on NCQA's evaluation of SNPs using MOC scoring guidelines. Based on their scores, SNPs receive an approval for a period of 1-, 2-, or 3-years. We are developing an MOC off-cycle revision process so that SNPs can revise the MOC to modify its processes and strategies for providing care during their MOC approval period. We will require that SNPs submit summaries of their MOC revisions to CMS for NCQA evaluation when a SNP makes significant changes to its MOC as described in the annual Announcement of Medicare Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call letter for CY 2015 and CY2016. The NCQA will review the summary of changes to verify that the revisions are consistent with the acceptable, high quality standards as included in the original approved MOC. The package has been revised subsequent to the publication of the 60-day **Federal Register** notice (June 17, 2015; 80 FR 34647). *Form Number:* CMS–10565 (OMB control number 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 313; *Total Annual Responses:* 421; *Total Annual Hours:* 2,400. (For policy questions regarding this collection contact Susan Radke at 410–786–4450).

Dated: September 30, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–25212 Filed 10–2–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0045]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ketamine and Nine 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 10 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 15, 2015.

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–2015–N–0045 for International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ketamine; Phenazepam; Etizolam; 1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine (MT-45); N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (Acetylfentanyl); α-Pyrrolidinovalerophenone (α-PVP); 4-Fluoroamphetamine (4-FA); para-Methyl-4-methylaminorex (4,4'-DMAR); para-Methoxymethylamphetamine (PMMA); 2-(ethylamino)-2-(3-methoxyphenyl)-cyclohexanone (Methoxetamine or MXE); 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 (emphasis 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-sixth Expert Committee on Drug Dependence (ECDD) will meet in Geneva from 16 to 20 November 2015 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. It is requested that the focal point's contact details (including email address) be emailed to: *ecddsecretariat@who.int.* The designated focal point, and only this person, should access and complete the questionnaires via these links:

1. Ketamine INN—*https://extranet.who.int/dataform/961512/lang-en*
2. Phenazepam—*https://extranet.who.int/dataform/482684/lang-en*
3. Etizolam—*https://extranet.who.int/dataform/278963/lang-en*
4. MT–45—*https://extranet.who.int/dataform/465468/lang-en*
5. Acetylfentanyl—*https://extranet.who.int/dataform/495475/lang-en*
6. α-Pyrrolidinovalerophenone (α-PVP)—*https://extranet.who.int/dataform/758275/lang-en*
7. 4-Fluoroamphetamine (4–FA)—*https://extranet.who.int/dataform/538126/lang-en*
8. para-Methyl-4-methylaminorex (4,4'-DMAR)—*https://extranet.who.int/dataform/422472/lang-en*
9. para-Methoxymethylamphetamine (PMMA)—*https://extranet.who.int/dataform/665818/lang-en*
10. Methoxetamine (MXE)—*https://extranet.who.int/dataform/266376/lang-en*

Upon accessing the links the focal point will be prompted for a token (password) which is the country name in English, non-case sensitive and without spaces.

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/*. 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 15 October 2015 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 37th 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, 11 September 2015

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

Ketamine is classified as a rapid-acting general anesthetic agent used for short diagnostic and surgical procedures that do not require skeletal muscle relaxation. It is marketed in the United States as an injectable product for medical and veterinary use. Ketamine is controlled in Schedule III of the CSA in the United States. It is not controlled internationally under either the Psychotropic Convention or the Single Convention on Narcotic Drugs. The WHO Expert Committee on Drug Dependence reviewed ketamine at its 34th, 35th, and 36th meetings. On March 13, 2015, the Commission on Narcotic Drugs decided by consensus to postpone the consideration of a proposal concerning the recommendation to place ketamine in Schedule IV of the Psychotropic Convention and to request additional information from the WHO.

Phenazepam and Etizolam belong to a class of substances known as benzodiazepines. Benzodiazepines produce central nervous system depression and are commonly used to treat insomnia, anxiety, and seizure disorders. Phenazepam and Etizolam are currently prescribed in some countries, but neither drug substance is approved for medical use or controlled in the United States under the CSA.

1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine (MT–45) is a synthetic opioid with potent analgesic activity comparable to morphine despite being structurally unrelated to most other opioids. MT–45 use has been associated with deaths in the United States and in other countries. MT–45 is not currently controlled in the United States under the CSA.

Acetylfentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) is a potent opioid analgesic in the phenylpiperidine class of synthetic opioids. With the exception of its analgesic effects, this fentanyl-like substance is similar to other opioid analgesics that produce a variety of pharmacological effects, including alteration in mood, euphoria, drowsiness, respiratory depression, constriction of pupils (miosis), and impaired gastrointestinal motility. Acetylfentanyl has been associated with

several confirmed deaths in the United States. On July 17, 2015, Acetylfentanyl 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.

α-Pyrrolidinovalerophenone (α-PVP or alpha-PVP) is a synthetic cathinone structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine (MDMA); cathinone; and other related substances. Effects reported by abusers of synthetic cathinone substances include euphoria; sense of well-being; and increased sociability, energy, empathy, alertness, and concentration and focus. Abusers also report experiencing unwanted effects such as tremor, vomiting, agitation, sweating, fever, and chest pain. Other adverse or toxic effects that have been reported with the abuse of synthetic cathinones include tachycardia, hypertension, hyperthermia, mydriasis, rhabdomyolysis, hyponatremia, seizures, altered mental status (*e.g.,* paranoia, hallucinations, or delusions), and even death. On March 7, 2014, alpha-PVP 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-Fluoroamphetamine (4–FA) is a psychoactive substance of the phenethylamine and substituted amphetamine chemical classes and produces stimulant effects. 4–FA is not currently controlled in the United States under the CSA.

Para-Methyl-4-methylaminorex (4,4'-DMAR) is a derivative of the stimulant drug 4-methylaminorex and has been involved in several deaths in the United States. 4,4'-DMAR is not currently controlled in the United States under the CSA.

Para-Methoxymethylamphetamine (PMMA) is a substituted amphetamine of the phenethylamine class, as well as a structural analog of para-methoxyamphetamine (PMA) which produces effects similar but not identical to that of MDMA. PMMA is not currently controlled in the United States under the CSA.

2-(ethylamino)-2-(3-methoxyphenyl)-cyclohexanone (Methoxetamine or MXE) is an arylcyclohexamine and is not currently controlled under the CSA in the United States. At its 36th meeting, the WHO Expert Committee on Drug Dependence noted the insufficiency of data regarding dependence, abuse, and risks to the public health, thereby recommending that Methoxetamine not be placed under international control but be kept under international surveillance.

IV. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA (21 U.S.C. 811(d)(2)(A)), FDA, on behalf of the Department of Health and Human Services (HHS), invites interested persons to submit comments regarding the 10 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 2016. 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 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25201 Filed 10–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Proposed Collection; Comment Request; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to this notice. This notice solicits comments on the collection of information contained in the Public Health Service (PHS) guideline entitled ''PHS Guideline on Infectious Disease Issues in Xenotransplantation'' dated January 19, 2001.

DATES: Submit either electronic or written comments on the collection of information by December 4, 2015.

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