

Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Recommendations

for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5657, Silver Spring, MD 20993–0002, 240–402–6169.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 29, 2017, FDA published a notice of availability with a 60-day comment period to request comments on draft guidance for industry and FDA staff entitled “Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies.” This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

The Agency has received a request for a 60-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 60 days, until March 30, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01350 Filed 1–25–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0181]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Carfentanil; 4-fluoroamphetamine (4-FA) and Ten Other Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States’ position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in March 2018. This notice is issued under the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments by February 26, 2018.

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 February 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 26, 2018. 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-2018-N-0181 for "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Carfentanil; 4-fluoroamphetamine (4-FA) and Ten Other Substances; 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>.

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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, james.hunter@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Section 201(d)(2)(B) of the CSA (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the Psychotropic Convention that the CND proposes to decide whether to add a drug or other substance to one of the schedules of the

Psychotropic Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received notification from the Secretary-General of the United Nations (the Secretary-General) regarding six substances to be considered for control under the Psychotropic Convention. This notification reflects the recommendation from the 39th WHO Expert Committee for Drug Dependence (ECDD), which met in November 2017. In the **Federal Register** of August 14, 2017 (82 FR 37866), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

The United States is also a party to the 1961 Single Convention on Narcotic Drugs (1961 Single Convention). The Secretary of State has received a notification from the Secretary-General regarding six substances to be considered for control under this convention. The CSA does not require HHS to publish a summary of such information in the **Federal Register**. Nevertheless, to provide interested and affected persons an opportunity to submit comments regarding the WHO recommendations for narcotic drugs, the notification regarding these substances is also included in this **Federal Register** notice. The comments will be shared with other relevant Agencies to assist the Secretary of State in formulating the position of the United States on the control of these substances. The HHS recommendations are not binding on the representative of the United States in discussions and negotiations relating to

the proposal regarding control of substances under the 1961 Single Convention.

The short 30-day time period for the submission of comments is needed to ensure that Health and Human Services may, in a timely fashion, carry out the required action and be responsive to the United Nations.

II. United Nations Notification

The formal notification from the United Nations that identifies the drug substances and explains the basis for the recommendations is reproduced as follows (non-relevant text removed):

Reference:

NAR/CL.4/2017

WHO/ECDD39; 1961C–Art.3; 1971C–Art.2
CU 2017/437/DTA/SGB

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that the Director-General of the World Health Organization (WHO), pursuant to article 3, paragraphs 1 and 3 of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (1961 Convention) and article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances of 1971 (1971 Convention) notified the Secretary-General of the following recommendations:

Substances recommended to be placed in Schedules I and IV of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Carfentanil

Chemical name: Methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl) amino]piperidine-4-carboxylate

Substances recommended to be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Ocfentanil

Chemical name: N-(2-Fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide

Furanyl fentanyl

Chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide

Acryloylfentanyl (Acryl fentanyl)

Chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide

4-Fluoroisobutyryl fentanyl (4-FIBF, pFIBF)

Chemical name: N-(4-Fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide

Tetrahydrofuranylfentanyl (THF-F)

Chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide

Substances recommended to be placed in Schedule II of the Convention on Psychotropic Substances (1971):

AB-CHMINACA

Chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-

(cyclohexylmethyl)-1H-indazole-3-carboxamide

5F-ADB (5F-MDMB-PINACA)

Chemical name: Methyl (2S)-2-[[1-(5-fluoropentyl)-1H-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate
AB-PINACA

Chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1H-indazole-3-carboxamide

UR-144

Chemical name: (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone

5F-PB-22

Chemical name: Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate
4-Fluoroamphetamine (4-FA)

Chemical name: 1-(4-Fluorophenyl)propan-2-amine

In addition, in the letter from the Director-General of the World Health Organization to the Secretary-General, reference is also made to the recommendations by the thirty-ninth meeting of the WHO Expert Committee on Drug Dependence (ECDD) for carrying out a critical review of preparations containing almost exclusively cannabidiol (CBD), Pregabalin, and Tramadol at a subsequent Expert Committee meeting, as well as for Etizolam to remain under surveillance. Furthermore, the letter also makes reference to the recommendation by the Expert Committee with regard to cannabis and its component substances.

