

Dated: December 12, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29701 Filed 12–18–14; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA–402]

#### Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cannabinoids Into Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of intent.

**SUMMARY:** The Deputy Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule three synthetic cannabinoids into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. The substances are: *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (common name: AB-CHMINACA), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (common name: AB-PINACA) and [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (common name: THJ-2201). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I substances under the CSA on the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of these synthetic cannabinoids.

**DATES:** December 19, 2014.

**FOR FURTHER INFORMATION CONTACT:**

Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

**SUPPLEMENTARY INFORMATION:** Any final order will be published in the **Federal Register** and may not be effective prior to January 20, 2015.

#### Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28

CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

#### Background

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.<sup>1</sup> The Deputy Administrator transmitted notice of his intent to place AB-CHMINACA, AB-PINACA, and THJ-2201 in schedule I on a temporary basis to the Assistant Secretary by letter dated September 17, 2014. The Assistant Secretary responded to this notice by letter dated September 30, 2014, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for AB-CHMINACA, AB-PINACA, or THJ-2201. The Assistant Secretary also stated that HHS has no objection to the temporary placement of AB-CHMINACA, AB-PINACA, and THJ-2201 into schedule I of the CSA. AB-CHMINACA, AB-PINACA, and THJ-2201 are not currently listed in any schedule under the CSA, a condition of 21 U.S.C. 811(h)(1).

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance’s history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for

<sup>1</sup> Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this notice of intent, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.” As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Assistant Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for AB-CHMINACA, AB-PINACA, and THJ-2201 indicate that these three synthetic cannabinoids (SCs) have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

### Synthetic Cannabinoids

SCs are chemicals synthesized in laboratories and mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. These chemicals, such as CP-47,497 and cannabicyclohexanol (both designed in the 1980s and currently controlled pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112-144), were initially used as research tools to investigate the biological mechanisms in the cannabinoid system and to develop novel therapies for various clinical conditions. Other SCs including JWH-018, JWH-073, and JWH-200 (all permanently controlled pursuant to FDASIA) were synthesized in the mid-1990s and studied to advance the understanding of drug-receptor interactions in the cannabinoid system.

SCs were marketed in several European countries as “herbal incense” before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. In 2009, their use began increasing in the United States with law enforcement encounters describing SCs laced on plant material and being abused for their psychoactive properties. In addition, forensic analyses by the DEA and other Federal, State, and local laboratories have identified multiple variations in both the type and amount of SC applied to the plant material.

As observed by the DEA and CBP, SCs originate from foreign sources, including China and other countries in Southeast Asia. Bulk substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. The powder form of SCs are typically dissolved in solvents (*e.g.*, acetone) before being applied to a green plant material or dissolved in a propellant intended for use in e-cigarette devices.

SCs are marketed under hundreds of different brand names, including “Spice,” “K2,” “Blaze,” “Red X Dawn,” “Paradise,” “Demon,” “Black Magic,” “Spike,” “Mr. Nice Guy,” “Ninja,” “Zohai,” “Yucatan,” “Fire,” “Crazy Clown,” “Mojo,” “Black Mamba,” “Black Voodoo,” “Scooby Snax,” “Bizzaro,” and many others. In addition, various “new generations” of SCs reflect the same or similar product labels while yielding a higher intensity and longer lasting highs, but with the user still being deprived of knowledge as to exactly what is contained inside the packaging.

The drug products laced with SCs are often sold under the guise of “herbal incense,” “potpourri,” etc., using various product names and routinely labeled “not for human consumption.” Additionally, these products are marketed as a “legal high” or “legal alternative to marijuana” and are readily available over the Internet, in head shops, or sold in convenience stores. There is an incorrect assumption that these products are safe and further, that mislabeling these products as “not for human consumption” is a legal defense to criminal prosecution.

These substances have no accepted medical use in the United States and have been reported to produce adverse health effects in humans while having a negative effect on communities. Acute and chronic abuse of SCs in general have been linked to adverse health effects including signs of addiction and withdrawal, numerous reports of emergency room admissions resulting from their abuse, overall toxicity, and death.

AB-CHMINACA, AB-PINACA, and THJ-2201 are SCs that have pharmacological effects similar to the schedule I hallucinogen THC and other temporarily and permanently controlled schedule I substances. With no approved medical use and limited safety or toxicological information, AB-CHMINACA, AB-PINACA, and THJ-2201 have emerged on the illicit drug market and are being abused for their psychoactive properties. The DEA’s analysis is available in its entirety under “Supporting and Related Material” of the public docket for this action at [www.regulations.gov](http://www.regulations.gov) under docket number DEA-402.

