

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

[Docket No. DEA-421]

**Schedules of Controlled Substances: Placement of MAB-CHMINACA 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-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (other names: MAB-CHMINACA; ADB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. If finalized, this action would 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 MAB-CHMINACA.

**DATES:** Comments must be submitted electronically or postmarked on or before March 1, 2018.

Interested persons 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 March 1, 2018.

**ADDRESSES:** Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). 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. To ensure proper handling of comments, please reference "Docket No. DEA-421" 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/ODW, 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 also 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/ODW, 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. 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 the person's interests in the proposed scheduling action, whether the person is adversely affected or aggrieved, and the objections or issues, if any, concerning which the person desires to be heard at a hearing. 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 participation must be sent to the DEA using the address information provided above.

### Legal Authority

The Controlled Substances Act (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);<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 for Health of the HHS (Assistant Secretary) and an evaluation of all other relevant data by the DEA. If finalized, this action would continue<sup>2</sup> 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 MAB-CHMINACA.

### Background

On February 5, 2016, the DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (other names: MAB-CHMINACA; ADB-CHMINACA) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 81 FR 6171. That temporary scheduling order was effective on the date of publication, and was based on findings by the Acting Administrator of the DEA (Acting Administrator) that the temporary scheduling of this synthetic cannabinoid 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 temporary control of this substance expire two

years from the effective date of the scheduling order, which was February 5, 2016. 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. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,<sup>3</sup> or on the petition of any interested party. An extension of the existing temporary order is being ordered by the Acting Administrator in a separate action, and is published elsewhere in this issue of the **Federal Register**.

The Acting Administrator, on his own motion pursuant to 21 U.S.C. 811(a), is initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule MAB-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 this synthetic cannabinoid. On May 18, 2016, the Acting Administrator submitted a request to the Assistant Secretary to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for MAB-CHMINACA, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on January 19, 2018, the Assistant Secretary submitted to the Acting Administrator HHS's scientific and medical evaluations for this substance. Upon receipt of the scientific and medical evaluation and scheduling recommendation 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 MAB-CHMINACA in accordance with 21 U.S.C. 811(c).

### Proposed Determination to Schedule MAB-CHMINACA

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a)(1), to add MAB-CHMINACA permanently to schedule I. The DEA has reviewed the scientific and medical evaluations and scheduling recommendation, received from HHS,

and all other relevant data and conducted its own eight-factor analysis of the abuse potential of MAB-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 January 19, 2018, 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-421."

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>4</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.*

Review of scientific and medical literature indicates that the ingestion of synthetic cannabinoids (SCs) leads to adverse health effects. Specifically, adverse effects following ingestion of MAB-CHMINACA have included: Tachycardia, aggressive or violent behavior, confusion, depressed mental status, severe agitation, psychosis, and death.

<sup>4</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.

<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.

<sup>2</sup> MAB-CHMINACA is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(b). 81 FR 8171, Feb. 5, 2016.

<sup>3</sup> Because the Secretary of HHS has delegated to the Assistant Secretary the authority to make domestic drug scheduling recommendations, for purposes of this proposed rulemaking, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

The American Association of Poison Control Centers (AAPCC) reported 7,779 exposures to SCs from January 1 to December 31, 2015. The significance of this value is based upon reporting of human exposures to SCs since 2011. While 2012–2014 saw a reduction in exposure calls to AAPCC, 2015 records demonstrate resurgence in calls to poison centers regarding SCs. In addition, the largest monthly tally of calls to poison centers ever recorded by AAPCC in reference to SCs occurred in April 2015, with 1,512 calls. Overdose data demonstrated that the largest outbreak from synthetic cannabinoids occurred from March–May, 2015, with MAB–CHMINACA as the primary substance confirmed by forensic toxicological analysis.

In a letter to DEA dated June 3, 2015, the HHS stated that there are no approved new drug applications or investigational new drug applications for MAB–CHMINACA. According to HHS's January 19, 2018, letter, MAB–CHMINACA is not approved for medical use in treatment in the United States and is not formulated or available for clinical use. Therefore the human use of this substance is likely 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, AAPCC reports, published scientific and medical literature, and law enforcement reports indicate that individuals are taking MAB–CHMINACA on their own initiative, rather than on the medical advice of a licensed practitioner.

As noted by the HHS, MAB–CHMINACA, similar to schedule I SCs, displays high affinity binding and potent agonist functional activity at the cannabinoid (CB1) receptor, while drug discrimination studies have demonstrated the ability of this substance to substitute for THC (see factor 2).