In accordance with the provisions of Article 3, paragraph 2 of the 1961 Convention and article 2, paragraph 2 of the 1971 Convention, the Secretary-General hereby transmits the notification as Annex I to the present note. Also in accordance with the same provisions, the notification from WHO will be brought to the attention of the sixty-first session of the Commission on Narcotic Drugs (12–16 March 2018).

In connection with the notification, WHO has also submitted the relevant extract from the report of the thirty-ninth meeting of the WHO Expert Committee on Drug Dependence which is hereby transmitted as Annex II.

In order to assist the Commission in reaching a decision, it would be appreciated if the Government could communicate any economic, social, legal, administrative or other factors that it considers relevant to the possible scheduling of the afore-mentioned substances that are recommended by WHO to be placed under international control under the 1961 Convention (namely: Carfentanil, Ocfentanil, Furanyl fentanyl, Acryloylfentanyl (Acryl fentanyl), 4-Fluoroisobutyryl fentanyl (4-FIBF, pFIBF), and Tetrahydrofuranylfentanyl (THF-F)) and the 1971 Convention (namely: AB-CHMINACA, 5F-ADB (5F-MDMB-PINACA), AB-PINACA, UR-144, 5F-PB-22 and 4-Fluoroamphetamine (4-FA)).

Communications are to be sent at the latest by 2 February 2018 to the Executive Director of the United Nations Office on Drugs and Crime, c/o Secretary, Commission on Narcotic Drugs, P.O. Box 500, 1400 Vienna, Austria, fax: +43-1-26060-5885, e-mail: sgb@unodc.org.

28 December 2017

His Excellency

Mr. Rex Tillerson

Secretary of State of the United States of America

Annex I

Letter Addressed to the Secretary-General of the United Nations From the Director-General of the World Health Organization

“The Thirty-Ninth meeting of the WHO Expert Committee on Drug Dependence convened from 6 to 10 November 2017, at WHO headquarters in Geneva. The objective of this meeting was to carry out an in-depth evaluation of psychoactive substances in order to determine whether or not WHO should recommend these substances to be placed under international control.

With reference to Article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances (1971) and Article 3, paragraphs 1 and 3 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, I am pleased to submit recommendations of the World Health Organization as follows:

To be placed in Schedules I and IV of the Single Convention on Narcotic Drugs (1961):

—Carfentanil

chemical name: Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl) amino]piperidine-4-carboxylate

To be placed in Schedule I of the Single Convention on Narcotic Drugs (1961):

—Ocfentanil

chemical name: N-(2-Fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide

—Furanyl fentanyl

chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide

—Acryloylfentanyl (Acryl fentanyl)

chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide

—4-Fluoroisobutyryl fentanyl (4-FIBF, pFIBF)

chemical name: N-(4-Fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide

—Tetrahydrofuranylfentanyl (THF-F)

chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide

To be placed in Schedule II of the Convention on Psychotropic Substances (1971):

—AB-CHMINACA

chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide

—5F-ADB (5F-MDMB-PINACA)

chemical name: Methyl (2S)-2-[[1-(5-fluoropentyl)-1H-indazole-3-carbonyl] amino]-3,3-dimethylbutanoate

—AB-PINACA

chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1H-indazole-3-carboxamide

—UR-144

chemical name: (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone

—5F-PB-22

chemical name: Quinolin-8-yl 1-(5-fluoropentyl)-1-*H*-indole-3-carboxylate
—4-Fluoroamphetamine (4-FA)

chemical name: 1-(4-Fluorophenyl)propan-2-amine

In addition, the Expert Committee recommended to carry out a critical review at a subsequent Expert Committee meeting for:

—Preparations containing almost exclusively cannabidiol (CBD)

chemical name: (1'*R*,2'*R*)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'-tetrahydro-[1,1'*b*]biphenyl]-2,6-diol

