the high rates of public health problems arising from cannabis use and the global extent of such problems and, for these reasons, recommended that cannabis and cannabis resin continue to be included in Schedule I of the 1961 Single Convention on Narcotic Drugs.

- *Recommendation 5.1:* The Committee recommended that Cannabis and Cannabis Resin be deleted from Schedule IV of the 1961 Single Convention on Narcotic Drugs.

5.2 Dronabinol (*delta*-9-tetrahydrocannabinol; Δ 9-THC)

The main psychoactive substance in the cannabis plant is one of the four stereoisomers of *delta*-9-tetrahydrocannabinol (Δ 9-THC). This substance has therapeutic uses and is sometimes known by its international non-proprietary name dronabinol. It is currently placed in Schedule II of the 1971 Convention on Psychotropic Substances.

At the time of the adoption of the 1961 Single Convention on Narcotic Drugs, scientific research had not identified Δ 9-THC as the main psychoactive compound in cannabis. Subsequently, Δ 9-THC was included in the 1971 Convention on Psychotropic Substances at its inception. In previous ECDD reviews, the active and naturally occurring stereoisomer of Δ 9-THC known as dronabinol had been considered in a synthetic form as a pharmaceutical preparation. Following a recommendation from the 27th ECDD, dronabinol was placed in Schedule II of

the 1971 Convention on Psychotropic Substances. The Commission on Narcotic Drugs, however, did not adopt a subsequent recommendation to place dronabinol in Schedule III of the 1971 Convention on Psychotropic Substances.

The Committee noted that whereas in these previous ECDD reviews Δ 9-THC, and especially its active stereoisomer dronabinol, had been considered in a synthetic form as a pharmaceutical preparation, Δ 9-THC today also refers to the main psychoactive component of cannabis and the principal compound in illicit cannabis-derived psychoactive products. Some of these products contain Δ 9-THC at concentrations as high as 90 percent. Butane hash oil is an example of a high purity Δ 9-THC illicit cannabis-derived product that has recently emerged and is being used by heating and inhalation of the vapor. In such high purity illicitly derived forms, Δ 9-THC produces ill-effects, dependence, and abuse potential that is at least as great as for cannabis, which is placed in Schedule I of the 1961 Single Convention on Narcotic Drugs.

A substance liable to similar abuse and productive of similar ill-effects as that of a substance already scheduled within the 1961 Single Convention on Narcotic Drugs would normally be scheduled in the same way as that substance. As Δ 9-THC is liable to similar abuse as cannabis and has similar ill-effects, it meets the criteria for inclusion in Schedule I of the 1961 Single Convention on Narcotic Drugs. It was further recognized that cocaine, the principal active compound in coca, is placed along with coca leaf in Schedule I of the 1961 Single Convention on Narcotic Drugs and morphine; the principal active compound in opium is placed with opium in the same schedule. Placing Δ 9-THC, the principal active compound in cannabis, in the same schedule as cannabis would be consistent with this approach.

Based on requests received from Member States and information received from other United Nations agencies, the Committee understood that placing Δ 9-THC under the same Convention and in the same schedule as cannabis, Schedule I of the 1961 Single Convention on Narcotic Drugs, would greatly facilitate the implementation of the control measures of the Conventions in Member States. Accordingly:

- *Recommendation 5.2.1:* The Committee recommended that dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) be added to Schedule I of the 1961 Single Convention on Narcotic Drugs.

As indicated in the "Guidance on the WHO review of psychoactive substances for international control," to facilitate efficient administration of the international control system, it is not advisable to place a substance under more than one Convention. Accordingly:

- *Recommendation 5.2.2:* The Committee recommended the deletion of dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) from the 1971 Convention on Psychotropic Substances, Schedule II, subject to the Commission's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the 1961 Single Convention on Narcotic Drugs.

5.3 Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol)

There are currently six isomers of tetrahydrocannabinol (THC) listed in Schedule I of the 1971 Convention on Psychotropic Substances. These six isomers are chemically similar to *delta*-9-tetrahydrocannabinol (Δ 9-THC), which is currently listed in Schedule II of the 1971 Convention on Psychotropic Substances, but which the Committee has recommended deleting from this Schedule and including in Schedule I of the 1961 Single Convention on Narcotic Drugs.

While these six isomers are chemically similar to Δ 9-THC, there is very limited to no evidence concerning the abuse potential and acute intoxicating effects of these isomers. There are no reports that the THC isomers listed in Schedule I of the 1971 Convention induce physical dependence or that they are being abused or are likely to be abused so as to constitute a public health or social problem. There are no reported medical or veterinary uses of these isomers.

