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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-819]

Specific Listing for 4F-MDMB-BINACA, a Currently Controlled Schedule I Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration is establishing a specific listing and Administration Controlled Substances Code Number (drug code) for 4F-MDMB-BINACA (also known as 4F-MDMB-BUTINACA or methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate) in schedule I of the Controlled Substances Act (CSA). Although 4F-MDMB-BINACA is not specifically listed in schedule I of the CSA with its own unique drug code, it has been controlled in the United States since April 2017 as a positional isomer of 5F-AMB, a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include 4F-MDMB-BINACA.

DATES: Effective June 22, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

4F-MDMB-BINACA Control

4F-MDMB-BINACA (also known as 4F-MDMB-BUTINACA or methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate) is a chemical substance which is structurally related to 5F-AMB (also known as methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-

methylbutanoate). 5F-AMB is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(74). The introductory text to subparagraph (d) provides: (1) A listed substance includes “any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible,” and (2) the term “isomer” includes the optical, position[al], and geometric isomers.

When compared to the chemical structure of 5F-AMB, 4F-MDMB-BINACA meets the statutory definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term “positional isomer” in 21 CFR 1308.11(d). Both 5F-AMB and 4F-MDMB-BINACA possess the same molecular formula and core structure, and have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety between functional groups. Accordingly, under 21 CFR 1308.11(d), 4F-MDMB-BINACA, as a positional isomer of 5F-AMB, has been and continues to be a schedule I controlled substance.¹

The Drug Enforcement Administration’s Authority To Control 4F-MDMB-BINACA

This rule is prompted by a letter dated May 7, 2020, in which the United States government was informed by the Secretary-General of the United Nations that 4F-MDMB-BINACA has been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention). This letter was prompted by a decision at the 63rd Session of the Commission on Narcotic Drugs (CND) in March 2020 to schedule 4F-MDMB-BINACA under Schedule II of the 1971 Convention (CND Dec/63/8). Preceding this decision, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the **Federal Register** with an opportunity to submit domestic information and opportunity to comment on this action, Sept. 10, 2019, 84 FR 47521 and Dec.

¹ 5F-AMB (and its isomers) has been subject to schedule I controls since April 2017, first pursuant to a temporary scheduling order (April 10, 2017, 82 FR 17119) and the subsequent one-year extension of that order (April 8, 2019, 84 FR 13796), and then permanently pursuant to a final rule which continued the imposition of those controls (Jan. 24, 2020, 85 FR 4211).

31, 2019, 84 FR 72370. In both instances, FDA noted that 4F-MDMB-BINACA was already controlled in schedule I of the Controlled Substances Act (CSA) as a positional isomer of 5F-AMB, and the December 2019 notice stated that no additional permanent controls for 4F-MDMB-BINACA under the CSA would be necessary to fulfill United States’ obligations as a party to the 1971 Convention.

As discussed above in this final rule, 4F-MDMB-BINACA—by virtue of being a positional isomer of 5F-AMB—has been controlled in schedule I of the CSA temporarily since April 10, 2017 (82 FR 17119), and permanently since January 24, 2020 (85 FR 4211). Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to 4F-MDMB-BINACA. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of 4F-MDMB-BINACA as a schedule I controlled substance in any way. This action, as an administrative matter, merely establishes a separate, specific listing for 4F-MDMB-BINACA in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for the substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of 4F-MDMB-BINACA, who had previously been granted individual quotas for such purposes under the drug code for 5F-AMB.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. 4F-MDMB-BINACA is currently controlled in schedule I as a positional isomer of 5F-AMB, and 4F-MDMB-BINACA has no currently accepted medical use in treatment to

qualify for placement in a schedule other than schedule I (see 21 U.S.C. 812(b)(2)–(5)).

