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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device AEGEA VAPOR SYSTEM. AEGEA VAPOR SYSTEM is indicated for ablation of the endometrial lining of the uterus in premenopausal women with menorrhagia due to benign causes in whom childbearing is complete. Subsequent to this approval, the USPTO received a patent term restoration application for AEGEA VAPOR SYSTEM (U.S. Patent No. 8,574,226) from Tsunami MedTech, LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 4, 2018, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of AEGEA VAPOR SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AEGEA VAPOR SYSTEM is 1,381 days. Of this time, 1,148 days occurred during the testing phase of the regulatory review period, while 233 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* September 4, 2013. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective September 4, 2013.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* October 25, 2016. The applicant claims December 17, 2015, as the date the premarket approval application (PMA) for AEGEA VAPOR SYSTEM (PMA P160047) was initially submitted. However, FDA records indicate that PMA P160047 was submitted as a complete application on October 25, 2016.

3. *The date the application was approved:* June 14, 2017. FDA has verified the applicant's claim that PMA P160047 was approved on June 14, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 931 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19496 Filed 9–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3968]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; APINACA; AB–FUBINACA; 5F–AMB; 5F–MDMB–PICA; 4–F–MDMB–BINACA; 4–CMC; N-ethylhexedrone; alpha-PHP; DOC; Crotonyl Fentanyl; Valeryl Fentanyl; Flualprazolam; Etizolam; and 8 Additional Preparations Listed in Schedule III of the 1961 Single Convention on Narcotic Drugs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

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 21 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, 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 (October 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 4, 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–3968 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; APINACA (AKB–48); AB–FUBINACA; 5F–AMB (5F–AMB–PINACA, 5F–MMB–PINACA); 5F–MDMB–PICA (5F–MDMB–2201); 4–F–MDMB–BINACA (4F–ADB); 4–CMC (4-chloromethcathinone; clefedrone); N-ethylhexedrone (NEH, hexen, ethyl-hex); *alpha*-PHP (PV–7, α-pyrrolidinohexanophenone); DOC (2,5-dimethoxy-4-chloroamfetamine); Crotonyl Fentanyl; Valeryl Fentanyl; Flualprazolam; Etizolam; Preparations listed in Schedule III of the 1961 Single Convention on Narcotic Drugs as follows: Acetyldihydrocodeine, Codeine; Dihydrocodeine; Ethylmorphine; Nicocodine; Nicodicodine; Norcodeine; Pholcodine: Request for Comments.'' 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 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.

Paragraph (d)(2)(A) 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.30.2019

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and in reference to C.L.14.2019 has the pleasure of informing that the 42nd Expert Committee on Drug Dependence (ECDD) will meet in Geneva from 21 to 25 October 2019. The Expert Committee on Drug Dependence meetings are of a closed nature, however a public information session on 21 October will be open to Member States.

Further information, including a full agenda of the meeting, will be available on the ECDD website: *https://www.who.int/medicines/access/controlled-substances/ecdd/ecdd/en/.*

The 42nd ECDD will convene to review psychoactive substances (attached) regarding their potential to cause dependence, abuse and harm to health, and their potential therapeutic applications. WHO will make recommendations to the UN Secretary-General on the need for and level of international control of these substances.

Member States are invited to collaborate in this process through designated national focal points, as in the past and in line with the publication ''*Guidance on the WHO review of psychoactive substances for international control*'' (EB126/2010/REC1, Annex 6, Para 21).[1]

For this purpose, a questionnaire was designed to gather country information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation.

National focal points designated by Member States following C.L.14.2019 will be approached to complete the questionnaire on substances under review at the 42nd ECDD meeting. Focal points will be given further instructions and direct access to online questionnaires. The questionnaires will be analysed by the Secretariat and prepared as a report that will be shared with the Committee for review.

Focal points are also encouraged to provide any additional relevant information (unpublished or published) on substances to be reviewed at the 42nd ECDD to: *ecddsecretariat@who.int* by 20 September 2019.

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

GENEVA, 29 July 2019

[1] *http://apps.who.int/gb/ebwha/pdf_files/EB126-REC1/B126_REC1-en.pdf#page=95.*

42nd Expert Committee on Drug Dependence (ECDD) 21 to 25 October 2019, WHO headquarters, Geneva, Switzerland
Substances Under Review

CRITICAL REVIEW

Synthetic cannabinoids	1. APINACA (AKB–48). 2. AB–FUBINACA. 3. 5F–AMB (5F–AMB–PINACA, 5F–MMB–PINACA).
Synthetic stimulants	4. 5F–MDMB–PICA (5F–MDMB–2201). 5. 4-F-MDMB-BINACA (4F-ADB). 6. 4–CMC (4-chloromethcathinone; clefedrone). 7. N-ethylhexedrone (NEH, Hexen, Ethyl-Hex). 8. Alpha–PHP (PV-7, α-pyrrolidinohexanophenone). 9. DOC (2,5-Dimethoxy-4-chloroamfetamine).
Fentanyl Analogues	10. Crotonyl fentanyl. 11. Valeryl fentanyl.
Benzodiazepines	12. Flualprazolam. 13. Etizolam.

