

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-421N]

Schedules of Controlled Substances: Temporary Placement of the Synthetic Cannabinoid MAB-CHMINACA Into Schedule I**AGENCY:** Drug Enforcement Administration, Department of Justice.**ACTION:** Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule the synthetic cannabinoid *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (common names, MAB-CHMINACA and ADB-CHMINACA) into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of this synthetic cannabinoid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I controlled substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of this synthetic cannabinoid.

DATES: September 16, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION: Any final order will be published in the **Federal Register** and may not be effective prior to October 16, 2015.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing

regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), 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 ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

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

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 she finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h)(1). 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). The Attorney General has delegated her scheduling 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 Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of the Administrator's intention to temporarily place a substance into schedule I of the CSA.¹

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 notice of intent, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As

The Administrator transmitted notice of intent to place *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (hereinafter referred to as MAB-CHMINACA) into schedule I on a temporary basis to the Assistant Secretary by letter dated May 14, 2015. The Assistant Secretary responded to this notice by letter dated June 3, 2015, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for MAB-CHMINACA. The Assistant Secretary also stated that HHS has no objection to the temporary placement of MAB-CHMINACA into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments. MAB-CHMINACA is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for MAB-CHMINACA under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of MAB-CHMINACA in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety.

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 section 201(c) of the CSA, 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

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

MAB-CHMINACA

Available data and information for MAB-CHMINACA, summarized below,

set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

indicate that this synthetic cannabinoid (SC) has 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. The DEA analysis is available in its entirety under the tab "Supporting and Related Material" of the public docket of this action at www.regulations.gov under Docket Number DEA-421N.

Synthetic Cannabinoids

Synthetic cannabinoids are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed SCs were first introduced on the designer drug market 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. From 2009 to present, misuse of SCs has increased in the United States with law enforcement encounters describing plant material laced with SCs intended for human consumption. It has been demonstrated that the substances and the associated designer products are abused for their psychoactive properties. With many generations of SCs being encountered since 2009, MAB-CHMINACA is one of the latest, and based upon reports from public health and law enforcement, the misuse and abuse of this substance is negatively impacting the public health and communities.

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

MAB-CHMINACA is a SC that has pharmacological effects similar to the schedule I hallucinogen THC and other temporarily and permanently controlled schedule I substances. MAB-CHMINACA has been shown to cause severe toxicity and adverse health effects following ingestion, including seizures, excited delirium, cardiotoxicity and death. With no approved medical use and limited safety or toxicological information, MAB-CHMINACA has emerged on the illicit

drug market and is being abused for its psychoactive properties.

Factor 4. History and Current Pattern of Abuse

SCs have been developed over the last 30 years as tools for investigating the cannabinoid system. SCs were first encountered by CBP within the United States in November 2008. Since then, the popularity of SCs and their associated products has increased steadily as evidenced by law enforcement seizures, public health information, and media reports. Amidst multiple administrative and legislative actions to place SCs found on the illicit market into schedule I of the CSA, new versions of SCs intended to circumvent current law continue to be encountered. MAB-CHMINACA is a SC that was encountered following the hospitalization of 125 individuals around the Baton Rouge, Louisiana area in October 2014 (see factor 6 of supporting materials). Since that time, multiple overdoses and deaths involving MAB-CHMINACA have been reported. For example, overdose clusters attributed to MAB-CHMINACA have been reported in Shreveport, Louisiana; Bryan, Texas; Beaumont, Texas; multiple cities in the State of Mississippi; Hampton, Virginia; and Hagerstown, Maryland (see factor 6 of supporting materials). Specifically, in April 2015, the largest nationwide outbreak involving SCs was reported by multiple news outlets. In addition, State public health entities have collectively reported over 2,000 overdoses and at least 33 deaths across at least 11 States attributed to the misuse of SCs. Of these overdoses and deaths, currently available toxicology results have determined that a number of overdoses from this most recent cluster were connected to ingestion of MAB-CHMINACA (see factor 6 of supporting materials).

On April 29, 2015, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) reported multiple outbreaks of intoxications within the United States resulting from the ingestion of products believed to contain SCs. EMCDDA further reported that MAB-CHMINACA had been implicated in at least some of those cases. EMCDDA also reported on two deaths involving MAB-CHMINACA, one in Hungary and the other in Japan.

A major concern, as reiterated by public health officials and medical professionals, remains the targeting and direct marketing of SCs and SC-containing products to adolescents and youth. This is supported by law enforcement encounters and reports

from emergency departments: however, all age groups have been reported by the media as abusing these substances and related products. Individuals, including minors, are purchasing SCs from the Internet, gas stations, convenience stores, and head shops.

Smoking mixtures of these substances for the purpose of achieving intoxication have resulted in numerous emergency department visits and calls to poison control centers. As reported by the American Association of Poison Control Centers (AAPCC), adverse effects including severe agitation, anxiety, racing heartbeat, high blood pressure, nausea, vomiting, seizures, tremors, intense hallucinations, psychotic episodes, suicide, and other harmful thoughts and/or actions can occur following ingestion of SCs. Presentations at emergency departments directly linked to the abuse of MAB-CHMINACA have resulted in similar symptoms, including severe agitation, seizures and/or death (see factor 6).

As discussed previously, it is believed most abusers of SCs or SC-related products smoke the product following application to plant material. Until recently, this was the preferred route of administration. Law enforcement has also begun to encounter new variations of SCs in liquid form. It is believed abusers have been applying the liquid to hookahs or "e-cigarettes," which allows the user to administer a vaporized liquid that can be inhaled.