Pursuant to 5 U.S.C. 553(b)(3)(B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing 4F-MDMB-BINACA and its DEA controlled substances code number in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of this drug as a schedule I controlled substance, but instead is “a minor or merely technical amendment in which the public is not particularly interested.” *National Nutritional Foods Ass’n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79–752, at 200 (1945)). See also *Utility Solid Waste Activities Group v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001) (the “unnecessary” prong “is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public”) (int. quotations and citation omitted). This rule is a “technical amendment” to 21 CFR 1308.11(d) as it is “insignificant in nature and impact, and inconsequential to the industry and public.” Therefore, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because 4F-MDMB-BINACA is already subject to domestic control under schedule I as a positional isomer of 5F-AMB and no additional requirements are being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of 4F-MDMB-BINACA. 4F-MDMB-BINACA is currently controlled as a schedule I controlled substance, and this level of control does not change with this rulemaking.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This rule is not a

significant regulatory action under E.O. 12866. 4F-MDMB-BINACA already is a controlled substance in the United States under schedule I, as it is a positional isomer of a schedule I hallucinogen, 5F-AMB. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list 4F-MDMB-BINACA in schedule I and to assign the DEA controlled substances code number 7043 to the substance. A separate listing for 4F-MDMB-BINACA and its DEA controlled substances code number will not alter the status of 4F-MDMB-BINACA as a schedule I controlled substance. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, 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 E.O. 13132. The rule does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from

notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement 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.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined 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.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this 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, DEA amends 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), 956(b), unless otherwise noted.

- 2. Amend § 1308.11 by adding paragraph (d)(87) to read as follows:

§ 1308.11 Schedule I.
* * * * *
(d) * * *

(87) methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (4F-MDMB-BINACA, 4F-MDMB-BUTINACA)

* * * * *

D. Christopher Evans,
Acting Administrator.

[FR Doc. 2021-13040 Filed 6-21-21; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2021-0401]

Safety Zone; Southern California Annual Fireworks for the San Diego Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Sea World Fireworks for nightly shows from Memorial Day to Labor Day in 2021, to provide for the safety of life on navigable waterways during this event. Our regulation for the Southern California annual fireworks for the San Diego Captain of the Port Zone identifies the regulated area for the events. During the enforcement period, no spectators shall anchor, block, loiter in, or impede the transit of official patrol vessels in the regulated area without the approval of the Captain of the Port, or his designated representative.

DATES: The regulations 33 CFR 165.1123 will be enforced for the location identified in Item 7 of Table 1 to § 165.1123 from 8:30 p.m. until 10 p.m., each day without actual notice from June 22, 2021 through September 6, 2021. For the purposes of enforcement, actual notice will be used from June 15, 2021 until June 22, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619-278-7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the regulations in 33 CFR 165.1123 for a safety zone for the Sea World Fireworks on the waters of Mission Bay, CA in § 165.1123, Table 1, Item 7 of that section, from 8:30 p.m. until 10 p.m. on specific evenings from Memorial Day to Labor Day in 2021. This action is being taken to provide for the safety of life on navigable waterways during the fireworks events. Our

regulation for Southern California annual fireworks events for the San Diego Captain of the Port Zone identifies the regulated area for the events. Under the provisions of § 165.1123, a vessel may not enter the regulated area, unless it receives permission from the Captain of the Port, or his designated representative. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or Local law enforcement agencies in enforcing this regulation.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners.

Dated: June 15, 2021.

T.J. Barelli,

Captain, U. S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2021-13022 Filed 6-21-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0435]

RIN 1625-AA00

Safety Zone; Northeast Shelter Island Closure, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone covering the channel closure for the Northeast Shelter Island Channel Entrance. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the California Department of Fish and Wildlife (CDFW) Oil Spill Prevention and Response (OSPR) Sensitive Site Strategy Evaluation Program (SSSEP) boom deployment exercise. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector San Diego.

DATES: This rule is effective from 8:30 a.m. until 10:30 a.m. on June 22, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0435 in the "SEARCH" box and click

"SEARCH." Click on Open Docket Folder on the line associate with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, Coast Guard; telephone 619-278-7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because NPRM would be impracticable. The Coast Guard did not receive the details of the Sensitive Site Strategy Evaluation Program boom deployment exercise with enough time to solicit and respond to public comments on an NPRM. As such, the channel closure on June 22, 2021 would occur before an NPRM and final rule could be issued.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest, because action is necessary to protect personnel, vessels, and the marine environment from the dangers associated with the CDFW OSPR SSSEP boom deployment exercise on June 22, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector San Diego (COTP) has determined that potential hazards associated with the CDFW OSPR SSSEP boom deployment exercise will be a safety concern to anyone