AD is required to be furnished with the aircraft, per 14 CFR 25.1581. Further, operators of the aircraft affected by this AD must operate in accordance with the limitations specified in the AFM, per 14 CFR 91.9.

Figure 1 to paragraph (g) of this AD – *AFM Certificate Limitations*

Engine Appendix - Certificate Limitations (Required by AD 2019-01-01)

ETOPS

For 787-8 airplanes equipped with at least one Rolls Royce Trent 1000-A (including -A/01 and –A/01A), Trent 1000-AE (including –AE/01A), Trent 1000-C (including –C/01 and –C/01A), Trent 1000-CE (including –CE/01A), Trent 1000-D (including –D/01 and –D/01A), Trent 1000-E (including –E/01 and –E/01A), Trent 1000-G (including –G/01 and –G/01A), and Trent 1000-H (including –H/01 and -H/01A) engine that has greater than 1,000 total accumulated engine cycles on the intermediate pressure compressor (IPC) Rotor 1 or Rotor 2 blades

- since new or
- since the replacement of blades in accordance with the instructions of Part B or C in Rolls Royce Non Modification Service Bulletin Trent 1000 72-K132 Original Issue or later authority-approved revision.

The following limitations apply:

- Planned maximum diversion time for single engine driftdown must not exceed 180 minutes, except that a planned maximum diversion time up to 207 minutes is allowed only under the provision of Title 14 Code of Federal Regulations, part 121, Appendix P, Section I, paragraph (h).

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(i) Related Information

For more information about this AD, contact Rebel Nichols, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3556; email: *Rebel.Nichols@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued in Des Moines, Washington, on January 23, 2019.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–00297 Filed 1–28–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–421]

Schedules of Controlled Substances: Placement of MAB-CHMINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (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. This action 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 MAB-CHMINACA.

DATES: Effective January 29, 2019.

FOR FURTHER INFORMATION CONTACT: Regulatory Drafting and Policy Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–8953.

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 (Administrator). 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, and is supported by, *inter alia,* a recommendation from the Acting Assistant Secretary for Health of the HHS (Acting Assistant Secretary) 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 MAB-CHMINACA.

[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.

Background

On February 5, 2016, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the synthetic cannabinoid *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-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 final 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 issuance date of the scheduling order, on or before February 4, 2018. 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 30, 2018, the DEA extended the temporary scheduling of MAB-CHMINACA by one year, or until February 5, 2019. 83 FR 4411. Also, on January 30, 2018, the DEA published a notice of proposed rulemaking (NPRM) to permanently control MAB-CHMINACA in schedule I of the CSA. 83 FR 4406. Specifically, the DEA proposed to add this synthetic cannabinoid to the hallucinogenic substances list under 21 CFR 1308.11(d).

DEA and HHS Eight Factor Analyses

On January 19, 2018, the HHS provided the DEA with a scientific and medical evaluation document prepared by the Food and Drug Administration (FDA) entitled ''Basis for the Recommendation to Place N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (MAB-CHMINACA; ADB-CHMINACA), and its salts, in Schedule I of the Controlled Substances Act.'' After considering the eight factors in 21 U.S.C. 811(c), 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 Acting Assistant Secretary recommended that MAB-CHMINACA be controlled in schedule I of the CSA. In response, the DEA conducted its own eightfactor analysis of MAB-CHMINACA. The DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–421/DEA–2018–0001) at *http://www.regulations.gov* under ''Supporting Documents.''

Determination to Schedule MAB-CHMINACA

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 MAB-CHMINACA into Schedule I.'' This NPRM proposed to control MAB-CHMINACA, and its salts, isomers, and salts of isomers in schedule I of the CSA. 83 FR 4406, January 30, 2018. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before March 1, 2018. 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 proposed rule on or before March 1, 2018.

Comments Received

The DEA received six comments on the proposed rule to control MAB-CHMINACA in schedule I of the CSA.

Not related to rulemaking: Four commenters submitted responses that did not pertain to the rulemaking and were not considered.

DEA's Future Diversion Efforts: One commenter quoted various statements from the proposed rule pertaining to the risk of MAB-CHMINACA to the public health (*i.e.,* information about clusters of overdoses, deaths, and adverse health effects associated with these incidents) and questioned the DEA's future response to stay ahead of synthetic cannabinoid manufacturers who alter the chemical formulation of substances to circumvent current controls.

