DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1308
[Docket No. DEA–479]

Schedules of Controlled Substances: Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: By this rule, the Drug Enforcement Administration permanently places five synthetic cannabinoids, as identified in this final rule, in schedule I of the Controlled Substances Act (CSA). This action results in the permanent control of five synthetic cannabinoids (SCs) in Schedule I—NM2201 or CBL2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. The CSA provides that issuing, amending, or repealing 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); or (3) on the petition of any interested party. 21 U.S.C. 811(a). The Attorney General initiated this action on his 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 (Assistant Secretary) and an evaluation of all relevant data by DEA. The regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities or chemical analysis, or possess) or propose to handle these five specified controlled substances will continue to apply.


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

SUPPLEMENTARY INFORMATION: In this final rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following five controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible:

- 1-(4-cyano-3-methyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: NM2201 or CBL2201)
- 5-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropropyl)-1H-indole-3-carboxylate (other names: 4-CN-CUMYL-BUTINACA, 4-cyano-CUMYL-BUTINACA, 4-CN-CUMYL BINACA, CUMYL-4CN-BINACA, or SGT-78)
- methyl 2-((cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (other names: MMB-CHMICA or AMB-CHMICA, and 1-(5-fluoropropyl)-N-(2-pyrrol-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (other name: 5F-CUMYL-P7AICA)
- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropropyl)-1H-indole-3-carboxamide (other name: 5F-AB-PINACA)
- 1-(4-cyano-3-methyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: NM2201 or CBL2201), 5F-CUMYL-BUTINACA, 4-CN-CUMYL-BINACA, CUMYL-4CN-BINACA or SGT-78; methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (other names: MMB-CHMICA or AMB-CHMICA, and 1-(5-fluoropropyl)-N-(2-pyrrol-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (other name: 5F-CUMYL-P7AICA)

Legal Authority
The CSA provides that issuing, amending, or repealing 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); or (3) on the petition of any interested party. 21 U.S.C. 811(a). The Attorney General initiated this action on his 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 (Assistant Secretary) and an evaluation of all relevant data by DEA. The regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities or chemical analysis, or possess) or proposes to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA will continue to apply as a result of this action.

Background
On July 10, 2018, DEA published an order in the Federal Register amending 21 CFR 1308.11(h) to temporarily place naphthalen-1-yl 1-(5-fluoropropyl)-1H-indole-3-carboxylate (other names: NM2201 or CBL2201), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropropyl)-1H-indazole-3-carboxamide [5F-AB-PINACA], 1-(4-cyano-3-methyl-1-oxobutan-2-yl)-1H-indole-3-carboxamide (other name: NM2201 or CBL2201), 5F-CUMYL-BUTINACA, 4-CN-CUMYL-BINACA, CUMYL-4CN-BINACA, or SGT-78, methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate [MMB-CHMICA; AMB-CHMICA, and 1-(5-fluoropropyl)-N-(2-pyrrol-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide [5F-CUMYL-P7AICA, CUMYL-5F-P7AICA, or SGT-263] and their 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 acceptable safety for use under medical supervision pursuant to 21 U.S.C.
812(b), the Assistant Secretary recommended that NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA be placed in schedule I of the CSA. In response, DEA conducted its own eight-factor analysis of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA.

The NPRM stated that the DEA and HHS analyses, as well as the Assistant Secretary’s May 29, 2020, letter to DEA, were available for viewing on the electronic docket. However, DEA discovered that these documents were not posted to the electronic docket as stated, and were only available for viewing at DEA headquarters. Upon publication of this final rule, DEA will post these documents in their entirety in the public docket for this rule (Docket Number DEA-479) at http://www.regulations.gov under “Supporting Documents.”

NPRM To Schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA

On July 13, 2020, DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in Schedule I.” 85 FR 42290. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before August 12, 2020. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before August 12, 2020.

Comments Received

DEA received two comments on the proposed rule to control NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in schedule I of the CSA. However, neither comment was relevant to this specific rule. One commenter discussed an electronic database for use in pain clinics, while the second commenter focused on deaths resulting from COVID-19. Therefore, DEA has no responses to these comments.

As indicated above, this final rule applies to five SCs that were the subject of a July 10, 2018 temporary scheduling order and the July 13, 2020 NPRM. These five substances will now be listed in 21 CFR 1308.11(d), as specified below.

Scheduling Conclusion

After considering the scientific and medical evaluations and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of abuse potential for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. DEA is therefore permanently scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA as controlled substances 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 and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (A³-THC) and JWH-018.
2. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA currently have no accepted medical use in treatment in the United States; and
3. There is a lack of accepted safety for use of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA under medical supervision.