While the Committee recognized that available evidence has not demonstrated abuse and ill-effects of these isomers similar to those associated with Δ 9-THC, it noted that, due to the chemical similarity of each of the six isomers to Δ 9-THC, it is very difficult to differentiate any of these six isomers from Δ 9-THC using standard methods of chemical analysis. The Committee understood that placing these six isomers under the same Convention and in the same Schedule as Δ 9-THC would facilitate the implementation of international control of Δ 9-THC, as well as assist Member States in the implementation of control measures at country level. Accordingly:

- *Recommendation 5.3.1:* The Committee recommended that

tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention on Psychotropic Substances) be added to Schedule I of the 1961 Single Convention on Narcotic Drugs, subject to the Commission's adoption of the recommendation to add dronabinol (*delta*-9-tetrahydrocannabinol) to the 1961 Single Convention on Narcotic Drugs in Schedule I.

As indicated in the "Guidance on the WHO review of psychoactive substances for international control," to facilitate efficient administration of the international control system, it is not advisable to place a substance under more than one Convention. Accordingly:

- *Recommendation 5.3.2:* The Committee recommended that tetrahydrocannabinol (understood to refer to the six isomers currently listed in Schedule I of the 1971 Convention on Psychotropic Substances) be deleted from the 1971 Convention on Psychotropic Substances, subject to the Commission's adoption of the recommendation to add tetrahydrocannabinol to Schedule I of the 1961 Single Convention on Narcotic Drugs.

5.4 Extracts and Tinctures of Cannabis

Extracts and tinctures of cannabis are preparations that are produced by application of solvents to cannabis and that are currently placed in Schedule I of the 1961 Single Convention on Narcotic Drugs. These include both medical preparations such as that containing an approximately equal mixture of *delta*-9-tetrahydrocannabinol (dronabinol; Δ 9-THC) and cannabidiol and non-medical preparations with high concentrations of Δ 9-THC such as butane hash oil. While the medical extracts and tinctures are administered orally, those produced and used illicitly are normally inhaled following heating and vaporization.

The Committee recognized that the term *Extracts and Tinctures of Cannabis* as cited in the 1961 Single Convention on Narcotic Drugs encompasses these diverse preparations that have psychoactive properties as well as those that do not. The Committee also recognized that the variability in psychoactive properties of these preparations is due principally to varying concentrations of Δ 9-THC, which is currently scheduled in the 1971 Convention on Psychotropic Substances, and that some extracts and tinctures of cannabis without psychoactive properties and including predominantly cannabidiol have

promising therapeutic applications. The fact that diverse preparations with a variable concentration of *delta*-9-THC are controlled within the same entry "Extract and Tinctures" and the same schedule, is a challenge for responsible authorities that implement control measures in countries.

As per the 1961 Single Convention on Narcotic Drugs, preparations are defined as mixtures, solid, or liquid containing a substance in Schedule I or II and are generally subject to the same measures of control as that substance. The Committee noted that, by this definition, the 1961 Single Convention on Narcotic Drugs may cover all products that are "extracts and tinctures" of cannabis as "preparations" of cannabis and also, if the Committee's recommendation to move dronabinol to Schedule I of the 1961 Single Convention on Narcotic Drugs was followed, as "preparations" of dronabinol and its stereoisomers. Accordingly:

- *Recommendation 5.4:* The Committee recommended deleting Extracts and Tinctures of Cannabis from Schedule I of the 1961 Single Convention on Narcotic Drugs.

5.5 Cannabidiol Preparations

At its 40th Meeting, the ECDD considered a critical review of cannabidiol and recommended that preparations considered to be pure cannabidiol should not be scheduled within the International Drug Control Conventions. Cannabidiol is found in cannabis and cannabis resin but does not have psychoactive properties and has no potential for abuse and no potential to produce dependence. It does not have significant ill-effects. Cannabidiol has been shown to be effective in the management of certain treatment-resistant, childhood-onset epilepsy disorders. It was approved for this use in the United States in 2018 and is currently under consideration for approval by the European Union.

Cannabidiol can be chemically synthesized or it can be prepared from the cannabis plant. The approved medication (Epidiolex) is a preparation of the cannabis plant. The Committee noted that medicines without psychoactive effects that are produced as preparations of the cannabis plant will contain trace amounts of *delta*-9-tetrahydrocannabinol (Δ 9-THC; dronabinol). The cannabidiol preparation approved for the treatment of childhood-onset epilepsy, Epidiolex, contains not more than 0.15 percent Δ 9-THC by weight and has no effects indicative of potential for abuse or dependence. In keeping with the

recommendation that preparations considered pure cannabidiol not be controlled and recognizing that trace levels of Δ 9-THC may be found in such preparations, such as the concentration of 0.15 percent in Epidiolex, while acknowledging that chemical analysis of Δ 9-THC to an accuracy of 0.15 percent may be difficult for some Member States:

- *Recommendation 5.5:* The Committee recommended that a footnote be added to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: "Preparations containing predominantly cannabidiol and not more than 0.2 percent of *delta*-9-tetrahydrocannabinol are not under international control."

5.6 Pharmaceutical Preparations of Cannabis and Dronabinol (*delta*-9-tetrahydrocannabinol)

There are currently two main types of registered medicines that contain *delta*-9-tetrahydrocannabinol (Δ 9-THC; dronabinol).