—Pregabalin

chemical name: (3*S*)-3-(Aminomethyl)-5-methylhexanoic acid

—Tramadol

chemical name: rac-(1*R*,2*R*)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol

It also recommended that the following substance remain under surveillance:

—Etizolam (INN)

chemical name: 4-(2-Chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*b*][1,2,4]triazolo[4,3-*a*][1,4]diazepine

The recommendations and the assessments and findings on which they are based are set out in detail in the Report of the 39th Expert Committee on Drug Dependence, which is the Committee that advises me on these issues. An extract of the Committee's Report is attached in Annex 1 to this letter.

I am very pleased with the ongoing collaboration among the United Nations Office on Drugs and Crime (UNODC), International Narcotics Control Board (INCB) and WHO, in particular, how this collaboration has supported the work of the WHO Expert Committee on Drug Dependence, and more generally, the implementation of operational recommendations from the United Nations General Assembly Special Session (UNGASS) 2016.

I would like to take this opportunity to inform you that the 40th Expert Committee on Drug Dependence will take place in May 2018 and will be specifically dedicated to the pre review of cannabis and its major components substances."

Annex II

Extract From the Report of the 39th Expert Committee on Drug Dependence

Substances recommended to be scheduled in Schedule I and Schedule IV of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Carfentanil

Chemically, carfentanil is Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl)amino]piperidine-4-carboxylate. Carfentanil has no stereoisomers.

Carfentanil has not been previously pre-reviewed or critically reviewed. A notification was received from a Party to the Conventions thus initiating a critical review.

Carfentanil is convertible into sufentanil and alfentanil, two very potent opioid analgesics controlled as Schedule I drugs under the Single Convention on Narcotic

Drugs of 1961. It is a μ -opioid receptor agonist, and its pharmacodynamic and clinical effects are similar to fentanyl but it is about 100 times more potent. It binds to opioid receptors, and produces respiratory depression, decreased consciousness, antinociception, and miosis. The substance has been associated with hundreds of deaths and nonfatal intoxications globally, and it has created significant concerns in a number of countries. Due to the extremely small doses that induce lethal effects, it poses a particularly serious threat to public health.

Carfentanil is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that carfentanil (Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl)amino]piperidine-4-carboxylate) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

The Committee considered and recognized the impact that international scheduling could have on veterinary access to carfentanil in relation to its therapeutic use in large animals. However, the Committee was particularly concerned regarding the extreme potency of the substance and serious risk to public health. The Committee felt that the therapeutic advantages did not offset the severe threat to human health. As such, and with consideration that substances in Schedule IV afford Parties the opportunity to adopt special measures for drugs with particularly dangerous properties, the Committee recommended that carfentanil (Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl)amino]piperidine-4-carboxylate) be also placed in Schedule IV of the Single Convention on Narcotic Drugs of 1961.

Substances recommended to be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Ocfentanil

Chemically, ocfentanil is *N*-(2-Fluorophenyl)-2-methoxy-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide. It has no stereoisomers.

Ocfentanil has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to the attention of WHO that ocfentanil is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any party.

Ocfentanil is an opioid that is structurally related to fentanyl that is regulated under Schedule I of the Single Convention on Narcotic Drugs of 1961, and produces opioid effects including analgesia, euphoria,

sedation, and potentially serious respiratory depression. Ocfentanil-related deaths have been reported, and it has come under national control in several countries in different regions of the world.

Ocfentanil is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that ocfentanil (*N*-(2-Fluorophenyl)-2-methoxy-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Furanyl fentanyl

Chemically, furanyl fentanyl is *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide. Furanyl fentanyl has no stereoisomers.

Furanyl fentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that furanyl fentanyl is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

Furanyl fentanyl is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that furanyl fentanyl (*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Acryloylfentanyl (Acryl fentanyl)

Chemically, acryloylfentanyl is *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide. It has no stereoisomers.

Acryloylfentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that acryloylfentanyl is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

Acryloylfentanyl is a compound liable to similar abuse and with similar ill effects to

controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that acryloylfentanyl (*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

4-Fluoroisobutyryl fentanyl (4-FIBF, pFIBF)

Chemically, 4-fluoroisobutyryl fentanyl (4-FIBF, pFIBF) is *N*-(4-Fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide.

4-Fluoroisobutyryl fentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that it is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

4-Fluoroisobutyryl fentanyl is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that 4-fluoroisobutyryl fentanyl (*N*-(4-Fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Tetrahydrofurfurylfentanyl (THF-F)

Chemically, tetrahydrofurfurylfentanyl is *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide. Tetrahydrofurfurylfentanyl contains a stereogenic centre allowing for the existence of a pair of enantiomers, (*S*)-tetrahydrofurfurylfentanyl and (*R*)-tetrahydrofurfurylfentanyl. There is no information on the actual enantiomers found on the illicit drug market at the time of the report.

Tetrahydrofurfurylfentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that tetrahydrofurfurylfentanyl is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

Tetrahydrofurfurylfentanyl is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that tetrahydrofurfurylfentanyl (*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Substances recommended to be scheduled in Schedule II of the Convention on Psychotropic Substances (1971):

AB-CHMINACA

Chemically, AB-CHMINACA is *N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide. AB-CHMINACA contains a chiral centre, so that two enantiomers exist: (*R*)-ABCHMINACA and (*S*)-AB-CHMINACA. Based on the literature and the most likely precursors to be used in manufacture, an (*S*)-configuration of the stereocenter should be expected.

AB-CHMINACA has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that AB-CHMINACA is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

AB-CHMINACA is a synthetic cannabinoid receptor agonist. It is clandestinely manufactured and sold under a variety of brand names. Its mode of action suggests also the potential for dependence and likelihood of misuse. Effects of AB-CHMINACA are consistent with those of synthetic cannabinoid receptor agonists and include relaxation, euphoria, depersonalization, distorted perception of time, impaired motor performance, hallucinations, paranoia, confusion, fear, anxiety, tachycardia, and nausea and vomiting. Its cannabimimetic effects are more potent than those of THC, which is listed in Schedule II in the Convention on Psychotropic Substances of 1971. There is evidence of an increase in number of persons using AB-CHMINACA in many countries that have included fatal and non-fatal cases. This substance causes substantial harm and has no therapeutic usefulness. AB-CHMINACA has similar abuse and similar ill effects as other synthetic cannabinoids receptor agonists already scheduled in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee recommended that AB-CHMINACA (*N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

5F-ADB/5F-MDMB-PINACA

Chemically, 5F-ADB (also known as 5F-MDMB-PINACA) is Methyl (2*S*)-2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate. 5F-ADB contains a chiral centre, so that two enantiomers exist: (*R*)-5F-ADB and (*S*)-5F-ADB.

5F-ADB has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that 5F-ADB is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

5F-ADB is a synthetic cannabinoid receptor agonist. It has cannabimimetic effects that are more potent than those of THC and MDMB-CHMICA, substances which are listed in Schedule II of the Convention on Psychotropic Substances of 1971. Its mode of action suggests the potential for dependence and likelihood of abuse. There is evidence of an increase in number of persons using 5F-ADB in many countries that have included fatal and non-fatal cases. This substance causes substantial harm and has no therapeutic usefulness. The Committee recommended that 5F-ADB, also known as 5F-MDMB-PINACA, (Methyl (2*S*)-2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

AB-PINACA

Chemically, AB-PINACA is *N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1*H*-indazole-3-carboxamide. AB-PINACA has stereoisomers.

AB-PINACA has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that AB-PINACA is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

The Committee considered that the degree of risk to public health and society associated with the abuse of AB-PINACA is substantial. Therapeutic usefulness has not been recorded. It recognized that AB-PINACA has similar abuse and similar ill-effects to other synthetic cannabinoids receptor agonists in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that AB-PINACA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that AB-PINACA (*N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1*H*-indazole-3-carboxamide) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

UR-144

Chemically, UR-144 is (1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone. It has no stereoisomers.

