having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–22449 Filed 9–16–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2633]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4-Methylethcathinone and Eleven Other Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 12 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 October 4, 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–2633 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (U-47700); Butyrfentanyl (Butyrylfentanyl); 4-Methylethcathinone (4-MEC); 3-Methylmethcathinone (3-methyl-N-methylcathinone; 3-MMC); Ethylone (3,4-methylenedioxy-N-ethylcathinone; bk-MDEA; MDEC); Pentedrone (α-Methylaminovalerophenone); Ethylphenidate (EPH); Methiopropamine (MPA); MDMB-CHMICA; 5F–APINACA (5F–AKB48); JWH–073; XLR–11 (5-Fluoro UR-144, 5F-UR-144); Request for Comments.'' 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: 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.

Section 201 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.28.2015

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of informing that the Thirty-eighth Expert Committee on Drug Dependence (ECDD) will meet in Geneva from 14 to 18 November 2016 to review a number of substances with potential for dependence, abuse and harm to health, and will make recommendations to the U.N. Secretary-General, on the need for and level of international control of these substances.

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 and answering the questionnaire. The designated focal point, and only this person, should access and complete the questionnaires:

1. U-47700;
2. Butyrfentanyl (Butyrylfentanyl);
3. 4-Methylethcathinone (4-MEC);
4. 3-Methylmethcathinone (3-methyl-N-methylcathinone; 3-MMC);
5. Ethylone (3,4-methylenedioxy-N-ethylcathinone; bk-MDEA; MDEC);
6. Pentedrone (α-Methylaminovalerophenone);
7. Ethylphenidate (EPH);
8. Methiopropamine (MPA);
9. MDMB-CHMICA;
10. 5F-APINACA (5F-AKB48);
11. JWH-073;
12. XLR-11 (5-Fluoro UR-144, 5F-UR-144).

For ease of reference a PDF version of the questionnaire in English, French and Spanish may be downloaded from the link *http://www.who.int/medicines/access/controlled-substances/ecdd/en/*. Please note that these versions are for reference only and all questionnaires must be answered through the online system. Further clarification regarding the questionnaire may be obtained from the Secretariat by emailing: *ecddsecretariat@who.int.*

Replies to the questionnaire must reach the Secretariat by 20 September 2016 in order to facilitate analyses and preparation of the report before the planned meeting. Where there is a competent National Authority under the International Drug Control Treaties, it is kindly requested that the questionnaire be completed in collaboration with such body.

The summary information from the questionnaire will be published online as part of the report on the Web site for the 38th ECDD linked to the Department of Essential Medicines and Health Products (EMP).

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 8 August 2016

HHS received an extension from WHO that replies to the questionnaire must reach the Secretariat by October 11, 2016. FDA has verified the Web site addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

III. Substances Under WHO Review

U-47700 is a synthetic opioid drug developed in the 1970s. U-47700 is structurally related to the opioid AH-7921. U-47700 is selective for the μ-opioid receptor. U-47700 has never been studied on humans, but would be expected to produce effects similar to those of other potent opioid agonists, including strong analgesia, sedation, euphoria, constipation, itching, and respiratory depression which could be harmful or fatal. Overdoses and overdose fatalities have been directly attributed to U-47700 misuse. There have been reports of U-47700 being encountered in counterfeit pills. On September 7, 2016, the Drug Enforcement Administration issued a notice of intent to temporarily schedule U-47700 into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act.

Butyrfentanyl (butyrylfentanyl) is a synthetic opioid and analog of fentanyl. Fentanyl is controlled in Schedule II of the CSA, and an active ingredient in drug products approved for medical use and marketed in the United States. Butyrylfentanyl has a pharmacological profile similar to that of fentanyl and other μ-opioid receptor agonists. Risks associated with abuse of butyrylfentanyl include development of substance use disorder, overdose, and death similar to that of other μ-opioid agonists. The U.S. Drug Enforcement Administration (DEA) is aware of at least 40 confirmed fatalities associated with butyrylfentanyl. It has no approved medical use in the United States. On May 12, 2016, butyrylfentanyl was temporarily placed into Schedule I of the CSA for 2 years upon finding that it posed an imminent hazard to the public safety. The Attorney General, though, may extend this temporary scheduling for up to 1 year.

4-Methylethcathinone (4-MEC), 3-Methylmethcathinone (3-methyl-N-methylcathinone; 3-MMC): 3-methyl-methcathinone (3-MMC), pentedrone, and ethylone (3,4-methylenedioxy-N-ethylcathinone; bk-MDEA; MDEC) are synthetic cathinones that are structurally and pharmacologically similar to amphetamine, 3-4 methylenedioxymethamphetamine (MDMA), cathinone, and other related substances. These substances are central nervous system stimulants with psychoactive properties similar to Schedule I and II amphetamine type substances. Public health risks associated with the use of synthetic cathinones suggest that these substances are associated with cardiac, psychiatric, and neurological symptoms that may lead to emergency department admissions, violent behaviors causing harm to self or others, or death. 4-MEC, 3-MMC, pentedrone, and ethylone have no known medical use in the United States. On March 7, 2014, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place 4-MEC and pentedrone into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). On March 4, 2016, the temporary Schedule I status of 4-MEC and pentedrone was extended for 1 year, or until permanent scheduling is completed. Permanent scheduling for 4-MEC and pentedrone was initiated on March 4, 2016, upon publication of the notice of proposed rulemaking. As a positional isomer of 4-methylmethcathinone, 3-MMC is considered a Schedule I substance under the CSA. In the United States,

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