

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-402]

#### Schedules of Controlled Substances: Placement of AB-CHMINACA, AB-PINACA and THJ-2201 Into Schedule I

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration proposes placing *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), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This proposed scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. If finalized, this action would continue to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle AB-CHMINACA, AB-PINACA and THJ-2201.

**DATES:** Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Comments must be submitted electronically or postmarked on or before February 27, 2017. Commenters should be aware that the electronic Federal Docket Management System

will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),” may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before February 27, 2017.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA-402” on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield,

Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

#### SUPPLEMENTARY INFORMATION:

##### Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such

as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

### Request for Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).” 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing held in relation to this rulemaking is restricted to: “(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed \* \* \*.” All requests for hearing and waivers of participation must be sent to the DEA using the address information provided above.

### Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 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. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. 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, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use in treatment in the United States, and the degree of dependence the 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 scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed \* \* \*.” The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);<sup>1</sup> or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. If finalized, this action would continue to impose the regulatory controls and administrative,

civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle AB–CHMINACA, AB–PINACA and THJ–2201.

### Background

On January 30, 2015, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the three synthetic cannabinoids [1-(5-Fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201); N-1-Amino-3-methyl-1-oxo-2-butanyl]-1-pentyl-1H-indazole-3-carboxamide (AB–PINACA); and N-[1-Amino-3-methyl-1-oxo-2-butanyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB–CHMINACA) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 80 FR 5042. That final order, which became effective on the date of publication, was based on findings by the Administrator of the DEA that the temporary scheduling of these three synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). At the time the final order took effect, section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), required that the temporary scheduling of a substance expire at the end of two years from the date of the scheduling order, and it provided that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance could be extended for up to 1 year. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of THJ–2201, AB–PINACA, and AB–CHMINACA expires on January 29, 2017, unless extended. An extension of the temporary order is being ordered by the DEA Administrator in a separate action.

The Administrator of the DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule THJ–2201, AB–PINACA and AB–CHMINACA. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these three synthetic cannabinoids. In accordance with 21 U.S.C. 811(b) and (c), on August 26, 2015, the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for THJ–2201, AB–PINACA and AB–CHMINACA. Upon evaluating the scientific and medical evidence, on November 14, 2016, the

<sup>1</sup> As discussed in a memorandum of understanding entered into by 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 Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

HHS submitted to the Administrator of the DEA its three scientific and medical evaluations for these substances. Upon receipt of the scientific and medical evaluations and scheduling recommendations from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of THJ-2201, AB-PINACA and AB-CHMINACA in accordance with 21 U.S.C. 811(c). The DEA has published a temporary order for the extension of the placement of THJ-2201, AB-PINACA and AB-CHMINACA into schedule I elsewhere in this issue of the **Federal Register**.

### **Proposed Determination To Schedule THJ-2201, AB-PINACA and AB-CHMINACA**

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by the Attorney General, or her delegate, the DEA Administrator. On August 26, 2015, the DEA requested scientific and medical evaluations and scheduling recommendations from the Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) for THJ-2201, AB-PINACA and AB-CHMINACA pursuant to 21 U.S.C. 811(b). Upon receipt of the scientific and medical evaluations and scheduling recommendations from the HHS dated November 14, 2016, the DEA reviewed the documents and all other relevant data and conducted its own eight-factor analysis of the abuse potential of THJ-2201, AB-PINACA and AB-CHMINACA pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its proposed scheduling action. Please note that both the DEA 8-Factor and HHS 8-Factor analyses and the Assistant Secretary's November 14, 2016, letter, are available in their entirety under the tab "Supporting Documents" of the public docket of this action at <http://www.regulations.gov>, under Docket Number "DEA-402."

1. *The Drug's Actual or Relative Potential for Abuse:* The term "abuse" is not defined in the CSA. However, the legislative history of the CSA suggests that the DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse:<sup>2</sup>

(a) *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or*

(b) *There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or*

(c) *Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*

(d) *The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

Through epidemiological and case report data, HHS has demonstrated that the ingestion of AB-CHMINACA, AB-PINACA and/or THJ-2201 in sufficient amounts is creating a hazard to the health and safety of both the individual users and others within the community. Adverse effects observed following the ingestion of synthetic cannabinoids (SCs), including AB-CHMINACA, AB-PINACA and THJ-2201, include nausea and vomiting, shortness of breath or depressed breathing, hypertension, tachycardia, chest pain, muscle twitching, acute renal failure, anxiety, agitation, psychosis, suicidal ideation, and cognitive impairment. The HHS also stated that SCs like AB-CHMINACA, AB-PINACA and THJ-2201 are easily accessible and difficult to detect in standard urine drug screens, which contributes to their popularity and high rates of abuse.