*2. Scientific Evidence of the Drug's Pharmacological Effects, if Known:* MAB–CHMINACA is a synthetic cannabinoid that has pharmacological effects similar to the schedule I hallucinogen delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) and other temporarily and permanently controlled schedule I SCs. In vitro receptor binding and functional assays were conducted with MAB–CHMINACA. In addition, drug discrimination assays using Sprague Dawley rats to identify drugs with THC-like similar subjective effects demonstrated that MAB–CHMINACA fully substituted for the discriminative stimulus effects of THC.

Based on results from the receptor binding (Ki), CB1 functional assay, and drug discrimination studies, the HHS concluded that MAB–CHMINACA acts as a full psychoactive cannabinoid agonist with no antagonist activity, and that MAB–CHMINACA is more potent than THC (schedule I), and is similar in activity to JWH–018, AM2201, ADB–PINACA, AB–FUBINACA, and AB–CHMINACA (schedule I). As stated by the HHS, these data indicate that MAB–CHMINACA is more potent than the schedule I cannabinoid THC in producing behavioral pharmacological effects and shares pharmacological effects with other SCs in schedule I, such as JWH–018.

*3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance:*

MAB–CHMINACA shares structural features with a number of schedule I SCs such as AKB48, AB–FUBINACA, ADB–PINACA, and AB–CHMINACA. AKB48, AB–FUBINACA, ADB–PINACA, AB–CHMINACA, and MAB–CHMINACA have the same indazole core structure with substitutions at the 1- and 3-positions of the indazole ring. All five substances are substituted at the 3-position with an amide. MAB–CHMINACA was first reported in the scientific literature in a Pfizer patent (WO/2009/106980) and identified as compound 13. A study conducted by the Department of Veterans Affairs Medical Center (Portland, OR) under the interagency agreement with the DEA indicated that MAB–CHMINACA binds to the CB1 receptor and acts as an agonist at this receptor, similar to results reported in the original Pfizer patent for compound 13 (WO/2009/106980).

The DEA is not aware of any currently accepted medical use in treatment in the United States for MAB–CHMINACA. The Administrator of the DEA sent a letter dated May 14, 2015, to the Assistant Secretary for Health for HHS notifying HHS of DEA's intent to temporarily place MAB–CHMINACA in schedule I and solicited comments, including whether there was an exemption or approval in effect for the substance under the Federal Food, Drug and Cosmetic Act. The Assistant Secretary of Health for the HHS advised the DEA that there are no approved new drug applications or investigational new drug applications for MAB–CHMINACA under section 505 (21 U.S.C. 355) of the Federal Food, Drug, and Cosmetic Act. HHS has no objection regarding the temporary placement of MAB–CHMINACA in schedule 1 of the CSA. In their scheduling recommendation, HHS stated that MAB–CHMINACA is

not approved for medical use, is not formulated or available for clinical use, and that all human self-administration 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.

*4. Its History and Current Pattern of Abuse:* As noted by the HHS, SCs have been developed over the last 30 years as tools for investigating the cannabinoid system. The first encounter of SC's within the United States occurred in November 2008 by the United States Customs and Border Protection. 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 scheduling actions placing SCs found on the illicit market in schedule I of the CSA, new versions of SCs intended to circumvent current controls continue to be encountered. MAB–CHMINACA is a SC that was associated with the hospitalization of 125 individuals around Baton Rouge and Shreveport, Louisiana in October, 2014. Since that time, multiple overdoses and deaths involving MAB–CHMINACA have been reported in Texas (in Bryan and Beaumont), Kansas (in Salina), Mississippi (in Philadelphia and Jackson), Virginia (in Hampton), and in Maryland (in Hagerstown). Specifically, in April 2015 originating in Texas, Mississippi and Alabama, the largest nationwide outbreak involving SCs was reported by multiple news outlets. State public health entities eventually reported over 2,000 overdoses and at least 33 deaths associated with abuse of SCs across at least 11 States between April and May of 2015. Of these overdoses and deaths, toxicology results have determined that a majority of overdoses from the April/May 2015 cluster were due to ingestion of MAB–CHMINACA. 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 the cases. EMCDDA also reported two deaths involving MAB–CHMINACA, one in Hungary and the other in Japan.

*5. The Scope, Duration, and Significance of Abuse:* Following multiple scheduling actions seeking to safeguard the public from the adverse effects associated with SCs, law enforcement and health care professionals continue to encounter novel SCs thereby indicating the

continuing abuse of these substances and their associated products. After each scheduling action of a SC, drug manufacturers and suppliers are adapting at an alarming pace to switch to new SCs to circumvent regulatory controls. Even before temporary control of AB-CHMINACA, AB-PINACA, and THJ-2201 on January 30, 2015, MAB-CHMINACA was available on the illicit market. From 2014 through 2016, multiple overdoses and deaths have been attributed to the abuse of MAB-CHMINACA. From September 2014 to the present, the National Forensic Laboratory Information System (NFLIS) has documented over 1,400 reports involving MAB-CHMINACA across the following states: Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, North Dakota, New Jersey, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, Virginia and Wisconsin.

