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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: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places *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 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. This rule continues the imposition of 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: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (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 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 his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a).

This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the DEA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of the HHS and an evaluation of all relevant data by the DEA. This action continues the imposition of 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 *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) 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 was effective on the date of publication, and 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). Section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), requires that the

¹ 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 Department of Health and Human Services (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.

temporary control of these substances expire two years from the issuance date of the scheduling order, on or before January 29, 2017. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling of that substance could be extended for up to one year. Accordingly, on January 27, 2017, the DEA extended the temporary scheduling of AB-CHMINACA, AB-PINACA and THJ-2201 by one year, or until January 29, 2018. 82 FR 8590. Also, on January 27, 2017, the DEA published a notice of proposed rulemaking (NPRM) to permanently control AB-CHMINACA, AB-PINACA and THJ-2201 in schedule I of the CSA. 82 FR 8593. Specifically, DEA proposed to add these three synthetic cannabinoids to 21 CFR 1308.11(d), hallucinogenic substances.

DEA and HHS Eight Factor Analyses

On November 14, 2016, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled “Basis for the Recommendation to Place [1-(5-Fluoropentyl)-1H-Indazol-3-yl] (Naphthalen-1-yl) Methanone (THJ-2201), N-[(2S)-1-Amino-3-Methyl-1-Oxo-2-Butanyl]-1-Pentyl-1H-Indazole-3-Carboxamide (AB-PINACA), and N-[(2S)-1-Amino-3-Methyl-1-Oxo-2-Butanyl]-1-(Cyclohexylmethyl)-1H-Indazole-3-Carboxamide (AB-CHMINACA) and their Salts in Schedule I of the Controlled Substances Act.” After considering the eight factors in 21 U.S.C. 811(c), and also considering each substance’s abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary of the HHS recommended that AB-CHMINACA, AB-PINACA and THJ-2201 be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of

AB-CHMINACA, AB-PINACA and THJ-2201. The DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA-402 / DEA-2017-0001) at <http://www.regulations.gov> under “Supporting Documents.”

Determination to Schedule AB-CHMINACA, AB-PINACA and THJ-2201

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendations from the HHS, the DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of AB-CHMINACA, AB-PINACA and THJ-2201 into Schedule I,” proposing to control AB-CHMINACA, AB-PINACA and THJ-2201, and their salts, isomers, and salts of isomers in schedule I of the CSA. 82 FR 8593, January 27, 2017. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before February 27, 2017. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before February 27, 2017.

Comments Received

The DEA received five comments on the proposed rule to control AB-CHMINACA, AB-PINACA and THJ-2201 in schedule I of the CSA.

Support for rulemaking: Five commenters gave support for the rulemaking stating in unison that these substances have no medical use and are a danger to the community.

DEA Response: The DEA appreciates the comments in support of this rulemaking.

Scheduling Conclusion

After consideration of the relevant matter presented as a result of public comments, the scientific and medical evaluations and accompanying recommendation of the HHS,

and after its own eight-factor evaluation, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of AB-CHMINACA, AB-PINACA and THJ-2201. As such, the DEA is permanently scheduling AB-CHMINACA, AB-PINACA and THJ-2201 as controlled substances under the CSA.

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 analyses and recommendations 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) *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) have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9 -THC) and JWH-018;

(2) *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) have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of *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) 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)-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, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

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

AB-CHMINACA, AB-PINACA and THJ-2201 will continue² to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, 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), or who 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.

² AB-CHMINACA, AB-PINACA or 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.

2. *Security.* AB-CHMINACA, AB-PINACA or THJ-2201 are 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 through 1301.93.

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

4. *Quota.* Only registered manufacturers are 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.* Every DEA registrant who possesses any quantity of AB-CHMINACA, AB-PINACA and THJ-2201 on the effective date of this final rule, must take an inventory of all stocks of these substances on hand as of [INSERT DATE OF PUBLICATION IN THE 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 a new 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.

6. *Records and Reports.* Every DEA registrant must 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 must continue 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 must continue 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 is unlawful, and may 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 final 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 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 rulemaking does not have federalism implications warranting the application of Executive Order 13132. The 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 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 final 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 substances 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 planning to handle these substances 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 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 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 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: “an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

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, 21 CFR part 1308 is amended 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,

- a. Add paragraphs (d)(69) through (71);
- b. Remove paragraphs (h)(1) through (3); and
- c. Redesignate paragraphs (h)(4) through (17) as (h)(1) through (14).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(69) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA).....(7031)

(70) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA).....(7023)

(71) [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201).....(7024)

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Dated: October 6, 2017

Robert Patterson,

Acting Administrator.

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