Based on these findings, the Acting Administrator concludes that naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM2201; CBL2201), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AB-PINACA), 1-(4-cyanobutyl)-N-(2-phenylethyl)-1H-indazole-3-carboxamide (other names: NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA) isomers, and salts of isomers is possible, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA will continue 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, or desires to handle, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 in accordance with 21 CFR parts 1301 and 1312.
2. Security. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these five substances must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.
3. Labeling and Packaging. All labels and labeling for commercial containers of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 825 and

2 Although there is no evidence suggesting that NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA have accepted medical use in treatment in the United States, DEA concludes that NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(b), by virtue of the July 10, 2018 temporary scheduling order (63 FR 31877) and the subsequent one year extension of that order (July 13, 2020, 85 FR 42296).
958(e), and be in accordance with 21 CFR part 1302.

4. Quota. Only registered manufacturers are permitted to manufacture NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA 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 NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA was required to keep an inventory of all stocks of these substances on hand as of July 10, 2018, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

6. Records and Reports. Every DEA registrant must maintain records and submit reports with respect to NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and/or 5F-CUMYL-P7AICA, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and/or 5F-CUMYL-P7AICA to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

7. Order Forms. Every DEA registrant who distributes NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA 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 NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA 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 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)**

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 (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

**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, 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 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 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 Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–606, 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 July 10, 2018, DEA published an order to temporarily place those five substances in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h).

DEA estimates that all entities handling or planning to handle these substances have already established and implemented the systems and processes required to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA as schedule I controlled substances.

There are currently 28 registrations authorized to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and/or 5F-CUMYL-P7AICA specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. DEA estimates these 28 registrations encompass 22 entities. Some of these entities are likely to be large entities. However, DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities. Therefore, DEA conservatively estimates as many as 22 small entities are affected by this rule.

A review of the 28 registrations indicates that all entities that currently handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA. Therefore, DEA anticipates that this rule will impose minimal or no economic impact 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., 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.

**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 final rule to the Government Accountability Office, the House, and the Senate under the CRA.
Exceptions to Regulations
Suspensions, Modifications, and
International Traffic in Arms

SUMMARY:
ACTION: Exceptions to certain provisions of the International Traffic in Arms Regulations (ITAR) to provide for temporary suspensions, modifications, and exceptions to the ITAR, that were necessary to ensure continuity of operations within the Directorate of Defense Trade Controls (DDTC) and among members of the regulated community.

DATES: This document is issued June 10, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Engda Wubneh, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–1809, or email ddtccustomerservice@state.gov. ATTN: Extension of Suspension, Modification, and Exception—Telework.

SUPPLEMENTARY INFORMATION: In March 2020 a national emergency was declared as a result of the COVID–19 pandemic. On May 1, 2020, the Department of State (the Department) published in the Federal Register a notification of certain temporary suspensions, modifications, and exceptions to the ITAR, that were necessary to ensure continuity of operations within the Directorate of Defense Trade Controls (DDTC) and among entities registered with DDTC pursuant to part 122 of the ITAR (85 FR 25287). These actions were taken pursuant to ITAR § 126.2, which allows for the temporary suspension or modification of provisions of the ITAR, and ITAR § 126.3, which allows for exceptions to provisions of the ITAR. These actions were taken in the interest of the security and foreign policy of the United States and were warranted due to the exceptional and undue hardships and risks to safety caused by the public health emergency related to the SARS–COV2 pandemic.

Subsequently, on June 10, 2020 (85 FR 35376), the Department published in the Federal Register a request for comment from the regulated community regarding the efficacy and termination dates of the temporary suspensions, modifications, and exceptions provided in 85 FR 25287, and requesting comment as to whether additional measures should be considered in response to the public health crisis. Of the four temporary suspensions, modifications, and exceptions to the ITAR announced in the May 1 notification referenced above, DDTC reviewed the public comments and decided to extend two measures until December 31, 2020: (1) ITAR § 120.39(a)(2) allowance for remote work; and (2) authorization to allow remote work under technical assistance agreement, manufacturing agreement, or exemption.

Based upon continued public health recommendations and as informed by responses to the request for public comment in June 2020, it is apparent to DDTC that regulated entities will continue to engage in telework for the foreseeable future. Many commenters,

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 paragraphs (d)(81) through (d)(85); and

b. Remove and reserve paragraphs (h)(31) through (35);

The additions read as follows:

§ 1308.11 Schedule I.

* * * * * (d) * * *

Department of State

22 CFR Part 120

[Public Notice: 11443]

International Traffic in Arms Regulations: Notification of Temporary Suspensions, Modifications, and Exceptions to Regulations

AGENCY: Department of State.

ACTION: Extension of temporary suspensions, modifications, and exceptions.

SUMMARY: The Department of State is issuing this document to inform the public of a third extension to temporary suspensions, modifications, and exceptions to certain provisions of the International Traffic in Arms Regulations (ITAR) to continue telework operations during the current SARS–COV2 public health emergency. This action is taken in order to ensure continuity of operations among members of the regulated community.

DATES: This document is issued June 10, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Engda Wubneh, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–1809, or email ddtccustomerservice@state.gov. ATTN: Extension of Suspension, Modification, and Exception—Telework.

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