One type is a preparation of cannabis that contains both the psychoactive Δ 9-THC and the non-psychoactive cannabidiol in approximately equal concentrations, e.g., Sativex. This is used for the treatment of spasticity due to multiple sclerosis.

A second type contains only Δ 9-THC as the active compound and is used for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS) and for nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Currently, approved medicines with Δ 9-THC as the only active compound use synthetically produced Δ 9-THC, e.g., Marinol, Syndros, although it is possible in the future that medicines with equivalent amounts of Δ 9-THC could be prepared from cannabis. There is no difference in the therapeutic effects or adverse effects of synthetic Δ 9-THC compared to Δ 9-THC from the cannabis plant.

These medicines are all taken orally and are approved for use in a number of countries.

The evidence concerning the use of these Δ 9-THC containing medicines is that they are not associated with problems of abuse and dependence and they are not diverted for the purpose of non-medical use.

The Committee recognized that such preparations are formulated in a way that they are not likely to be abused, and there is no evidence of actual abuse or ill-effects to an extent that would justify

the current level of control associated with Schedule I of the 1961 Single Convention on Narcotic Drugs for cannabis-based preparations such as Sativex and the level of control associated with Schedule II of the 1971 Convention on Psychotropic Substances, for preparations using synthetic *delta*-9 THC, *e.g.*, Marinol and Syndros.

To impede access to these medicines and in reference to Article 3.4 of the 1961 Single Convention on Narcotic Drugs:

- **Recommendation 5.6:** The Committee recommended that preparations containing *delta*-9-tetrahydrocannabinol (dronabinol), produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health, be added to Schedule III of the 1961 Convention on Narcotic Drugs.

III. Discussion

At this time, it is uncertain whether the above notification from WHO of recommendations for proposed scheduling action on cannabis and cannabis related substances will be acted upon by 62nd session of the Commission on Narcotic Drugs (from 14 to 22 March 2019). The Bureau of the 62nd Commission is currently considering whether to postpone voting on the cannabis-related recommendations until the reconvened meeting in December, or the 63rd session of the Commission on Narcotic Drugs, March 2020. If voting is deferred to a later date the comment period will be reopened.

Although WHO has made specific scheduling recommendations for each of the drug substances, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the 1971 Psychotropic Convention include the following: (1) Accept the WHO recommendations; (2) accept the recommendations to control but control the drug substance in a schedule other than that recommended; or (3) reject the recommendations entirely.

Cannabis, also known as marijuana, is a plant known by biological names *Cannabis sativa* or *Cannabis indica*. It is a complex plant containing multiple cannabinoids and other compounds, including the psychoactive substance THC and other structurally similar

compounds. Cannabinoids are defined as having activity at cannabinoid 1 and 2 (CB1 and CB2, respectively) receptors. Agonists of CB1 receptors are widely abused and are known to modulate motor coordination, memory processing, pain, and inflammation, and have anxiolytic effects. Marijuana is the most commonly used illicit drug in the United States.

The principal cannabinoids in the cannabis plant include THC, CBD, and cannabitol. These substances are controlled in Schedule I under the CSA. The synthetically derived single pure stereoisomer, *delta*-9-tetrahydrocannabinol (also known as dronabinol) is the active ingredient in two approved drug products in the United States, MARINOL (dronabinol) capsules, also available as a generic, and SYNDROS (dronabinol) oral solution. MARINOL is controlled in Schedule III, while SYNDROS is controlled in Schedule II under the CSA. Both MARINOL and SYNDROS are approved to treat anorexia associated with weight loss in patients with AIDS, and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatment.

CBD is another cannabinoid constituent of the cannabis plant. In the United States, one CBD-containing product, Epidiolex oral solution, has received marketing approval by the FDA for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients 2 years of age and older. On September 28, 2018, the Drug Enforcement Administration placed FDA-approved product Epidiolex to be marketed into Schedule V of the CSA. Currently, CBD that is not contained in an FDA-approved product with less than 0.1 percent THC is controlled as a Schedule I substance under the CSA. CBD is not specifically listed in the schedules of the 1961, 1971, or 1988 International Drug Control conventions.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the 1971 Psychotropic

Convention at the CND meeting in March 2019.

Comments regarding the WHO recommendations for control of Cannabis and Cannabis Resin; Dronabinol (*delta*-9-tetrahydrocannabinol); Tetrahydrocannabinol (Isomers of *delta*-9-tetrahydrocannabinol); Extracts and Tinctures of cannabis; Cannabidiol Preparations; Preparations Produced Either by Chemical Synthesis or as Preparation of Cannabis; under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

Dated: February 25, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0671]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Cyclopropyl Fentanyl; Methoxyacetyl Fentanyl; Ortho-Fluorofentanyl; Para-Fluorobutyrfentanyl; N-Ethylnorpentylone; and Four Additional Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of comment.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States' position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in March 18-22, 2019. This notice is issued under the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments by March 14, 2019.