this AD requires performing the corrective action in accordance with FAA-approved procedures.

(3) Where paragraph (4) of EASA AD 2018–0284 specifies an alternative method to comply with the requirements of paragraph (3) of EASA AD 2018–0284 by replacing an affected part, this AD requires removing the affected part from service as an alternative method.

(4) Where paragraph (1) of EASA AD 2018–0284 specifies a compliance time of ''3 months or 50 flight hours, whichever occurs first,'' this AD requires a compliance time of within 50 hours time-in-service (TIS) from the effective date of this AD.

(5) Where paragraph (2) of EASA AD 2018–0284 specifies a compliance time of ''15 days,'' this AD requires using a compliance time of ''30 days.''

(6) The ''Remarks'' section of EASA AD 2018–0284 does not apply to this AD.

**(i) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@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.

**(j) Related Information**

(1) For EASA AD 2018–0284, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0199.

(2) For more information about this AD, contact Katherine Venegas, Aviation Safety Engineer, Los Angeles ACO Branch, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5353; email *katherine.venegas@faa.gov.*

Issued on March 24, 2021.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2021–06473 Filed 3–29–21; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1308

**[Docket No. DEA–491]**

## Schedules of Controlled Substances: Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration proposes placing ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 *N*-(4-fluorobenzyl)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144), including their 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 make permanent the existing 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 with, or possess) or propose to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144.

**DATES:** Comments must be submitted electronically or postmarked on or before April 29, 2021.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before April 29, 2021.

**ADDRESSES:** To ensure proper handling of comments, please reference ''Docket No. DEA–491'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The Drug Enforcement Administration (DEA) 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 on-line instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *http://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been submitted successfully, and there is no need to resubmit the same comment. 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.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, send via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW 8701 Morrissette Drive, Springfield, Virginia 22152.

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

**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 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 to make it 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 to make it 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.

DEA will generally make available in publicly redacted form comments containing personal identifying information and confidential business information identified as directed above. If a comment has so much confidential business information that it cannot be effectively redacted, DEA may not make available publicly all or part of that comment. 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 a 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, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and they shall include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to 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. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144.

**Background**

On April 16, 2019, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the **Federal Register** (84 FR 15505) temporarily placing ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144) in schedule I of the CSA upon finding that these five synthetic cannabinoids (SCs) pose an imminent hazard to the public safety. That temporary order was effective on the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary control of these substances is set to expire on April 16, 2021. However, this same subsection also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to a substance, the temporary scheduling of that substance may 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 DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,[1] or on the petition of any interested party. An extension of the existing temporary order is being ordered by the Acting Administrator of DEA (Acting Administrator) in a separate action, and is being simultaneously published elsewhere in this issue of the **Federal Register.**

The Acting Administrator, on his own motion, is initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. DEA gathered the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these five SCs. On December 4, 2019, the former Acting Administrator submitted this data to the Assistant Secretary for Health of HHS (Assistant Secretary), and requested that HHS provide DEA with a scientific and medical evaluation and a scheduling recommendation for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on February 26, 2021, the Acting Assistant Secretary submitted HHS's scientific and medical evaluation and scheduling recommendation for these five substances to the Acting Administrator. Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, in accordance with 21 U.S.C. 811(c).

**Proposed Determination To Schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144**

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21

[1] Because the Secretary of HHS has delegated to the Assistant Secretary for Health of HHS (Assistant Secretary) the authority to make domestic drug scheduling recommendations, for purposes of this proposed scheduling action, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

U.S.C. 811(a)(1), to add 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 permanently to schedule I of the CSA. DEA has reviewed the scientific and medical evaluation and scheduling recommendation received from HHS, and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both DEA Eight-Factor and HHS Eight-Factor analyses and the Acting Assistant Secretary's February 26, 2021, 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–491.''