UR-144 was previously critically reviewed by the 36th ECDD in 2014. The Committee

recommended that UR-144 not be placed under international control at that time but be kept under surveillance.

Of particular significance to the Committee was the lack of analytically confirmed cases of non-fatal and fatal intoxications at the time involving solely UR-144. Subsequent data collected from the literature and from different countries indicating that this substance may cause substantial harm and that it has no medical use, warranted an updated critical review.

The Committee considered that the degree of risk to public health and society associated with the abuse of UR-144 is substantial. Therapeutic usefulness has not been recorded. It recognized that UR-144 has similar abuse and similar ill-effects to other synthetic cannabinoids receptor agonists in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that UR-144 is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that UR-144 ((1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

5F-PB-22

Chemically, 5F-PB-22 is Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate. It has no stereoisomers.

5F-PB-22 has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that 5F-PB-22 is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

The Committee considered that the degree of risk to public health and society associated with the abuse of 5F-PB-22 is substantial. Therapeutic usefulness has not been recorded. It recognized that 5F-PB-22 has similar abuse and similar ill-effects to other synthetic cannabinoids receptor agonists in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that 5F-PB-22 is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that 5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

4-Fluoroamphetamine (4-FA)

The chemical name of 4-FA is 1-(4-Fluorophenyl)propan-2-amine. The presence of a chiral centre gives rise to the enantiomeric pair of (S)-4-FA and (R)-4-FA, respectively. 4-FA is most likely to be available as the racemic mixture.

4-FA underwent a critical review in 2015. At that time, the committee recommended that 4-FA not be placed under international control due to insufficient evidence regarding dependence, abuse, and risks to public

health. However, it was kept under surveillance. Preliminary information collected from various sources indicated that this substance may cause substantial harm and that it has no medical use, thereby warranting an updated critical review.

4-FA is a ring-substituted derivative of amphetamine that is listed in Schedule II of the Convention on Psychotropic Substances of 1971. The clinical features associated with 4-FA intoxications include agitation, tachycardia, hypertension, hyperthermia, cardiovascular toxicity and cerebrovascular complications such as severe headaches and cerebral hemorrhage. Some severe adverse reactions required hospitalizations and others resulted in death.

The Committee considered that the degree of risk to public health and society associated with the abuse of 4-FA is substantial. Therapeutic usefulness has not been recorded. It recognized that 4-FA has similar abuse and similar ill-effects to substances in Schedule II of the Convention on Psychotropic Substances of 1971.

The Committee considered that there is sufficient evidence that 4-FA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that 4-FA (1-(4-Fluorophenyl)propan-2-amine) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

Substances recommended for critical review:

Preparations Containing Almost Exclusively Cannabidiol (CBD)

Chemically, cannabidiol is (1'R,2'R)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'-tetrahydro-[1,1'-biphenyl]-2,6-diol. Cannabidiol (CBD) is normally taken to refer to the naturally occurring (-)- enantiomer.

Cannabidiol has not been previously pre-reviewed or critically reviewed by the Expert Committee on Drug Dependence (ECDD). The current review was based on the recommendation from the 38th ECDD that pre-review documentation on cannabis-related substances, including cannabidiol, be prepared and evaluated at a subsequent committee meeting.

CBD is not specifically listed in the schedules of the 1961, 1971 or 1988 International Drug Control Conventions. There is no evidence that CBD as a substance is liable to similar abuse and similar ill-effects as substances in the 1961 or 1971 Conventions (including cannabis and dronabinol (THC), respectively). The purpose of the pre-review was to determine whether current information justifies an Expert Committee critical review whereby the Committee finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions. As CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), current information does not justify a change in this scheduling position and does not justify scheduling of the substance.

However, CBD is produced for pharmaceutical purposes as an extract of

cannabis, and cannabis extracts and tinctures are included in the Single Convention on Narcotic Drugs of 1961. The pre-review of Cannabis Extracts and Tinctures will be held at the 40th ECDD meeting in May 2018. Therefore it is also recommended that extracts or preparations containing almost exclusively CBD (cannabidiol; (1'R,2'R)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'-tetrahydro-[1,1'-biphenyl]-2,6-diol) be subject to critical review at that meeting.

