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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: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule three synthetic cannabinoids (SCs) into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). The substances are: (1) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide ("AB-CHMINACA"); (2) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide ("AB-PINACA"); and (3) [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone ("THJ-2201"). This action is based on a finding by the Administrator that the placement of these synthetic cannabinoids and their optical, positional, and geometric isomers, salts, and salts of isomers into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on

persons who handle (manufacture, distribute, import, export, engage in research, or possess), or propose to handle these SCs.

DATES: This final order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

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. 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, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use, 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.

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 an 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 his authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the DEA to notify the Department of Health and Human Services (HHS) of the intent to temporarily place a substance into schedule I of the CSA.[1] The DEA transmitted notice of the intent to place

[1] 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 Final Order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth 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

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.

The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). AB-CHMINACA, AB-PINACA, and THJ-2201 are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for AB-CHMINACA, AB-PINACA, or THJ-2201 under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the scheduling of AB-CHMINACA, AB-PINACA, and THJ-2201 in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule these three synthetic cannabinoids (SCs) was published in the *Federal Register* on December 19, 2014. 79 FR 75767.

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 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

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Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

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 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 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. Forensic analyses by the DEA and other Federal, State, and local laboratories have identified multiple variations in both the type and amount of SCs 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 manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. The powder form of SCs is 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 while the user remains unaware of the package's exact contents.

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, and 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 in treatment in the United States 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* under docket number DEA-402.

Factor 4. History and Current Pattern of Abuse

SCs were initially developed over the last 30 years as part of research efforts to investigate the cannabinoid system. SCs intended for illicit use were first reported in the United States in a November 2008 encounter, when a shipment of "Spice" was seized and analyzed by CBP in Dayton, Ohio, and later identified as containing JWH-018. At approximately the same time, in December 2008, JWH-018 and cannabicyclohexanol (CP-47,497 C8 homologue) were identified by German forensic laboratories. Since then,

many other SCs have been found applied on plant material and encountered as drug products. Beginning in January 2010, the popularity of these cannabinoids and their associated products appears to have increased in the United States as evidenced by seizure exhibits and public health and media reports.

Numerous SCs have previously been identified as product adulterants, and law enforcement officials have seized bulk amounts of these substances.[2] 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 UR-144, XLR11, AKB48, PB-22, 5F-PB-22, AB-FUBINACA, ADB-PINACA, and numerous others that vary only slightly in 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 into 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 SCs, 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.

Recently, another generation of SCs including AB-CHMINACA, AB-PINACA, and THJ-2201 has been encountered. AB-CHMINACA, AB-PINACA, and THJ-2201 are not included among the 15 SCs that are specifically controlled under FDASIA, and do not fall under the definition of "cannabimimetic agents" as provided under FDASIA.

[2] While seizure evidence is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

Furthermore, as detailed in reports, law enforcement and public health officials are encountering the abuse of these substances and products laced with these substances, which are commonly marketed under the guise of being a "legal high" with a disclaimer that the products are "not for human consumption."

As with the older generation of SCs, the major concern of public health officials and medical professionals regarding these new products is the targeting and direct marketing toward 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, media reports indicate that all age groups abuse these substances and related products. Additionally, 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 using 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 with 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 therefore 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 undertaken by the DEA 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, the number of AAPCC exposure reports has begun to increase, demonstrating 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 (when there were 459). As of November 30, 2014, the AAPCC has received approximately 3,359 calls involving exposure to SCs for 2014.

The following information details information obtained through STRIDE[3] and NFLIS,[4] including the number of exhibits/reports, dates of first encounter, and locations of those encounters where available:[5]

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[3] 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. STRIDE was last queried on October 1, 2014. Note that reporting via STRIDE ceased on September 30, 2014.

[4] 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. NFLIS was last queried on November 25, 2014.

[5] *Supra* note 2.

For AB-CHMINACA, STRIDE contained 21 exhibits, with the first encounter in March 2014. NFLIS contained 586 reports, with the first encounter in February 2014, and locations of all encounters spanning Arkansas, Arizona, California, Colorado, Georgia, Iowa, Indiana, Kansas, Kentucky, Louisiana, Missouri, North Dakota, New Jersey, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, and Wisconsin.