PRE-REVIEW

Preparations listed in Schedule III of the 1961 Single Convention on Narcotic Drugs.	Preparations of: ○ Acetyldihydrocodeine. ○ Codeine. ○ Dihydrocodeine. ○ Ethylmorphine. ○ Nicocodine. ○ Nicodicodine. ○ Norcodeine. ○ Pholcodine. when compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 percent in undivided preparation.

FDA has verified the website addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/medicines/access/controlled-substances/ecdd_41_meeting/en/.*

III. Substances Under WHO Review

APINACA (AKB–48) (chemical name: *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide) is a synthetic cannabinoid with a high affinity for the CB1 receptor. This substance functionally (biologically) mimics the effects of delta-9-tetrahydrocannabinol (THC), a Schedule I substance, and the main psychoactive constituent in the cannabis (marijuana) plant. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. Chronic abuse of synthetic cannabinoids has been linked to adverse health effects including signs of addiction and withdrawal, as well as numerous reports of emergency room admissions resulting from their abuse. There are no commercial or approved medical uses for APINACA. On May 16, 2013, APINACA was temporarily controlled as a Schedule I substance under the CSA. On May 11, 2016, APINACA was permanently placed in Schedule I under the CSA.

AB–FUBINACA (chemical name: *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide) is a synthetic cannabinoid

that is a potent full agonist at CB1 receptors. This substance functionally (biologically) mimics the effects of the structurally unrelated THC, a Schedule I substance, and the main psychoactive chemical constituent in marijuana. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. AB–FUBINACA use has been associated with serious adverse events including death in the United States. There are no commercial or approved medical uses for AB–FUBINACA. On February 10, 2014, AB–FUBINACA was temporarily controlled as a Schedule I substance under the CSA. On September 6, 2016, AB–FUBINACA was permanently placed as a Schedule I controlled substance under the CSA.

5F–AMB (5F–AMB–PINACA, 5F–MMB–PINACA) (chemical name: Methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate) is a synthetic cannabinoid that is a potent full agonist at CB1 receptors. This substance functionally (biologically) mimics the effects of THC, a Schedule I substance, and the main psychoactive constituent in marijuana. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. The use of synthetic cannabinoids, including, 5F–AMB has been associated with nausea and vomiting, shortness of breath or depressed breathing, hypertension, tachycardia, chest pain, muscle twitching, acute renal failure, anxiety, agitation, psychosis, suicidal ideation, and/or cognitive impairment. There are no commercial or approved medical uses for 5F–AMB. On April 10, 2017, 5F–AMB was temporarily controlled as a Schedule I substance under the CSA. This temporary rule was extended effective April 10, 2019. On April 8, 2019, a Drug Enforcement Administration Notice of Proposed Rulemaking proposed permanently placing 5F–AMB into Schedule I of the CSA.

5F–MDMB–PICA (5F–MDMB–2201) (chemical name: Methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate) is a synthetic cannabinoid that has been sold online and used to mimic the biological effects of THC, the main psychoactive constituent in marijuana. Research and clinical reports have demonstrated that synthetic cannabinoids are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive ''high.'' Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. 5F–MDMB–PICA has been associated with law enforcement seizures and overdoses requiring emergency medical intervention. On April 16, 2019, 5F–MDMB–PICA was temporarily controlled as a Schedule I substance under the CSA.

4F–MDMB–BINACA (4F–ADB) (chemical name: Methyl 2-(1-(4-fluorobutyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate) is a synthetic cannabinoid that is a potent full agonist at CB1 receptors. This substance functionally (biologically) mimics the effects of THC, a Schedule I substance, and the main psychoactive constituent in marijuana. 4F–MDMB–BINACA has been encountered in numerous synthetic cannabinoid products that are smoked for their psychoactive effects. Multiple law enforcement encounters of 4F–MDMB–BINACA have been reported involving overdose deaths, illicit use, and seizures of drug evidence between December 2018 and February 2019. There are no commercial or approved medical uses for 4F–MDMB–BINACA. 4F–MDMB–BINACA is a positional isomer of 5F–AMB (chemical name: Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate), as defined by 21 CFR 1300.01, and has been a Schedule I controlled substance under the CSA since April 10, 2017.

4–CMC (4-chloromethcathinone; clefedrone, clephedrone) (chemical name: 1-(4-chlorophenyl)-2-(methylamino)propan-1-one) is a synthetic cathinone. 4–CMC produces central nervous system stimulant effects and is abused for its psychoactive properties. 4–CMC abuse has been associated with adverse health effects. 4–CMC has no currently accepted medical use in treatment in the United States. 4–CMC is not controlled under the CSA, but it is considered a Schedule I controlled substance by a number of states in the United States.

N-Ethylhexedrone (chemical name: 2-(ethylamino)-1-phenylhexan-1-one; NEH, hexen, Ethyl-Hex) and *alpha*-PHP (chemical name: 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; PV–7, α-pyrrolidinohexanophenone) are synthetic cathinones. *N*-Ethylhexedrone and *alpha*-PHP produce central nervous system stimulant effects and are abused for their psychoactive properties. *N*-Ethylhexedrone and *alpha*-PHP have been associated with adverse health effects leading to emergency department admissions, and deaths. *N*-Ethylhexedrone and *alpha*-PHP have no currently accepted medical use in treatment in the United States. On July 18, 2019, *N*-Ethylhexedrone and *alpha*-PHP were temporarily controlled as a Schedule I substance under the CSA.