Pregabalin

Chemically, pregabalin is (3S)-3-(Aminomethyl)-5-methylhexanoic acid. Pregabalin is the (S)-(+)-isomer of 3-isobutyl-GABA.

Pregabalin has not been previously pre-reviewed or critically reviewed. A pre-review at the 39th ECDD was proposed based on information received by the WHO Secretariat regarding the misuse of pregabalin.

Pregabalin, a gabapentinoid, is an analogue of gamma amino butyric acid (GABA), but does not act at GABA receptors or synapses or bind to benzodiazepine receptors. While pregabalin has therapeutic uses, the increasing evidence of its misuse and abuse in many countries is becoming a growing cause for concern.

Pregabalin has been shown to have the capacity to produce a state of dependence. On this basis, the Committee recommended that pregabalin ((3S)-3-(Aminomethyl)-5-methylhexanoic acid) proceed to a future critical review. The Committee requested that the Secretariat collect further data to support the critical review.

Tramadol

Chemically, tramadol is rac-(1R,2R)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol. Tramadol has two chiral centres and consequently, four different stereoisomers exist: (1R,2R), (1S,2S), (1R,2S), and (1S,2R).

Pre-reviews of Tramadol have been carried out by the ECDD in 1992, 2000, 2006, and 2014 and a critical review in 2002. The Committee most recently at its 36th meeting in 2014, and based on the evidence available regarding dependence, abuse and risks to public health, recommended that a critical review of tramadol was not warranted at that time. On the basis of information received by the WHO Secretariat regarding the misuse of tramadol, it was recommended that a pre-review of tramadol be carried out at the 39th ECDD in November 2017.

Tramadol is used as a medication for controlling moderate acute and chronic painful conditions, and it is listed in several national essential medicines lists. It produces opioid-like effects predominately through the conversion of tramadol into its active metabolite. There is growing evidence of abuse of tramadol in many countries, accompanied by adverse reactions, and tramadol-associated deaths. The Committee recommended that tramadol ((rac)-(1R,2R)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol) proceed to a critical review at a subsequent meeting. The Committee requested the Secretariat to collect additional data for the critical review, including engagement with Member States to

obtain information on the extent of problems associated with tramadol misuse. Also, the Committee asked for information on the medical use of tramadol including the extent that low income countries, countries facing conflicts and aid and relief agencies use and possibly rely on tramadol for provision of analgesia.

Substance recommended to remain under surveillance:

Etizolam (INN)

Chemically, etizolam is 4-(2-Chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine. It does not have stereoisomers.

The ECDD reviewed etizolam at the 26th meeting (1989) and the 27th meeting (1990). At the 37th ECDD in 2015, the committee pre-reviewed etizolam and recommended that a critical review of etizolam was warranted for a future meeting. The Committee noted deficiencies in information and suggested several potential sources that could be helpful in the preparation of the critical review, including those from traffic accident reports, seizure data, user forums, and pharmacovigilance data.

Owing to the lack of significantly more information since the pre-review conducted by the 37th ECDD in 2015, and considering the current insufficiency of data regarding dependence, abuse and risks to public health, the Committee recommended that etizolam (4-(2-Chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine) be kept under surveillance. The Committee asked the Secretariat to request more data from Member States that may be affected by the misuse of etizolam, and which could facilitate a future review.

III. Discussion

Although WHO has made specific scheduling recommendations for each of the drug substances, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the Psychotropic Convention include the following: (1) Accept the WHO recommendations; (2) accept the recommendations to control, but control the drug substance in a schedule other than that recommended; or (3) reject the recommendations entirely.