### Factor 4. History and Current Pattern of Abuse

SCs have been developed over the last 30 years as tools for investigating the cannabinoid system. Synthetic cannabinoids intended for illicit use were first reported in the United States in a November 2008 encounter, where a

shipment of “Spice” was seized and analyzed by CBP in Dayton, Ohio. At approximately the same time, in December 2008, JWH-018 and cannabicyclohexanol (CP-47,497 C8 homologue) were identified by German forensic laboratories. Since the initial identification of JWH-018 (November 2008), many other SCs have been found applied on plant material and encountered as drug products. The popularity of these cannabinoids and their associated products appears to have increased since January 2010 in the United States based on seizure exhibits and public health and media reports.

Numerous SCs have been identified as product adulterants, and law enforcement has seized bulk amounts of these substances. The first SCs identified as being abused include JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 homologue, followed shortly thereafter by new generations of SCs including drugs such as UR-144, XLR11, AKB48, PB-22, 5F-PB-22, AB-FUBINACA, ADB-PINACA, and numerous other SCs varying only by slight modifications to their chemical structure. JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 homologue were temporarily scheduled on March 1, 2011 (76 FR 11075), and later permanently placed in schedule I by Section 1152 of FDASIA on July 9, 2012. Section 1152 of FDASIA amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 synthetic phenethylamines of the 2C- series) into schedule I. UR-144, XLR11, and AKB48 were temporarily scheduled on May 16, 2013 (78 FR 28735). PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA were temporarily scheduled on February 10, 2014 (79 FR 7577).

Another generation of SCs including AB-CHMINACA, AB-PINACA, and THJ-2201 has recently been encountered. AB-CHMINACA, AB-PINACA, and THJ-2201 are not included among the 15 SCs that are specifically named under FDASIA, and do not fall under the legal definition of cannabimimetic agents as provided under FDASIA. These substances and products laced with these substances are commonly marketed under the guise of being a “legal high” with a disclaimer of “not for human consumption.” As detailed in reports, law enforcement and public health officials are encountering the abuse of these substances.

A major concern as reiterated by public health officials and medical professionals remains the targeting and direct marketing of SCs and SC-

containing products to adolescents and youth. This is supported by law enforcement encounters and reports from emergency rooms (see Factor 6 of Background Information and Evaluation of “Three Factor Analysis” (Factors 4, 5, and 6) for Temporary Scheduling); however, all age groups have been reported by media as abusing these substances and related products. Recently, law enforcement has been encountering new variations of SCs in liquid form. The liquids contain one or more SCs, including AB-CHMINACA and AB-PINACA. Users have been identified applying the liquid to hookahs (an instrument for vaporizing and smoking a given material whereby the smoke or vapor passes through a water basin prior to inhalation), vaporizers (also known as “vaping” or an “e-cigarette,” which allows the user to administer a liquid to be aerosolized and then inhaled), and hookah pens (a type of vaporizer, often much smaller and intended for increased discretion while smoking). Similar to conventional illicit manufacturing of SC products, liquid preparations of these substances do not adhere to any manufacturing standards with regard to dosage, the substance(s) included, purity, or contamination. It is important to note that following manufacturing principles or standards would not eliminate the adverse effects observed with SC products and SCs would still be considered a threat to public safety.

#### **Factor 5. Scope, Duration and Significance of Abuse**

Despite multiple scheduling actions in an attempt to safeguard the public from the adverse effects and safety issues associated with SCs, encounters by law enforcement and health care professionals demonstrate the continued abuse of these substances and their associated products. With the passing of each Federal control action, clandestine drug manufacturers and suppliers are adapting at an alarmingly quick pace to switch the ingredients to new, non-controlled variations of SCs. Exposure incidents involving SCs continue to be documented by poison control centers in the United States as the abuse of these substances remain a threat to both the short- and long-term public health and safety. Exposures to SCs were first reported to the American Association of Poison Control Centers (AAPCC) in 2011. Recently, AAPCC exposure reports have begun to increase. The number of exposures reported demonstrates the dangerous health effects observed involving these chemicals. Exposures for August 2014 (442) were the highest received in a

monthly period by the AAPCC since July 2012 (459). As of October 31, 2014, the AAPCC has received approximately 2,996 calls involving exposure to SCs for 2014.

The following information details information obtained through STRIDE<sup>2</sup> and NFLIS<sup>3</sup> (queried on October 1, 2014 (STRIDE); November 25, 2014 (NFLIS)), including dates of first encounter, exhibits/reports, and locations.

**AB-CHMINACA:** STRIDE –21 exhibits, first encountered in March 2014; NFLIS–586 reports, first encountered in February 2014, locations include Arkansas, Arizona, California, Colorado, Georgia, Iowa, Indiana, Kansas, Kentucky, Louisiana, Missouri, North Dakota, New Jersey, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas and Wisconsin.

