TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

Type of respondent	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Establishments listing fewer than 10 SUDs	58	2	116	0.1 (6 minutes)	12
Establishments listing 10 or more SUDs	9	34	306	0.1 (6 minutes)	31
Total					43

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

The burden for this information collection has not changed since the last OMB approval.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07152 Filed 4–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1072]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; Cannabidiol; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of five drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (the CSA).

DATES: Submit either electronic or written comments by April 23, 2018.

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 April 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 23, 2018. 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–2018–N–1072 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol (THC); Stereoisomers of THC; Cannabidiol; 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, email: *james.hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (the U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Paragraph (d)(2)(A) of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (non-relevant text removed):

Ref.: C.L.2.2018

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of informing that the 40th Expert Committee on Drug Dependence (ECDD) will meet in Geneva from 4 to 8 June 2018. The 40th ECDD will convene in a special session to review cannabis and cannabis-related substances on their potential to cause dependence, abuse and harm to health, and potential therapeutic applications. WHO will make recommendations to the UN Secretary-General on the need for and level of international control of these substances. Recommendations made from the 39th meeting can be found on the ECDD website (*https://www.who.int/mason/entity/medicines/news/2017/letter-DG-39thECDDrecommendations.pdf?ua=1*).

At its 126th session in January 2010, the Executive Board approved the publication ''Guidance on the WHO review of psychoactive substances for international control'' (EB126/2010/REC1, Annex 6) which requires the Secretariat to request relevant information from Ministers of Health in Member States to prepare a report for submission to the ECDD. For this purpose, a questionnaire was designed to gather information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation. Member States are invited to collaborate, as in the past, in this process by providing pertinent information as requested in the questionnaire and concerning substances under review.

It would be appreciated if a person from the Ministry of Health could be designated as the focal point responsible for coordinating answers to the questionnaires. A list of focal points designated by Member States for the 39th ECDD in November 2017 is attached. It is requested that if a focal point's contact details including email address are to be added or amended, that Member States inform the Secretariat by 26 February 2018. Any additions or amendments to focal point designations should be emailed to *ecddsecretariat@who.int.*

If no additions or amendments to focal point details are made by this date, the focal point from 2017 will be approached by the Secretariat for questionnaire completion. Where there is a competent National Authority under the International Drug Control Treaties, it is kindly requested that the questionnaires be completed in collaboration with such body.

Once the Secretariat has received the contact details, focal points will be given further instructions and direct access to an online questionnaire. The questionnaires will be analysed by the Secretariat and prepared as a report that will be published on the ECDD website (*https://www.who.int/medicines/access/controlled-substances/ecdd/en/*) prior to the 40th ECDD meeting. The provisional agenda for the meeting will also be made available in advance on the ECDD website.

Member States are also encouraged to provide any additional relevant information (unpublished or published) that is available on these substances to: *ecddsecretariat@who.int.* This information will be an invaluable contribution to the ECDD and all submissions will be treated as confidential.

The WHO takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.
GENEVA, 30 January 2018

FDA has verified the website addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/medicines/access/controlled-substances/ecdd/en/.*

III. Substances Under WHO Review

WHO will convene in a special session to review the following substances: Cannabis plant and resin; extracts and tinctures of cannabis; delta-9-tetrahydrocannabinol (THC; stereoisomers of THC; and cannabidiol (CBD).

The Committee from the 37th ECDD requested that Secretariat begin collecting data towards a pre-review of cannabis, cannabis resin, extracts, and tinctures of cannabis at a future meeting. Subsequent to this request, WHO commissioned two updates on the scientific literature for cannabis and cannabis resin, which were prepared and presented to the 38th ECDD. That Committee noted that the current Schedule I under the 1961 Convention groups together cannabis and cannabis resin, extracts, and tinctures of cannabis, that cannabis plant and cannabis resin are also in Schedule IV of the 1961 Convention, that there are natural and synthetic cannabinoids in Schedule I and Schedule II of the 1971 Convention, and that cannabis had never been subject to pre-review or critical review by the ECDD. The Committee also noted an increase in the use of cannabis and its components for medical purposes and the emergence of new cannabis-related pharmaceutical preparations for therapeutic use. From this review, the 38th ECDD Committee recommended that preparations be made to conduct pre-reviews at a future meeting dedicated to the following substances: Cannabis plant and cannabis resin, extracts and tinctures of cannabis, THC, CBD, and stereoisomers of THC. An excerpt from the report of the 38th ECDD stated that the purpose of the pre-review was to determine whether current information justifies an Expert Committee critical review. They noted that the categories of information for evaluating substances in pre-reviews are identical to those used in critical reviews and that the pre-review is a preliminary analysis, and findings should not determine whether the

control status of a substance should be changed.

Cannabis, also known as marijuana, refers to the dried leaves, flowers, stems, and seeds from the *Cannabis sativa* or *Cannabis indica* plant. It is a complex plant substance containing multiple cannabinoids and other compounds, including the psychoactive chemical 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 cannabinol. FDA has not approved any product containing or derived from botanical marijuana for any indication. These substances are controlled in Schedule I under the CSA. Synthetic THC (dronabinol) is the active ingredient in two approved drug products in the United States, MARINOL capsules (and generics) and SYNDROS 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 acquired immunodeficiency syndrome (AIDS), and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatment.

CBD is another cannabinoid identified in cannabis. CBD has been tested in experimental animal and laboratory models of several neurological disorders, including those of seizure and epilepsy. In the United States, CBD-containing products are in human clinical testing in several therapeutic areas, but no such products have marketing approval by FDA for any medical purposes in the United States. CBD 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.

At the 39th (2017) meeting of the ECDD, the committee pre-reviewed CBD and recommended that extracts or preparations containing almost exclusively CBD be subject to critical review at the 40th ECDD meeting.

IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the five drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation of these drug substances, responsive to the WHO Questionnaire request for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in mid-2018. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA.

Dated: April 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07225 Filed 4–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1175]

Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs; 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 ''Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs.'' This draft guidance addresses FDA's current thinking about the relevant age groups to study and how early in the drug development pediatric patients should be incorporated during development of systemic drugs for atopic dermatitis (AD).

DATES: Submit either electronic or written comments on the draft guidance by June 8, 2018 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:

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–2018–D–1175 for ''Atopic Dermatitis: Timing of Pediatric Studies During