The American Association of Poison Control Centers (AAPCC) reported 7,779 calls to poison centers about exposures to SCs from January 1, 2015 through December 31, 2015. This number is significantly higher than the number of calls in all of 2014 (3,682), or all of 2013 (2,668). In 2015, there was a notable increase in calls during April (1,512) and May (1,205), falling to a stable, but higher baseline for the rest of the year: A seasonal pattern not seen in previous years. In 2016, the numbers of exposure calls (2,695) have dropped again, mirroring those of 2013 (2,668).

Although the AAPCC does not identify specific cannabinoid substances, their data do support the high prevalence of toxic exposures to SCs in general. In 2015, at least 15 calls to Poison Centers regarding SCs exposures were associated with deaths, which is triple the 5 deaths associated with such calls for all of 2014.

The HHS stated that there are no FDA-approved drug products containing AB-CHMINACA, AB-PINACA and THJ-2201 in the United States and there appear to be no legitimate sources for these substances as marketed drugs. Therefore, this criterion for assessing the abuse potential of these SCs is not applicable. According to the HHS, because AB-CHMINACA, AB-PINACA and THJ-2201 are not approved for medical use and are not formulated or available for clinical use, the human use of these substances is assumed to be on an individual's own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer drugs. Further, published scientific and medical literature, and reports from AAPCC and law enforcement, indicate that individuals are taking these SCs on their own initiative, rather than on the basis of medical advice of a licensed practitioner. As noted by the HHS, pharmacological studies sponsored by the National Institute on Drug Abuse (NIDA) have demonstrated that AB-CHMINACA, AB-PINACA and THJ-2201 are similar to other schedule I SCs. All three of these substances, similar to schedule I SCs, display high affinity binding and potent agonist functional activity at the cannabinoid (CB1) receptor, while drug discrimination studies have demonstrated the ability of all three substances to substitute for  $\Delta^9$ -tetrahydrocannabinol ( $\Delta^9$ -THC) (see factor 2). The HHS stated in their review that AB-CHMINACA, AB-PINACA and THJ-2201 are markedly more potent at CB1 receptors than the natural phytocannabinoids (cannabinoids that occur naturally in the cannabis plant, *i.e.*  $\Delta^9$ -THC).

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* In vitro receptor binding and functional assays were conducted with AB-CHMINACA, AB-PINACA and THJ-2201. In addition, drug discrimination assays using Sprague Dawley rats were performed to identify drugs with similar subjective effects to  $\Delta^9$ -THC. The tetrad assay was also conducted for AB-CHMINACA and AB-PINACA. These results indicate that AB-CHMINACA, AB-PINACA and THJ-2201, similar to other schedule I SCs, bind to CB1

<sup>2</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.A.N. 4566, 4603.

receptors with high affinity and act as agonists at CB1 receptors.

Based on results from the receptor binding (Ki), CB1 functional assay, and drug discrimination studies, the HHS concluded that AB-CHMINACA, AB-PINACA and THJ-2201 act as full psychoactive cannabinoid agonists with no antagonist activity, and that these three substances are more potent than  $\Delta^9$ -THC (schedule I), and are similar in activity to JWH-018, AM2201, ADB-PINACA, and AB-FUBINACA (schedule I). As stated by the HHS, these data indicate that AB-CHMINACA, AB-PINACA and THJ-2201 are more potent at producing behavioral pharmacological effects that are recognizable as those produced by the schedule I cannabinoid  $\Delta^9$ -THC.

**3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance:** The DEA is not aware of any currently accepted medical uses for AB-CHMINACA, AB-PINACA and THJ-2201. A letter dated September 17, 2014 was sent from the DEA Deputy Administrator to the Acting Assistant Secretary for Health, of the Department for Health and Human Services as notification of intent to temporarily place these three substances in schedule I and solicited comments, including whether an exemption or approval was in effect for the substances in question under the Federal Food, Drug and Cosmetic Act. The Acting Assistant Secretary of Health responded that there were no current INDs or NDAs for these synthetic cannabinoids in a letter to the DEA Deputy Administrator dated September 30, 2014. The HHS in its scientific and medical evaluation and scheduling recommendation dated November 14, 2016 reiterated that these three SCs are not the subjects of any approved new drug applications (NDAs) or investigational new drug applications (INDs); are not currently marketed as approved drug products; and have no accepted medical uses in the United States.