**AB-PINACA:** STRIDE–245 exhibits, first encountered in June 2013; NFLIS–3,783 reports, first encountered in March 2013, locations include Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Mississippi, North Dakota, Nebraska, New Hampshire, New Jersey, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, West Virginia and Wyoming.

**THJ-2201:** STRIDE–65 exhibits, first encountered in September 2013; NFLIS–220 reports, first encountered in January 2014, locations include Arkansas, Arizona, Connecticut, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Minnesota, Missouri, North Dakota, Nebraska, New Hampshire, New Jersey, Ohio, Pennsylvania, Tennessee and Wisconsin.

#### **Factor 6. What, if Any, Risk There Is to the Public Health**

THJ-2201 was first observed in September 2013 while AB-CHMINACA was first observed in February 2014. AB-PINACA has been for sale on the illicit drug market as early as March 2013. From December 2013 through September 2014, CBP reported select encounters of these substances with most shipments originating in China

<sup>2</sup> System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other Federal agencies, and law enforcement agencies.

<sup>3</sup> National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

and intended for destinations within the United States: AB-CHMINACA–17 seizures involving 15.825 kg; AB-PINACA–4 seizures involving 6 kg; THJ-2201–6 seizures involving 5.5 kg (see Three Factor Analysis). The DEA has reported multiple encounters of large quantities of AB-CHMINACA, AB-PINACA and THJ-2201 that have been confirmed by forensic laboratories (STRIDE and/or NFLIS).

From October 2013 to the present, multiple deaths and severe overdoses have occurred involving AB-CHMINACA and AB-PINACA. Adverse effects reported from these incidences have included a variety of the following effects: Seizures, coma, severe agitation, loss of motor control, loss of consciousness, difficulty breathing, altered mental status, and convulsions that in some cases resulted in death. There have been multiple overdose reports involving AB-CHMINACA, AB-PINACA, or a combination of both substances. In addition, there have been at least four documented deaths involving AB-CHMINACA and three documented deaths involving AB-PINACA.

Since abusers obtain these drugs through unknown sources, the identity and purity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. By sharing pharmacological similarities with schedule I substances ( $\Delta^9$ -THC, JWH-018 and other temporarily and permanently controlled schedule I substances), AB-CHMINACA, AB-PINACA, and THJ-2201 pose a risk to the abuser. AB-CHMINACA, AB-PINACA, and THJ-2201 are being encountered on the illicit drug market and have no accepted medical use within the United States. Regardless, these products continue to be easily available and abused by diverse populations.

#### **Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety**

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of AB-CHMINACA, AB-PINACA, and THJ-2201 pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these SCs in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States,

and a lack of accepted safety for use under medical supervision. Available data and information for AB—CHMINACA, AB—PINACA, and THJ—2201 indicate that these three SCs have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Deputy Administrator, through a letter dated September 17, 2014, notified the Assistant Secretary of the DEA's intention to temporarily place these three SCs in schedule I.

### Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule three SCs, *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB—CHMINACA), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB—PINACA) and [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ—2201) in schedule I of the CSA, and finds that placement of these SCs into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these SCs into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Deputy Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. AB—CHMINACA, AB—PINACA, and THJ—2201 will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance.

Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done “on the record after opportunity for a hearing” conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

### Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

In as much as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Deputy Administrator will take into consideration any comments submitted by the Assistant Secretary

with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

### PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(29) through (31) to read as follows:

#### § 1308.11 Schedule I.

\* \* \* \* \*

(h) \* \* \*

(29) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7031 (Other names: AB—CHMINACA)

(30) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7023 (Other names: AB—PINACA)

(31) [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers—7024 (Other names: THJ-2201)

\* \* \* \* \*

Dated: December 12, 2014.

**Thomas M. Harrigan,**

*Deputy Administrator.*

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## DEPARTMENT OF EDUCATION

### 34 CFR Chapter VI

[Docket ID ED–2014–OPE–0161]

RIN 1840–AD18

#### **Negotiated Rulemaking Committee; Negotiator Nominations and Schedule of Committee Meetings—William D. Ford Federal Direct Loan Program**

**AGENCY:** Office of Postsecondary Education, Department of Education.

**ACTION:** Notice of intent to establish negotiated rulemaking committee.

**SUMMARY:** We announce our intention to establish a negotiated rulemaking committee to prepare proposed regulations governing the William D. Ford Federal Direct Loan (Federal Direct Loan) Program authorized under title IV of the Higher Education Act of 1965, as amended (HEA). The committee will include representatives of organizations or groups with interests that are significantly affected by the topics proposed for negotiations. We request nominations for individual negotiators who represent key stakeholder constituencies for the issues to be negotiated to serve on the committee, and we set a schedule for committee meetings.