For AB-PINACA, STRIDE contained 245 exhibits, with the first encounter in June 2013. NFLIS contained 3,783 reports, with the first encounter in March 2013, and locations of all encounters spanning 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.

For THJ-2201, STRIDE contained 65 exhibits, with the first encounter in September 2013. NFLIS contained 220 reports, with the first encounter in January 2014, and locations of all encounters spanning 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

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

and intended for destinations within the United States. Specifically, there were 17 seizures of AB-CHMINACA involving 15.825 kilograms total; 4 seizures of AB-PINACA 6 kilograms total; and 6 seizures of THJ-2201 involving 5.5 kilograms total (see Three Factor Analysis). Additionally, 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 September 2014, multiple deaths and severe overdoses occurred involving AB-CHMINACA and AB-PINACA. Adverse effects reported from these incidences have included: 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. Because the three SCs share pharmacological similarities with schedule I substances such as Δ9-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. Furthermore, despite being encountered on the illicit drug market and having no accepted medical use in treatment within the United States, these products continue to be easily available and abused across age groups.

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

Based on the data and information summarized above, the continued uncontrolled manufacturing, distribution, importation, exportation, and abuse of AB-CHMINACA, AB-PINACA, and THJ-2201 pose an imminent hazard to the public safety. Furthermore, 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 under 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 DEA, 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

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily place three synthetic cannabinoids, AB-CHMINACA, AB-PINACA, and THJ-2201 into schedule I of the CSA, and hereby

finds that placement of these synthetic cannabinoids into schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into schedule I to avoid an imminent hazard to the public safety, the 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).

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).

Requirements for Handling

Upon the effective date of this final order, AB-CHMINACA, AB-PINACA, and THJ-2201 are subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities with, or possesses), or desires to handle, AB-CHMINACA, AB-PINACA, or THJ-2201, must 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 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles AB-CHMINACA, AB-PINACA, or THJ-2201, and is not registered with the DEA, must submit an application for registration and may not continue to handle AB-CHMINACA, AB-PINACA, or THJ-2201 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA.

2. *Security*. AB-CHMINACA, AB-PINACA, and THJ-2201are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71-1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

3. *Labeling and Packaging*. All labels, labeling, and packaging for commercial containers of AB-CHMINACA, AB-PINACA, and THJ-2201 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

4. *Inventory*. Every DEA registrant who possesses any quantity of AB-CHMINACA, AB-PINACA, or THJ-2201on the effective date of this order, must take an inventory of all stocks of these substances on hand as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d). Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements.

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

5. *Records*. All DEA registrants must maintain records with respect to AB-CHMINACA, AB-PINACA, or THJ-2201 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1307, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants authorized to handle AB-CHMINACA, AB-PINACA, or THJ-2201 shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

6. *Reports*. All DEA registrants who manufacture or distribute AB-CHMINACA, AB-PINACA, or THJ-2201must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304, 1307, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

7. *Order Forms*. All registrants who distribute AB-CHMINACA, AB-PINACA, or THJ-2201must comply with order form requirements pursuant to 21 U.S.C. 828 and in

accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Importation and Exportation*. All importation and exportation of AB-CHMINACA, AB-PINACA, or THJ-2201must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Quota.* Only registered manufacturers may 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.

10. *Liability*. Any activity involving AB-CHMINACA, AB-PINACA, or THJ-2201 not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

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).

Inasmuch 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 temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the 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. Further, the DEA believes that this temporary scheduling action final order 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 (RFA). 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 (OMB).

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.

Pursuant to section 808(2) of the Congressional Review Act (CRA), "any rule for which an agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances into schedule I because they pose an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order shall take effect immediately upon its publication.

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 amends 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. Amend § 1308.11, by adding 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: January 23, 2015

Michele M. Leonhart,
Administrator.

[FR Doc. 2015-01776 Filed 01/29/2015 at 8:45 am; Publication Date: 01/30/2015]