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; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice entitled ''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'' that appeared in the **Federal Register** of March 1, 2019. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on March 1, 2019 (84 FR 7064). Submit either electronic or written comments by September 30, 2019.

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 September 30, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 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; Dronabinol (*delta*-9 tetrahydrocannabinol) and its Stereoisomers; Cannabis, Cannabis Resin, Extracts and Tinctures; Cannabidiol Preparations; and Pharmaceutical Preparations of Cannabis.'' 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 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: In the **Federal Register** of March 1, 2019 (84 FR 7064), FDA published a notice with a 14-day comment period to request comments on the notice entitled ''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.'' FDA is reopening the comment period until September 30, 2019. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments.

When the notice was initially published, FDA noted the need for a shortened time period for the submission of comments to ensure that the U.S. Department of Health and Human Services may in timely fashion carry out the required action and be responsive to the United Nations. FDA also noted that if voting on the cannabis-related recommendations was deferred to a later date, the comment period would reopen. The Bureau of the 62nd Commission on Narcotic Drugs decided to postpone the voting on the cannabis-related recommendations by adopting decision 62/14 (available at: *https://www.unodc.org/documents/commissions/CND/Drug_Resolutions/2010-2019/2019/Decisions/CND_Decision_62_14.pdf*). Therefore, FDA is reopening the comment period to allow interested persons an additional 30 days to comment.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18714 Filed 8–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Information Collection Request Title: Forms for Use With Applications to the Maternal and Child Health Bureau Research and Training Grants, New

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR must be received no later than September 30, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Forms for Use with Applications for the Maternal and Child Health Bureau Research and Training Grants, OMB No. 0906–xxxx—New.

Abstract: HRSA proposes to collect information in conjunction with applications for Maternal and Child Health Bureau (MCHB) grants that describes the qualifications of proposed researchers and the description of expected research participants. This is in compliance with the Social Security Act, Title V, § 501(a)(2) (42 U.S.C. 701(a)(2)), as amended, and the Public Health Service Act, § 399BB(f), (42 U.S.C. 280i–1(f)) as amended by the Autism CARES Act of 2014 (Pub. L. 113–157).

Need and Proposed Use of the Information: In MCHB's research and training grant programs, the applicants will complete the Biographical Sketch form to summarize the qualifications of each key personnel on their proposed research team. The grant reviewers will utilize this information to assess the capabilities of the research team to carry out the planned research project. Applicants will also complete the Inclusion Enrollment form to summarize their expected population of research study participants at the time of submission of their proposal. This information supports decision-making as part of the annual Noncompeting Continuation Award process. Monitoring inclusion enrollment is an important component of ensuring demographic diversity (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. This allows MCHB to determine to what extent individuals of different backgrounds are participating in MCHB research and training programs.

A 60-day notice was published in the **Federal Register** on September 13, 2018, vol. 83, No. 178; pp. 46504–05. There were no public comments.

Likely Respondents: Potential applicants to HRSA's MCHB research and training programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Biographical Sketch for MCHB research and training grant applicants	200	5	1,000	2.0	2,000
PHS Inclusion Enrollment form for MCHB research and training grant applications	200	1	200	0.5	100
Total	400		1,200		2,100