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 DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse: [2]

*(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 to 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.*

In its recommendation, HHS noted that the abuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 is creating a hazard to the health and safety of both the individual users and others within the community. Adverse effects have been observed following the ingestion of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 (see factor 6). SCs, including 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, are easily accessible and difficult to detect in standard urine drug screens. These factors are contributing to their popularity and high rates of abuse, while resulting in serious harm to users. In addition, poison centers continue to report the abuse and harm of SCs in general and their associated products. SCs continue to remain a threat to both the short- and long-term public health and safety.

HHS stated in their letter to DEA dated September 6, 2018, and reiterated in their recommendation dated February 26, 2021, that there are no Food and Drug Administration (FDA)-approved drug products containing 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 in the United States and there appear to be no legitimate sources for these substances as marketed drugs. In their recommendation dated February 26, 2021, HHS stated that FDA is not aware of any diversion, from schedule I research or manufacturing activities, related to these five SCs for the purpose of legitimate drug research.

HHS stated that because 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are not approved for medical use and are not formulated or available for clinical use, the human use of these substances 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. Further, published scientific and medical literature and law enforcement reports indicate that individuals are taking these SCs on their own initiative, rather than on the basis of medical advice of a licensed practitioner.

HHS noted that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, similar to schedule I SCs (*e.g.,* JWH-018), bind to and activate the cannabinoid type 1 (CB1) receptors (see factor 2). In addition, drug discrimination studies conducted in rodents demonstrate that these five SCs, similar to other schedule I SCs (*e.g.,* JWH-018; AM2201; ADB-PINACA, AB-FUBINACA, etc.), fully substitute for delta-9-tetrahydrocannabinol (THC) in animals trained to discriminate THC from vehicle control (see factor 2).

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* In their recommendation, HHS described *in vitro* receptor binding and functional assays that were conducted using 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. These results indicate that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, similar to other schedule I SCs, bind to CB1 receptors and act as agonists at CB1 receptors. HHS also noted that drug discrimination studies were conducted in animals to evaluate whether the five SCs have cannabinoid characteristics similar to other substances in schedule I of the CSA. Each of the five SCs were shown to fully substitute for the discriminative stimulus effects produced by delta-9-THC. No human studies involving 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 have been reported.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* HHS stated that it is important to highlight the fact that the five SCs are structurally unrelated to THC, the principle psychoactive chemical in marijuana. Instead, they are potent cannabinoids that are reported to be smoked for recreational purposes. 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are all CB1 receptor agonists that are pharmacologically similar to THC.

As stated by HHS, when FDA approves a drug under the Federal Food, Drug, and Cosmetic Act for human or animal medical use, such drug is considered to have a currently accepted medical use in the United States. In the absence of such approval by FDA, a drug may be considered to have a currently accepted medical use in the United States if DEA concludes that the drug satisfies all of the following five elements: [3]

*a. The drug's chemistry is known and reproducible;*

*b. There are adequate safety studies;*

*c. There are adequate and well-controlled studies proving efficacy;*

*d. The drug is accepted by qualified experts; and*

*e. The scientific evidence is widely available.*

According to the HHS recommendation, none of the five SCs has been approved by FDA as a human or animal drug product in the United States or, to FDA's knowledge, been approved for medical use in any other country. Moreover, there are no well-controlled clinical studies showing safety or efficacy for any of these

[2] 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.C.A.N. 4566, 4603.

[3] 57 FR 10492 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

cannabinoids. In addition, there is no evidence by qualified experts that any of the five cannabinoids are accepted as having therapeutic uses. Therefore, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have no currently accepted medical use for treatment in the United States.

