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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-472]

Schedules of Controlled Substances: Placement of FUB-AMB in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) places methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA), 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 FUB-AMB.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION:

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)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 DEA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of HHS and an evaluation of all relevant data by 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 FUB-AMB.

Background

On November 3, 2017, DEA published an order in the Federal Register amending 21 CFR 1308.11(h) to temporarily place methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 82 FR 51154. That temporary scheduling order was effective on the date of publication, and was based on findings by the former Acting Administrator of the DEA (Acting Administrator) that the temporary scheduling of FUB-AMB was

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.

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 expires two years from the issuance date of the scheduling order, on or before November 3, 2019. 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 October 30, 2019, DEA extended the temporary scheduling of FUB-AMB by one year, or until November 2, 2020. 84 FR 58045. Also, on October 30, 2019, DEA published a notice of proposed rulemaking (NPRM) to permanently control FUB-AMB in schedule I of the CSA. 84 FR 58090. Specifically, DEA proposed to add FUB-AMB to the hallucinogenic substances list under 21 CFR 1308.11(d).

DEA and HHS Eight Factor Analyses

On September 19, 2019, HHS provided DEA with a scientific and medical evaluation document prepared by the Food and Drug Administration (FDA) entitled “Basis for the Recommendation to Place Methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (FUB-AMB, MMB-FUBINACA, AMB-FUBINACA), and its salts, in schedule I of the CSA.” After considering the eight factors in 21 U.S.C. 811(c), FUB-AMB’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), HHS Assistant Secretary recommended that FUB-AMB be controlled in schedule I of the CSA. In response, DEA conducted its own eight-factor analysis of FUB-AMB and concluded that this substance warrants control in schedule I of the CSA. Both DEA’s and HHS’s eight-factor analyses are available in their entirety in the public docket for this

rule (Docket Number DEA-472) at <http://www.regulations.gov> under “Supporting Documents.”

Determination to Schedule FUB-AMB

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from HHS, DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of FUB-AMB in Schedule I.” This NPRM proposed to control FUB-AMB, and its salts, isomers, and salts of isomers in schedule I of the CSA. 84 FR 58090, October 30, 2019. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before November 29, 2019. No requests for such a hearing were received by DEA. The Notice of Proposed Rulemaking also provided an opportunity for interested persons to submit comments on the proposed rule on or before November 29, 2019.

Comments Received

DEA received four comments on the proposed rule to control FUB-AMB in schedule I of the CSA.

Support for rulemaking: One commenter recognized the dangers and public health risks, and supported the rulemaking to permanently place FUB-AMB in schedule I.

DEA Response: DEA appreciates the comment in support of this rulemaking.

Unrelated to rulemaking: One comment did not pertain to the rulemaking.

Mixed support for rulemaking: One commenter referred to FUB-AMB as a stimulant, and stated that they knew why the situation is being addressed following its abuse. The

commenter stated that there are people that need this substance, and stimulants in general, for their health, but did not go further into details specifically for FUB-AMB.

DEA Response: Contrary to the commenter's statement, FUB-AMB is not a stimulant, and is a synthetic cannabinoid substance. As stated by HHS in its letter dated June 9, 2017 to DEA, there are currently no approved drug applications or active investigational new drug applications for FUB-AMB, and FUB-AMB has not been shown to be safe and effective for any clinical condition. Therefore, FUB-AMB has no accepted medical use for treatment in the United States. Further, since its initial identification in the United States in June 2014, serious adverse effects including deaths have been reported following its use (see eight-factor analysis at Docket Number DEA-472).

Research on Schedule I Controlled Substances: One commenter stated that no drug should be barred from use in academic and clinical research settings. The commenter stated that it is important to study the therapeutic effects and potential benefits of a substance. The commenter further mentioned that placing drugs in schedule I reduces their access and prohibits research. The commenter also suggested decriminalization of all drugs.

DEA response: DEA disagrees with the commenter's statement that schedule I drugs are prohibited from being researched by the scientific community. Placing a substance in schedule I of the CSA does not prohibit research on that substance, including FUB-AMB. The CSA provided the specific administrative process to approve the bonafide research with schedule I drug substances. A schedule I registrant can conduct research with schedule I substances upon receiving appropriate approval from DEA.