**4. Its History and Current Pattern of Abuse:** Synthetic cannabinoids intended for illicit use were first encountered in the United States in November 2008 during seizure and analysis by the United States Customs and Border Protection (CBP) of a shipment of "Spice" in Dayton, Ohio. The popularity of these cannabinoids and their associated products has increased since January 2010 in the United States as evidenced by the increasing number of seizures and public health and media reports. The HHS noted that SC abuse has been repeatedly noted in athletes, military personnel, employees who undergo frequent drug testing, and other

individuals seeking intoxication while hoping to evade detection. AB-CHMINACA, AB-PINACA and THJ-2201 are another generation of SCs encountered by law enforcement. These substances and their products are commonly marketed as "legal highs" 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.

Most users of SCs abuse these substances by smoking the product following application to plant material. Recently, law enforcement has also been encountering new variations of SCs in liquid form. The liquids contain one or more SC(s), including AB-CHMINACA and AB-PINACA, as well as previously controlled substances including AB-FUBINACA and XLR11. Users have been identified as 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). As reported by users, specifically adolescents, this method of vaporizing and inhaling SCs is viewed as being safer than traditional smoking (blunt, pipe, cigarette, etc.). In a recent study, 91% of SC users reported inhalation of the product via a cigarette or blunt, 27% of the respondents also reported using methods that included vaporization, water pipe, bong, or hookah as a delivery method.

**5. The Scope, Duration, and Significance of Abuse:** AB-CHMINACA, AB-PINACA and THJ-2201 are SCs that have pharmacological effects similar to the schedule I hallucinogen  $\Delta^9$ -THC. Poison control centers continue to report toxic exposures to SCs and their associated products. These substances remain a threat to both the short- and long-term public health and safety. THJ-2201 was first reported in September 2013 while AB-CHMINACA was first reported in February of 2014. AB-PINACA was encountered on the illicit drug market as early as March 2013. From December 2013 through May 2015, CBP reported select encounters of these substances with most shipments originating in China and intended for destinations within the United States: AB-CHMINACA—50 seizures involving 56.29 kg; AB-PINACA—11 seizures involving 15 kg; THJ-2201—6 seizures involving 5.5 kg. The DEA has reported multiple encounters of large quantities

of AB-CHMINACA, AB-PINACA and THJ-2201 that have been confirmed by forensic laboratories.

**6. What, if Any, Risk There is to the Public Health:** Clinical symptoms as reported from overdoses with AB-CHMINACA and AB-PINACA in particular have included excited delirium, seizure, coma, agitation, myocardial infarction, convulsions, difficulty breathing, and an altered state of consciousness. The HHS reported that despite the increasing public recognition of the harms of SCs, multiple groups, including athletes, military personnel, employees who undergo frequent drug testing, and individuals seeking intoxication, continue to abuse these substances while hoping to evade detection.

Since abusers obtain these drugs through unknown sources, the purity of these drugs is uncertain, thus posing significant adverse health risks to these users. From October 2013 through the present, multiple deaths and severe overdoses have occurred involving AB-CHMINACA, AB-PINACA and/or THJ-2201.

**7. Its Psychic or Physiological Dependence Liability:** As stated by the HHS, AB-CHMINACA, AB-PINACA and THJ-2201 have pharmacological profiles that are similar to other schedule I SCs. Although there are no clinical studies evaluating dependence liabilities specific for AB-CHMINACA, AB-PINACA and THJ-2201, the pharmacological profiles of these substances strongly suggest that they possess dependence liabilities that are qualitatively similar to, and potentially stronger than  $\Delta^9$ -THC (schedule I) or marijuana (schedule I) and likely to be similar to other schedule I synthetic cannabinoids such as, JWH-018.

**8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:** AB-CHMINACA, AB-PINACA and THJ-2201 are not immediate precursors of any controlled substance of the CSA.