DEA Response: The DEA continues to monitor various synthetic cannabinoids and has taken additional control actions against new substances as they are encountered. The DEA is continuing to use all available resources to address the

issue of trafficking and abuse of novel psychoactive substances to safeguard the public from hazards associated with these substances.

Dissent for rulemaking: One commenter acknowledged that MAB-CHMINACA has no currently accepted medical use in treatment and there is a lack of accepted safety for its use under medical supervision. However, the commenter believes this does not represent the danger or high abuse potential of the substance, attributed to it by DEA. Rather, the commenter believes MAB-CHMINACA is so similar to tetrahydrocannabinol (THC) that its use is ''a symptom of'' the schedule I controls placed on THC, and questions the reliability of the data that DEA provided—as reported by state public health entities over a two-month period in 2015—to support Factor 4 (Its History and Current Pattern of Abuse). The commenter predicted that use of this drug has likely dropped since 2015 due to ''medicinal THC use'' becoming more acceptable by the general public nationwide, and therefore does not reflect the current abuse potential. Additionally, this commenter expressed concern that placing MAB-CHMINACA in schedule I would prevent medical research.

DEA Response: The DEA does not agree. Both the DEA and HHS analyses documented serious adverse effects including the deaths of individuals following the ingestion of MAB-CHMINACA. Pharmacology studies, overdose reports, law enforcement seizures, and other data collectively demonstrated the hazard to public safety and the dangers associated with this substance. With regard to the commenter's prediction that abuse of MAB-CHMINACA will become secondary due to the notion that THC is becoming more widely accepted, it is important to note that the extent of trafficking and abuse of a given substance at a given time is not typically determined by a sole factor. Complex factors related to the substance's abuse potential, market dynamics such as availability of similar other novel substances, and drug use trends in the drug abuser community are also considered when scheduling a substance. In fact, following temporary control of MAB-CHMINACA, several pharmacologically similar new substances appeared on the illicit market and the DEA has taken control actions on these substances. While MAB-CHMINACA continues to be abused in the United States, law enforcement encounters have decreased, as normally occur following the control of synthetic cannabinoids, including MAB-CHMINACA. As with other dangerous substances, the placement of a drug in schedule I does require additional regulatory controls. The Diversion Control Division's mission is to prevent, detect and investigate the diversion of controlled substances while ensuring an adequate and uninterrupted supply of these substances to meet legitimate medical, commercial and scientific needs. The DEA ensures that adequate security measures and background investigations are conducted for researchers who have legitimate need to conduct research and development with schedule I controlled synthetic drug substances.

Scheduling Conclusion

After consideration of the relevant matter presented as a result of public comments, the scientific and medical evaluations and accompanying recommendation of 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 MAB-CHMINACA. As such, the DEA is permanently scheduling MAB-CHMINACA as a controlled substance 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 and review of all other available data, the Acting Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (MAB-CHMINACA; ADB-CHMINACA) has 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-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (MAB-CHMINACA; ADB-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 *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (MAB-CHMINACA; ADB-CHMINACA) under medical supervision.

Based on these findings, the Acting Administrator concludes that *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (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, warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling MAB-CHMINACA

MAB-CHMINACA will continue [2] 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, MAB-CHMINACA 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. *Security.* MAB-CHMINACA is 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.

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.* Every DEA registrant who possesses any quantity of MAB-CHMINACA on the effective date of this final rule, must take an inventory of all stocks of these substances on hand as of January 29, 2019, 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 MAB-CHMINACA) on hand on a

[2] 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.

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 MAB-CHMINACA 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 MAB-CHMINACA 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 MAB-CHMINACA 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 MAB-CHMINACA 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, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''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.

This final rule does not meet the definition of an Executive Order 13771 regulatory action. 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.

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 Acting Administrator, in accordance with the Regulatory Flexibility Act, 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 February 6, 2016, the DEA published a final order to temporarily place this substance 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 these substances have already established and implemented the systems and processes required to handle MAB-CHMINACA. As of January 2018, there were 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 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 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 the Congressional Review Act (CRA), 5 U.S.C. 804. 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 United States-based enterprises to compete with foreign-based enterprises 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 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, add paragraph (d)(72) and 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)-1*H*-indazole-3-carboxamide (MAB-CHMINACA; ADB-CHMINACA).....(7032)

* * * * *

Dated: January 18, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–00254 Filed 1–28–19; 8:45 am]

BILLING CODE 4410–09–P