Factor 5. Scope, Duration and Significance of Abuse

Following multiple scheduling actions designed to safeguard the public from the adverse effects and safety issues associated with SCs, encounters by law enforcement and health care professionals indicate the continued abuse of these substances and their associated products. With each action to control SCs, drug manufacturers and suppliers are adapting at an alarmingly quick pace to design new SCs that circumvent regulatory controls. Even before DEA temporarily controlled the latest group of SCs, AB-CHMINACA, AB-PINACA, and THJ-2201, on January 30, 2015, MAB-CHMINACA was already available on the illicit market and responsible for overdoses and deaths (see factor 6 of supporting materials). From October 2014 to the present, multiple overdoses and deaths have been attributed to the abuse of MAB-CHMINACA.

On October 29, 2014, the State of Louisiana issued an emergency rule adding N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (MAB-

CHMINACA) to the list of schedule I Controlled Dangerous Substances section of the Louisiana Administrative Code (La. Admin. Code tit. 46, section 2704 (2014)), upon the determination that it had a high potential for abuse and should be scheduled as a controlled substance to avoid an imminent peril to the public health, safety, and welfare.

Poison control centers continue to report the abuse of SCs and their associated products. These substances remain a threat to both the short- and long-term public health and safety. Exposures to SCs were first reported to the AAPCC in 2011. The most alarming report via the AAPCC was published on April 23, 2015. The AAPCC reported a dramatic spike in poison center exposure calls throughout the United States in 2015. The AAPCC reported 1,512 exposure calls in April 2015, representing an almost three-fold increase in exposures to SCs as compared to the previous largest monthly tally (657 exposures in January 2012) since reporting began in 2011. It is likely that many of the calls are directly attributable to the abuse of MAB-CHMINACA based on its high prevalence in drug seizure reports and specimen test reports (see factor 6 and table 3 of supporting materials). Further, exposure calls to the AAPCC from within the first five months of 2015 (January 1 to June 1) are greater than the total exposure calls involving SCs from all of 2014. In addition, a majority of exposure incidents from 2011 to the present resulted in individuals seeking medical attention at health care facilities.

The following information regarding MAB-CHMINACA was obtained through NFLIS² (queried on May 27, 2015):

MAB-CHMINACA: NFLIS-451 reports; first encountered in September 2014; locations include Arkansas, Indiana, Kansas, Louisiana, Missouri, Oklahoma, Texas, Virginia, and Wisconsin.

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

MAB-CHMINACA was identified in a cluster of 125 subjects that presented to emergency facilities within the Baton Rouge and Shreveport, Louisiana areas in October 2014. On October 29, 2014, the Louisiana Secretary of the Department of Health and Hospitals announced the addition of MAB-

CHMINACA into schedule I of the Controlled Dangerous Substances section of the Louisiana Administrative Code (La. Admin. Code tit. 46, section 2704 (2014)). From October 2014 to the present, multiple clusters of overdoses involving MAB-CHMINACA and at least four deaths attributed to the misuse and abuse of MAB-CHMINACA have been reported. (see factor 6 and table 3 of supporting materials). Adverse health effects reported from use of MAB-CHMINACA 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.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. The SCs encountered on the illicit drug market have no accepted medical use within the United States. Regardless, SC products continue to be easily available and abused by diverse populations. Unknown factors including detailed product analysis and dosage variations between various packages and batches present a significant danger to an abusing individual. Designer drug products have been found to vary in the amount and type of SC that plant material is laced with, which could be one explanation for the numerous emergency department admissions that have been connected to these substances. Similar to previous SCs, MAB-CHMINACA has been found on plant material.

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 manufacture, distribution, importation, exportation, and abuse of MAB-CHMINACA poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for MAB-CHMINACA in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for MAB-CHMINACA indicate that this substance has 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 May 14, 2015, notified the Assistant Secretary of the DEA's intention to temporarily this substance in schedule I.

Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule MAB-CHMINACA in schedule I of the CSA, and finds that placement of this SC into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

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

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary

²National 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.

scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

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

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 the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 5 U.S.C. 553, 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.

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

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

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and,

accordingly, this action has not been reviewed by the Office of Management and Budget.

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

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11, add paragraph (h)(25) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(25) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7032 (Other names: MAB—CHMINACA; ADB—CHMINACA)

Dated: September 10, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015-23198 Filed 9-15-15; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-139483-13]

RIN 1545-BL87

Treatment of Certain Transfers of Property to Foreign Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of proposed rulemaking by cross-reference to temporary regulation.

SUMMARY: This document contains proposed regulations relating to certain transfers of property by United States persons to foreign corporations. The proposed regulations affect United States persons that transfer certain property, including foreign goodwill and going concern value, to foreign corporations in nonrecognition transactions described in section 367 of the Internal Revenue Code (Code). The proposed regulations also combine portions of the existing regulations under section 367(a) into a single regulation. In addition, in the Rules and Regulations section of this issue of the **Federal Register**, temporary regulations are being issued under section 482 to clarify the coordination of the transfer pricing rules with other Code provisions. The text of those temporary regulations serves as the text of a portion of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by December 15, 2015.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-139483-13), Internal Revenue Service, Room 5203, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-139483-13), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224; or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-139483-13).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Ryan A. Bowen, (202) 317-6937; concerning submissions of comments or requests for a public hearing, Regina Johnson, (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in the regulations have been submitted for review and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507 (d)) under control number 1545-0026.

The collections of information are in § 1.6038B-1(c)(4) and (d)(1). The collections of information are mandatory. The likely respondents are domestic corporations. Burdens associated with these requirements will