Carfentanil, also known as 4-carbomethoxyfentanyl, is an extremely potent synthetic opioid that is similar in structure to and approximately 100 times more potent than fentanyl as an analgesic. At one time legitimately produced, carfentanil is no longer manufactured, marketed, or used in the United States; it is approved by FDA for use under restricted conditions by veterinarians as an immobilizing agent for certain large animals. Illicitly produced carfentanil is a particularly harmful fentanyl analogue that is also being laced into heroin or sold by itself

and trafficked in the United States. It is not approved for human use. Drug seizure data indicate that carfentanil is typically used in small doses to cut heroin and other illicitly abused drugs. The significant risk to public health associated with carfentanil use stems from its respiratory depressive effects with very small amounts. Several fatalities have been reported as the result of carfentanil overdoses. On October 28, 1988, the Drug Enforcement Administration (DEA) published a Final Rule that placed carfentanil in Schedule II of the CSA (53 FR 43684). As such, no additional controls will be necessary to fulfill U.S. obligations if carfentanil is placed in Schedules I and IV of the Single Convention on Narcotic Drugs (1961).

Ocfentanil is a synthetically produced opioid that is structurally related to fentanyl and approximately equipotent in effect. Reported risks associated with use of ocfentanil include development of opioid use disorder, overdose, and fatal overdose. It has no approved medical use in the United States. The DEA initiated the temporary placement of this substance under Schedule I by publishing a notification of intent in the **Federal Register** on December 13, 2017 (82 FR 58575). As such, additional controls will be necessary to fulfill U.S. obligations if ocfentanil is placed in Schedules I of the Single Convention on Narcotic Drugs (1961).

Furanyl fentanyl (Fu-F) is a potent clandestinely produced synthetic opioid that is an analog of fentanyl. Evidence suggests that the pattern of abuse of fentanyl analogues, including furanyl fentanyl, parallels that of heroin and prescription opioid analgesics. Fu-F produces typical opioid effects that include respiratory depression and loss of consciousness. Seizures of Fu-F have been encountered in powder form. Fu-F has been connected to fatal overdoses, in which intravenous routes of administration are documented. It has no approved medical use in the United States. On November 29, 2016, the DEA issued a final order to temporarily schedule Fu-F and its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (81 FR 85873). As such, additional permanent controls will be necessary to fulfill U.S. obligations if Fu-F is controlled under Schedule I of the 1961 Single Convention.

Acryloylfentanyl (Acryl fentanyl) belongs to the 4-anilidopiperidine class of synthetic opioids and is similar in structure to fentanyl. Acryloylfentanyl is a clandestinely produced analog of fentanyl and sold illegally as a research

chemical on several websites.

Acryloylfentanyl has also been associated with adverse events typically associated with opioid use such as respiratory depression, anxiety, constipation, tiredness, hallucinations, and withdrawal. The use of acryloylfentanyl has also been linked to the development of opioid use disorder, overdose, and fatal overdose.

Acryloylfentanyl has no commercial or medical uses. On July 14, 2017, the DEA issued a temporary order to temporarily schedule acryloylfentanyl, its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (82 FR 32453). As such, additional permanent controls will be necessary to fulfill U.S. obligations if Fu-F is controlled under Schedule I of the 1961 Single Convention.

4-fluoroisobutyryl fentanyl (4-FIBF) is a clandestinely produced synthetic opioid that is an analog of fentanyl. It has m-receptor agonist activity similar to that of fentanyl. This would result in effects associated with opioid agonists such as analgesia, respiratory depression, anxiety, constipation, tiredness, hallucinations, withdrawal, development of opioid use disorder, overdose, and fatal overdose. The use of 4-FIBF has been implicated in several cases of overdose and fatal overdoses. 4-FIBF has not been approved for medical use in the United States. On May 3, 2017, the DEA issued a temporary order to temporarily schedule 4-FIBF, its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (82 FR 20544). As such, additional permanent controls will be necessary to fulfill U.S. obligations if 4-FIBF is controlled under Schedule I of the 1961 Single Convention.

