ethylone has been sold as the street drug ''Molly'' and encountered as a replacement for methylone. As a positional isomer of the controlled drug butylone, ethylone is considered a Schedule I controlled substance under the CSA.

Ethylphenidate (EPH) is structurally related to methylphenidate. Methylphenidate is controlled in Schedule IV of the CSA, and an active ingredient in drug products approved for medical use and marketed in the United States. Ethylphenidate is not approved for medical use in the United States. Ethylphenidate is structurally related to methylphenidate are being marketed as novel psychoactive substances with psychoactive effects similar to methylphenidate, therefore posing similar health risks to the users. Ethylphenidate is a controlled substance in several European countries, and is not a controlled substance in the United States under the CSA.

Methiopropamine (MPA) is a structural analogue of the Schedule II controlled substance methamphetamine. Pharmacologically, it functions as a norepinephrine-dopamine reuptake inhibitor and, secondarily, as a serotonin reuptake inhibitor. MPA is a thiophene based analog of methamphetamine. It has stimulant properties as an inhibitor of dopamine, norepinephrine transporters in the central nervous system. MPA was critically reviewed by the WHO at its 36th meeting of the Expert Committee on Drug Dependence in June 2014. It is not approved for medical use or controlled in the United States under the CSA, but is a controlled substance in the United Kingdom.

MDMB-CHMICA is an indole-based synthetic cannabinoid that is a potent full agonist at CB1 receptors and mimics functionally (biologically) the effects of the structurally unrelated delta-9-tetrahydrocannabinol (THC), a Schedule I substance, and the main active ingredient of marijuana. Synthetic cannabinoids are marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. MDMB-CHMICA use is associated with serious adverse events including death in several European countries. There are no commercial or approved medical uses for MDMB-CHMICA. MDMB-CHMICA is not controlled under the CSA, but may be treated as a ''controlled substance analogue'' under the CSA pursuant to 21 U.S.C 802(32)(A) and 813, and is a controlled substance in the State of Louisiana.

5F-APINACA (5F-AKB48) is a synthetic cannabinoid belonging to a chemical structural class with an indazole core. In vitro studies show that it binds to the cannabinoid CB1 receptors and displays agonist properties in functional assays, suggesting that it would share in vivo effects with delta-9-THC and various synthetic cannabinoids. There are no commercial or medical uses for 5F-APINACA. Synthetic cannabinoids are marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. SF-APINACA is not a controlled substance under the CSA, but may be treated as a ''controlled substance analogue'' under the CSA pursuant to 21 U.S.C. 802(32)(A) and 813.

JWH-073 is an indole-based synthetic cannabinoid agonist without the classical cannabinoid chemical structure. Pharmacology studies have been conducted on this substance. Behavioral pharmacology studies show that JWH-073 has delta-9-THC-like activity in animals. Synthetic cannabinoids are marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. On March 1, 2011, JWH-073 was temporarily controlled in Schedule I and on July 9, 2012, JWH-073 was permanently controlled as a Schedule I substance under the CSA.

XLR-11 (5-Fluoro-UR-144, 5F-UR-144) is an indole-based synthetic cannabinoid and acts as an agonist at cannabinoid CB1 receptors. Animal studies indicate that it mimics functionally (biologically) the effects of the structurally unrelated delta-9-THC, a Schedule I substance, and the main active ingredient of marijuana and numerous other Schedule I synthetic cannabinoids. Synthetic cannabinoids are marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. On May 16, 2013, XLR-11 was temporarily placed under Schedule I and on May 11, 2016, XLR11 was permanently controlled as a Schedule I substance under the CSA.

IV. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA, FDA, on behalf of the Department of Health and Human Services (HHS), invites interested persons to submit comments regarding the 12 named drugs. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation of these drugs. HHS will forward a scientific and medical evaluation of these drugs to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs 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 drugs, 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 early 2017. Any HHS position regarding international control of these drugs will be preceded by another **Federal Register** notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22472 Filed 9–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1112]

Health Canada and United States Food and Drug Administration Joint Public Consultation on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting and Webcast

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and Webcast; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public meeting (which will also be Webcast) entitled ''Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Council for Harmonisation of Technical

Requirements for Pharmaceuticals for Human Use (ICH).'' The goal of this meeting is to provide information and receive comments on the current activities of ICH, as well as the upcoming ICH meetings in Osaka, Japan, in November 2016. The topics to be discussed are the topics for discussion at the forthcoming ICH Assembly Meeting in Osaka. The purpose of this public meeting is to solicit public input prior to the next ICH Assembly meeting and the Expert Working Group meetings in Osaka, Japan, scheduled for November 6 through November 11, 2015.

DATES: The public meeting will be held on October 24, 2016, from 1 p.m. to 3 p.m., EST. Registration to attend the meeting and requests for oral presentations must be received by October 21, 2016; see the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Interested persons may submit either electronic or written comments to the public docket (see **ADDRESSES**) by October 19, 2016.

ADDRESSES: The meeting will be held at Sir Frederick G. Banting Research Centre, 251 Sir Frederick Banting Driveway, Ottawa, ON K1Y 0M1, Canada. It will also be broadcast on the Web allowing participants to join in person or via the Web.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1112 for ''Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993, 301–796–4548, email: *Amanda.Roache@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The ICH, formerly known as the International Conference on Harmonisation was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness. In 2015 the ICH was reformed to make the ICH a true global initiative that expands beyond the previous ICH members. More involvement from regulators around the world is expected, as they will join their counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH regulatory members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH process has achieved significant harmonization of

the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

II. Webinar Attendance and Participation

A. Registration

If you wish to attend the meeting, please register at the following Web site: *https://healthcanada-usfda_ich_consultation.eventbrite.ca.* Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. If you need special accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the Webinar.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public Webinar. Public oral presentations will be scheduled between approximately 2:30 p.m. and 3 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) by October 19, 2016, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, FAX, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public Webinar will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm516166.htm.*

Dated: September 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22471 Filed 9–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2683]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic clearance to collect information to support social and behavioral research used by FDA about drug products.

DATES: Submit either electronic or written comments on the collection of information by November 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–2683 for ''Data To Support Social and Behavioral Research as Used by the Food and Drug Administration.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*