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

Development of Systemic Drugs; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' 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.

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, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Dawn Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5168, Silver Spring, MD 20993–0002, 301–796–5376; or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 AD.

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 the timing of pediatric studies during development of systemic drugs for atopic dermatitis. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: April 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07150 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–2014–N–1414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls Guidance Document: Labeling Natural Rubber Latex Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by May 9, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0633. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms—21 CFR 884.5300

OMB Control Number 0910–0633—Extension

Under the Medical Device Amendments of 1976 (Pub. L. 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and