DOC (chemical names: 2,5-Dimethoxy-4-chloroamfetamine; 2,5-dimethoxy-4-chloroamphetamine; 1-(4-chloro-2,5-dimethoxyphenyl)propan-2-amine) is a hallucinogenic substance with psychedelic effects. Law enforcement has encountered DOC in tablet, capsule, powder, liquid, and blotter paper forms. Its use has been associated with at least one death. DOC has no currently accepted medical use in treatment in the United States. DOC is not controlled under the CSA but is a Schedule I controlled substance in the state of Florida.

Crotonyl fentanyl (chemical name: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbut-2-enamide) and valeryl fentanyl (chemical name: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide) are synthetic opioids that have a pharmacological profile similar to other Schedule I and II controlled opioid substances such as cyclopropyl fentanyl, fentanyl, and other related mu-opioid receptor agonist substances. They are clandestinely produced and associated with adverse events typically associated with opioid use such as respiratory depression, anxiety, constipation, tiredness, hallucinations, and withdrawal. Crotonyl fentanyl and valeryl fentanyl have been encountered by law enforcement and/or reported in the scientific literature by public health officials as being illicitly distributed and abused. Crotonyl fentanyl and valeryl fentanyl have no commercial or currently accepted medical uses in the United States. On February 1, 2018, valeryl fentanyl was temporarily placed into Schedule I of the CSA. The chemical structure of crotonyl fentanyl defines it as a fentanyl-related substance, as defined in 21 CFR 1308.11(h)(30); therefore, crotonyl fentanyl was temporarily controlled as a Schedule I controlled substance under the CSA as of February 6, 2018.

Flualprazolam 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. Etizolam is currently prescribed in some countries; however, neither drug substance is approved for medical use in the United States. Currently, flualprazolam and etizolam are not controlled under the CSA, but are controlled in a number of States.

Acetyldihydrocodeine is an opiate derivative of low to moderate potency used as a cough suppressant and analgesic in various other countries. Acetyldihydrocodeine is not approved for medical use in the United States and is controlled under Schedule I of the CSA.

Codeine is an opioid drug closely related to morphine. Codeine can cause opioid tolerance, dependence, addiction, poisoning, and respiratory depression in high doses. It is an active ingredient in several approved narcotic analgesic and antitussive medicines in the United States. Codeine is approved for marketing in the United States and available as a single-ingredient product, or in combination with one or more nonnarcotic ingredients in recognized therapeutic amounts. Codeine is controlled in Schedule II of the CSA. Some codeine combination products are controlled in Schedule III and some in Schedule V, depending on the concentration or amount of codeine present in the approved product.

Dihydrocodeine is a semisynthetic narcotic related to codeine. Dihydrocodeine is an active ingredient in prescription-only oral tablet combination products approved for marketing in the United States for the treatment of moderate to moderately severe pain. Dihydrocodeine is controlled in Schedule II of the CSA. Some dihydrocodeine-containing combination products are controlled in Schedule III and some in Schedule V, depending on the concentration or amount of dihydrocodeine present in the approved product.

Ethylmorphine is a derivative of morphine with analgesic and antitussive effects. It is not approved for medical use in the United States but is approved for use in various other countries around the world. Ethylmorphine is controlled in Schedule II of the CSA. Some ethylmorphine containing combination products are controlled in Schedule III and some in Schedule V, depending on the concentration or amount of ethylmorphine present in the approved product.

Nicocodine (nicocodeine) and nicodicodine (nicodicodeine) are esters of codeine and dihydrocodeine, respectively. They are opioids with analgesic and cough suppressant effects. They are not approved for medical use in the United States. Nicocodeine is controlled in Schedule I of the CSA. As an ester of dihydrocodeine, nicodicodeine is controlled in Schedule II of the CSA.

Pholcodine is an opiate with cough suppressant effects but little to no analgesic effects. It is an active ingredient in cough lozenges in some countries but is not an ingredient in any products approved for medical use in the United States. Pholcodine is controlled in Schedule I of the CSA.

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 21 drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire 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 late 2019. 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: September 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19492 Filed 9–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office for Human Research Protections, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), a program office in the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS (Secretary), through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill three positions on the Committee membership that will be vacated during the 2020 and 2021 calendar years.

DATES: Nominations for membership on the Committee must be received no later than 45 days from the date of this publication.

ADDRESSES: Nominations may be emailed to *SACHRP@hhs.gov.* Nominations may also be mailed or delivered Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Nominations will not be accepted by facsimile.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240–453–8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP website at *www.hhs.gov/ohrp/sachrp,* or requesting via email at *sachrp@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Committee provides advice on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the Committee provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, the decisionally impaired, pregnant women, embryos and fetuses, individuals and populations in international studies, investigator conflicts of interest and populations in which there are