6. *What, if Any, Risk There is to the Public Health:* MAB-CHMINACA was associated with a cluster of 125 subjects who presented to emergency facilities within the Baton Rouge and Shreveport, Louisiana areas in October 2014. On October 29, 2014, the Secretary of the Louisiana 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 (LAC 46:LIII.2704.A.3). From October 2014 to the present, multiple clusters of overdoses involving MAB-CHMINACA and at least eight deaths attributed to the abuse of MAB-CHMINACA have been reported.

Adverse health effects associated with these incidents involving 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. One case report noted the presence of MAB-CHMINACA within the body fluids and tissue samples of a recently deceased individual. A subsequent case report concluded that synergistic toxicity of MAB-CHMINACA and another SC, 5-fluoro-ADB, led to death.

The abuse of MAB-CHMINACA, a SC with no accepted medical use in treatment in the United States, poses a serious risk to both the abuser and those connected to the abuse. HHS noted that by sharing pharmacological similarities with schedule I substances ( $\Delta^9$ -THC, JWH-018 and other temporarily and permanently controlled schedule I SCs),

SCs pose a risk to the abuser and those connected to the abuse of these dangerous substances.

7. *Its Psychic or Physiological Dependence Liability:* As stated by the HHS, MAB-CHMINACA has a pharmacological profile that is similar to other schedule I SCs. Although there are no clinical studies evaluating dependence liabilities specific for MAB-CHMINACA, the pharmacological profile of this substance strongly suggests that it possesses dependence liabilities that are qualitatively similar to, and potentially stronger than, THC (schedule I) or marijuana (schedule I).

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* MAB-CHMINACA is not an immediate precursor of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

*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 MAB-CHMINACA. As such, the DEA hereby proposes to permanently schedule MAB-CHMINACA as a schedule I controlled substance 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. MAB-CHMINACA has a high potential for abuse;
2. MAB-CHMINACA has no currently accepted medical use in treatment in the United States; and
3. There is a lack of accepted safety for use of MAB-CHMINACA under medical supervision.

Based on these findings, the Administrator of the DEA concludes that *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (other names: MAB-CHMINACA; ADB-CHMINACA) including its 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 MAB-CHMINACA

If this rule is finalized as proposed, MAB-CHMINACA would continue<sup>5</sup> 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, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) MAB-CHMINACA, or who desires to handle MAB-CHMINACA, is 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.* MAB-CHMINACA is subject to schedule I security requirements and must 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 and labeling for commercial containers of MAB-CHMINACA 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 MAB-CHMINACA 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 registered with the DEA to handle MAB-CHMINACA must have an initial inventory of all stocks of controlled substances (including MAB-CHMINACA) 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 MAB-CHMINACA) 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 is required to maintain records and submit reports with respect to MAB-CHMINACA, pursuant to 21 U.S.C. 827 and 958(e), and in

<sup>5</sup> MAB-CHMINACA is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 81 FR 6171, Feb. 5, 2016.

accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes MAB-CHMINACA is 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 MAB-CHMINACA must 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 MAB-CHMINACA not authorized by, or in violation of, the CSA or its implementing regulations is 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.

*Executive Order 13771*

This proposed rule does not meet the definition of an Executive Order 13771 regulatory action, and the repeal and cost offset requirements of Executive Order 13771 have not been triggered. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under Section 3(f) of Executive Order 12866.

*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 February 5, 2016, the DEA published a final order to temporarily place MAB-CHMINACA in 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 this substance have already established and implemented the systems and processes required to handle MAB-CHMINACA. There are currently 16 registrations authorized to handle MAB-CHMINACA specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 16 registrations represent 14 entities, of which 8 are small entities. Therefore, the DEA estimates eight small entities are affected by this proposed rule.

A review of the 16 registrations indicates that all entities that currently handle MAB-CHMINACA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle MAB-CHMINACA. 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 as follows:

**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), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Add paragraph (d)(72); and

■ b. Remove and reserve paragraph (h)(1).

The addition to read as follows:

**§ 1308.11 Schedule I.**

\* \* \* \* \*

(d) \* \* \*

(72) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, (MAB-CHMINACA, ADB-CHMINACA) (7032)

\* \* \* \* \*

Dated: January 24, 2018.

**Robert W. Patterson,**  
*Acting Administrator.*

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