**DATES:** We must receive your nominations for negotiators to serve on the committee on or before January 20, 2015. The dates, times, and locations of the committee meetings are set out in the *Schedule for Negotiations* section in the **SUPPLEMENTARY INFORMATION** section.

**ADDRESSES:** Please send your nominations for negotiators to Wendy Macias, U.S. Department of Education, 1990 K Street NW., Room 8017, Washington, DC 20006. Telephone: (202) 502–7526 or by email: [wendy.macias@ed.gov](mailto:wendy.macias@ed.gov).

**FOR FURTHER INFORMATION CONTACT:** For information about the content of this notice, including information about the negotiated rulemaking process or the nomination submission process,

contact: Wendy Macias, U.S. Department of Education, 1990 K Street NW., Room 8017, Washington, DC 20006. Telephone: (202) 502–7526 or by email: [wendy.macias@ed.gov](mailto:wendy.macias@ed.gov).

For information about negotiated rulemaking in general, see *The Negotiated Rulemaking Process for Title IV Regulations, Frequently Asked Questions* at <http://www2.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html>.

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), call the Federal Relay Service (FRS) toll free at 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:** On September 3, 2014, we published a notice in the **Federal Register** (79 FR 52273) announcing our intent to establish a negotiated rulemaking committee under section 492 of the HEA to develop proposed regulations to allow more student borrowers of Federal Direct Loans to use a “Pay as You Earn” repayment plan in accordance with the Presidential Memorandum issued on June 9, 2014 (available at [www.whitehouse.gov/the-press-office/2014/06/09/presidential-memorandum-federal-student-loan-repayments](http://www.whitehouse.gov/the-press-office/2014/06/09/presidential-memorandum-federal-student-loan-repayments)). We also announced two public hearings at which interested parties could comment on the topic suggested by the U.S. Department of Education (Department) and suggest additional topics for consideration for action by the negotiated rulemaking committee. Those hearings were held on October 23, 2014, in Washington, DC, and on November 4, 2014, in Anaheim, California. We invited parties to comment and submit topics for consideration in writing as well. Transcripts from the public hearings are available at <http://www2.ed.gov/policy/highered/reg/hearulemaking/2015/index.html>. Written comments submitted in response to the September 3, 2014, notice may be viewed through the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). Instructions for finding comments are available on the site under “How to Use Regulations.gov” in the Help section. Individuals can enter docket ID ED–2014–OPE–0124 in the search box to locate the appropriate docket.

**Regulatory Issues:** After considering the information received at the regional hearings and the written comments, we have decided to establish a negotiating committee to (1) prepare proposed regulations to establish a new Pay as You Earn repayment plan for those not covered by the existing Pay as You Earn Repayment Plan in the Federal Direct

Loan Program, and (2) establish procedures for Federal Family Education Loan (FFEL) Program loan holders to use to identify U.S. military servicemembers who may be eligible for a lower interest rate on their FFEL Program loans under section 527 of the Servicemembers Civil Relief Act (SCRA).

Under the Department’s current regulations, once a loan holder (the Secretary or a FFEL loan holder) receives a servicemember’s written request and a copy of the servicemember’s military orders, the maximum interest rate on any Federal Direct Loan or FFEL program loan made prior to the borrower entering active-duty status is six percent while the borrower is on active-duty status. (See 34 CFR 685.202(a)(4) and 682.202(a)(8)). On August 25, 2014, the Department published Dear Colleague Letter GEN–14–16 (available at <http://ifap.ed.gov/dpclatters/GEN1416.html>) announcing that the Department had adopted new procedures for determining a borrower’s eligibility for benefits under the SCRA and authorizing FFEL loan holders to adopt similar procedures. The Department now seeks to include those procedures in the regulations and to require FFEL loan holders to use those procedures.

These topics are tentative. Topics may be added or removed as the process continues.

We intend to select negotiators for the committee who represent the interests significantly affected by the topics proposed for negotiations. In so doing, we will follow the requirement in section 492(b)(1) of the HEA that the individuals selected must have demonstrated expertise or experience in the relevant topics proposed for negotiations. We will also select individual negotiators who reflect the diversity among program participants, in accordance with section 492(b)(1) of the HEA. Our goal is to establish a committee that will allow significantly affected parties to be represented while keeping the committee size manageable.

We generally select a primary and alternate negotiator for each constituency represented on the committee. The primary negotiator participates for the purpose of determining consensus. The alternate participates for the purpose of determining consensus in the absence of the primary. Either the primary or the alternate may speak during the negotiations.

The committee may create subgroups on particular topics that may involve individuals who are not members of the committee. Individuals who are not