AB-CHMINACA is a clandestinely produced synthetic cannabinoid agonist that is approximately 16 times more potent than delta-9-tetrahydrocannabinol. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, organ failure, anxiety, acute psychosis, and death. AB-CHMINACA has been detected in illicit synthetic cannabinoid substances and found in cases of overdose and hospitalizations. On October 16, 2017, the DEA published a Final Rule to permanently control AB-CHMINACA as a Schedule I substance under the CSA (82 FR 47971). As such, additional permanent controls will be not necessary to fulfill U.S. obligations if AB-CHMINACA is controlled under

Schedule I of the 1961 Single Convention.

5F-ADB is a clandestinely produced synthetic cannabinoid agonist. In general, adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, and acute psychosis. 5F-ADB has been identified in overdose and/or cases involving death attributed to their abuse. Adverse health effects reported from incidents involving 5F-ADB and other synthetic cannabinoids have included: nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, and/or cardio toxicity. On April 10, 2017, the DEA issued a temporary scheduling order to temporarily schedule 5F-ADB, its isomers, esters, ethers, salts and salts of isomers, esters, and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (82 FR 17119). As such, additional permanent controls will be necessary to fulfill U.S. obligations if 5F-ADB is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

AB-PINACA is a clandestinely produced synthetic cannabinoid agonist approximately 1.5 times as potent as delta-9-tetrahydrocannabinol. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. AB-PINACA has been detected in illicit synthetic cannabinoid substances, and reported in cases of overdose and hospitalizations. It has not been approved for medical use in the United States. On October 16, 2017, the DEA published a Final Rule to permanently control AB-PINACA as a Schedule I substance under the CSA (82 FR 47971). As such, additional permanent controls will not be necessary to fulfill U.S. obligations if AB-PINACA is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

UR-144 is a clandestinely produced synthetic cannabinoid agonist. In general, adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. UR-144 has been detected in herbal smoking blends that are sold as herbal incense. On May 11, 2016, the DEA issued a Final Rule to permanently schedule UR-144 into Schedule I of the CSA (81 FR 29142). As such, additional permanent controls will not be necessary to fulfill U.S. obligations if UR-144 is controlled under Schedule II of the 1971

Convention on Psychotropic Substances.

5F-PB-22 is a synthetic cannabinoid agonist with similar effects to delta-9-tetrahydrocannabinol, one of the main psychoactive components of cannabis. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. 5F-PB-22 is clandestinely produced. It has been found laced on plant material and marketed as herbal products, and is smoked for its psychoactive effects. According to the WHO, 5F-PB-22 has been associated with fatal intoxications. On September 6, 2016, the DEA issued a Final Rule to permanently place 5F-PB-22 into Schedule I of the CSA (81 FR 61130). As such, additional permanent controls will not be necessary to fulfill U.S. obligations if 5F-PB-22 is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

4-Fluoroamphetamine (4-FA) is a psychoactive substance of the phenethylamine and substituted amphetamine chemical classes and produces stimulant effects. WHO reports that 4-FA is clandestinely produced, and its use is associated with fatal and non-fatal intoxications. 4-FA is not approved for medical use in the United States and it is not controlled under the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if 4-FA is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the Psychotropic Convention at the CND meeting in March 2018.

Comments regarding the WHO recommendations for control of carfentanil, ocfentanil, furanyl fentanyl (Fu-F), acryloylfentanyl (acryl fentanyl), 4-fluoroisobutyl fentanyl (4-FIBF), and tetrahydrofuranlylfentanyl (THF-F), under the 1961 Single Convention, will also be forwarded to the relevant Agencies for consideration in

developing the U.S. position regarding narcotic substances at the CND meeting.

Dated: January 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Idaho National Laboratory in Scoville, Idaho, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C-46, Cincinnati, OH 45226-1938, Telephone 877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

On November 22, 2017, as provided for under 42 U.S.C. 7384l(14)(C), the Acting Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Idaho National Laboratory (INL) in Scoville, Idaho, and who were monitored for external radiation at the Idaho Chemical Processing Plant (CPP) (e.g., at least one film badge or TLD dosimeter from CPP) between January 1, 1975, and December 31, 1980, for a number of work days aggregating at least 250 work days, occurring solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on December 22, 2017. Therefore, beginning on December 22, 2017, members of this class of employees,