**Conclusion:** After considering the scientific and medical evaluation conducted by the HHS, the HHS's recommendation, and the DEA's own eight-factor analysis, the DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of AB-CHMINACA, AB-PINACA and THJ-2201. As such, the DEA hereby proposes to schedule AB-CHMINACA, AB-PINACA and THJ-2201 as controlled substances under the CSA.

#### **Proposed Determination of Appropriate Schedule**

The CSA establishes five schedules of controlled substances known as

schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. AB-CHMINACA, AB-PINACA and THJ-2201 have a high potential for abuse that is comparable to other schedule I substances such as delta 9-tetrahydrocannabinol ( $\Delta^9$ -THC) and JWH-018;

2. AB-CHMINACA, AB-PINACA and THJ-2201 have no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of AB-CHMINACA, AB-PINACA and THJ-2201 under medical supervision.

Based on these findings, the Administrator of the DEA concludes that N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA) and [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

#### Requirements for Handling AB-CHMINACA, AB-PINACA and THJ-2201

If this rule is finalized as proposed, AB-CHMINACA, AB-PINACA and THJ-2201 would continue<sup>3</sup> to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, of schedule I substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) AB-CHMINACA, AB-PINACA or THJ-2201, or who desires to handle AB-CHMINACA, AB-PINACA or THJ-2201, would continue to be required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822,

823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* AB-CHMINACA, AB-PINACA or THJ-2201 would continue to be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823 and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of AB-CHMINACA, AB-PINACA or THJ-2201 would continue to need to be in compliance with 21 U.S.C. 825 and 958(e), and continue to be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers would continue to be permitted to manufacture AB-CHMINACA, AB-PINACA or THJ-2201 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person who becomes registered with the DEA on or after the effective date of the final rule must take an initial inventory of all stocks of controlled substances (including AB-CHMINACA, AB-PINACA and THJ-2201) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including AB-CHMINACA, AB-PINACA and THJ-2201) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant would continue to be required to maintain records and submit reports with respect to AB-CHMINACA, AB-PINACA and/or THJ-2201 pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes AB-CHMINACA, AB-PINACA or THJ-2201 would continue to be required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of AB-CHMINACA, AB-PINACA or THJ-2201 would continue to need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving AB-CHMINACA, AB-PINACA or THJ-2201 not authorized by, or in violation of, the CSA or its implementing regulations would continue to be

unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

#### Regulatory Analyses

##### *Executive Orders 12866 and 13563*

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

##### *Executive Order 12988*

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

##### *Executive Order 13132*

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

##### *Executive Order 13175*

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

##### *Regulatory Flexibility Act*

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On January 30, 2015, the DEA published a final order to temporarily place these three SCs into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA estimates that all entities handling or

<sup>3</sup> AB-CHMINACA, AB-PINACA and THJ-2201 are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 80 FR 5042, Jan. 30, 2015.

planning to handle AB-CHMINACA, AB-PINACA or THJ-2201 have already established and implemented the systems and processes required to handle AB-CHMINACA, AB-PINACA or THJ-2201. There are currently 25 registrations authorized to handle AB-CHMINACA, AB-PINACA and/or THJ-2201 specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 25 registrations represent 18 entities, of which 8 are small entities. Therefore, the DEA estimates eight small entities are affected by this proposed rule.

A review of the 25 registrations indicates that all entities that currently handle AB-CHMINACA, AB-PINACA or THJ-2201 also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle AB-CHMINACA, AB-PINACA or THJ-2201. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the eight affected small entities.

Therefore, the DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, the DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year \* \* \*." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Paperwork Reduction Act of 1995*

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of

information unless it displays a currently valid OMB control number.

**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:

**PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

- 2. In § 1308.11,
  - a. Add new paragraphs (d)(59) through (61); and
  - b. Remove paragraphs (h)(11) through (13); and
  - c. Redesignate paragraphs (h)(14) through (19) as (h)(11) through (16);
 The additions to read as follows:

**§ 1308.11 Schedule I.**  
 \* \* \* \* \*  
 (d) \* \* \*

(59) <i>N</i> -(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide (AB-CHMINACA) .....	(7031)
(60) <i>N</i> -(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (AB-PINACA) .....	(7023)
(61) [1-(5-fluoropentyl)-1 <i>H</i> -indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201) .....	(7024)

\* \* \* \* \*

Dated: January 17, 2017.  
**Chuck Rosenberg,**  
*Acting Administrator.*  
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