With regard to the commenter's statement related to drug policy involving decriminalization of all drugs, this comment is outside the scope of the current scheduling action. DEA's mission is to enforce the controlled substance laws and regulations. The CSA contains specific mandates pertaining to the scheduling of controlled substances. DEA has followed all of those mandates regarding the scheduling of FUB-AMB, including receiving from HHS Assistant Secretary a scientific and medical evaluation, and scheduling recommendation regarding control (21 U.S.C. 811(b)); considering the factors enumerated in 21 U.S.C. 811(c); determining, based on the above, appropriate scheduling for FUB-AMB (21 U.S.C. 812(b)); and conducting a formal rulemaking to schedule FUB-AMB (21 U.S.C. 811(a)). FUB-AMB satisfies the CSA's criteria for placement in schedule I by virtue of its high potential for abuse, the fact that FUB-AMB has no currently accepted medical use in treatment in the United States, and its lack of accepted safety for use of this substance under medical supervision. 21 U.S.C. 812(b)(1).

Additional information about FUB-AMB can be viewed in the public docket for this rule (Docket Number DEA-472) at <http://www.regulations.gov> under "Supporting Documents."

Scheduling Conclusion

After consideration of the relevant matter presented as a result of public comments, the scientific and medical evaluation and the accompanying scheduling recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of FUB-AMB. As such, DEA is permanently scheduling FUB-AMB 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 analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) Methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) 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) Methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) has no currently accepted medical use in treatment in the United States²; and

(3) There is a lack of accepted safety for use of methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) under medical supervision.

² Although there is no evidence suggesting that methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

- i. the drug's chemistry must be known and reproducible;
 - ii. there must be adequate safety studies;
 - iii. there must be adequate and well-controlled studies proving efficacy;
 - iv. the drug must be accepted by qualified experts; and
 - v. the scientific evidence must be widely available.
- 57 FR 10499 (1992).

Based on these findings, the Acting Administrator of DEA concludes that methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA), 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 FUB-AMB

FUB-AMB will continue³ 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, FUB-AMB, must be registered with 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.* FUB-AMB is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.93.
3. *Labeling and Packaging.* All labels and labeling for commercial containers of FUB-AMB must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

³ FUB-AMB is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 82 FR 51154, November 3, 2017.

4. *Quota.* Only registered manufacturers are permitted to manufacture FUB-AMB 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 whose registration currently authorizes handling FUB-AMB and who possesses any quantity of FUB-AMB on the effective date of this final rule must maintain an inventory of all stocks of FUB-AMB on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Any person who becomes registered with DEA on or after the effective date of this final rule must take an initial inventory of all stocks of FUB-AMB on hand 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 FUB-AMB) 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 must maintain records and submit reports with respect to FUB-AMB, 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 FUB-AMB 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 FUB-AMB 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 FUB-AMB 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 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.

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, Civil Justice Reform

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, Federalism

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, Consultation and Coordination With Indian Tribal Governments

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 (RFA)

The Acting Administrator, in accordance with the 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 November 3, 2017, DEA published an order to temporarily place FUB-AMB in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). On October 30, 2019, DEA published a temporary scheduling order extending the temporary scheduling of FUB-AMB for up to one year pursuant to 21 U.S.C. 811(h)(2). Accordingly, all entities that currently handle or plan to handle FUB-AMB have already established and implemented the systems and processes required to handle FUB-AMB. There are currently 22 registrations authorized to handle FUB-AMB specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 22 registrations represent 20 entities, of which 12 are small entities.

Therefore, DEA estimates 12 small entities are affected by this rule.

A review of the 22 registrations indicates that all entities that currently handle FUB-AMB also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle FUB-AMB. Therefore, 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 12 affected small entities. Therefore, 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 (UMRA)

In accordance with the UMRA of 1995, 2 U.S.C. 1501 *et seq.*, 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 annually for inflation) in any 1 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 (CRA)

This rule is not a major rule as defined by the 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, 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:

- a. Add paragraph (d)(79); and
- b. Remove and reserve paragraph (h)(18).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(79) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate,
(FUB-AMB, MMB-FUBINACA, AMB-FUBINACA).....(7021)

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Dated: March 13, 2020

Uttam Dhillon,
Acting Administrator.

[FR Doc. 2020-06176 Filed: 3/27/2020 8:45 am; Publication Date: 3/30/2020]