4. *Its History and Current Pattern of Abuse:* FUB-144 was first identified in seized drug evidence in January, 2014, followed by FUB-AKB48 (March 2014), 5F-MDMB-PICA (July 2014), 5F-EDMB-PINACA (October 2017) and 5F-CUMYL-PINACA (February 2018) (National Forensic Laboratory Information System [NFLIS], 2021).[4] Following their manufacture in China, SCs are often encountered in countries including New Zealand, Australia and Russia before appearing throughout Europe and eventually in the United States. 5F-CUMYL-PINACA was first reported in the German and Swiss illicit drug market in 2015 but did not appear in the United States until February 2018. 5F-EDMB-PINACA was reported in China in 2016 but didn't appear in the United States until October 2017. 5F-MDMB-PICA was first reported in the scientific literature in Germany and Belgium in late 2016. While two reports of 5F-MDMB-PICA were noted in NFLIS occurring in 2014 and 2016, it was not until 2017 and 2018 that there was a dramatic increase in 5F-MDMB-PICA reports in the United States. These data further support that based upon trends, SCs appear in the illicit drug markets of other countries including those in Europe often before being reported in the United States. Law enforcement has seized 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 and misuse of these SCs has been associated with overdoses requiring emergency medical intervention (*see* Factor 6).

The powder form of SCs is typically dissolved in solvents (*e.g.,* acetone) before being applied to plant material, or dissolved in a propellant intended for use in electronic cigarette devices. In addition, 5F-EDMB-PINACA was identified as an adulterant on pieces of paper that were smuggled into a detention facility and later found partially burned (see Factor 6). 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, similar to other SCs, have been found in powder form or mixed with dried leaves or herbal blends that were marketed for human use.

[4] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States.

5. *The Scope, Duration, and Significance of Abuse:* According to HHS, SCs continue to be encountered on the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel SCs continue to be encountered that differ only by small chemical structural modifications intended to avoid prosecution, while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products. NFLIS detailed 8,207 reports from forensic laboratories for these five substances as follows: 667 reports of 5F-EDMB-PINACA, 6,014 reports of 5F-MDMB-PICA, 411 reports of FUB-AKB48, 117 reports of 5F-CUMYL-PINACA, and 998 reports of FUB-144 for a period from 2014 through 2020.[5] A full presentation of the NFLIS reports by substance and year are available in DEA's eight-factor analysis within the Supporting Documents section of the public docket available at *http://www.regulations.gov.*

6. *What, if Any, Risk There is to the Public Health:* HHS and DEA documented multiple cases where 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have been identified in overdoses and/or cases involving death attributed to their abuse in the United States and abroad. Emergency medical intervention has been required as well as serious adverse health effects reported from these incidents involving 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. Adverse effects have included seizures, diaphoresis, hypertension, tachycardia, cerebral edema and/or death. By sharing pharmacological similarities with other schedule I substances (THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 pose serious risk to the abuser.

7. *Its Psychic or Physiological Dependence Liability:* There are no clinical studies evaluating dependence liabilities specific for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. However, scientific data indicate that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have pharmacological profiles that are similar to other schedule I SCs. HHS stated that based upon this similar pharmacological profile, it is reasonable to assume that these cannabinoids retain a physiological and psychological dependence liability that is similar to that of Δ9-THC (a schedule I drug) and to other schedule I synthetic cannabinoids, such as JWH-018, XLR11, and AKB-48.

[5] Query date February 12, 2021.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* As noted by HHS, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are not immediate precursors 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 HHS, HHS's recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. As such, DEA hereby proposes to permanently schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 as controlled substances 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 Acting Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have a high potential for abuse that is comparable to other schedule I substances such as THC and JWH-018;

2. 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, including their salts, isomers, and salts of isomers, 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144**

If this rule is finalized as proposed, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 would continue [6] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 is required to 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.* 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are 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 1301.71–1301.76. 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, labeling, and packaging for commercial containers of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 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 DEA to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must have an initial inventory of all stocks of controlled substances (including 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144) 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144) 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Order Forms.* Every DEA registrant who distributes 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 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 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

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

*Executive Order 12988, Civil Justice Reform*

This proposed 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 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, Consultation and Coordination With Indian Tribal Governments*

This proposed 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. 601–602, 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 April 16, 2019, DEA published an order to temporarily place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 have already established and implemented the systems and processes required to handle these substances. There are currently 28 unique registrations authorized to specifically handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. From a review of entity names, DEA estimates

[6] 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 84 FR 15505, April 16, 2019.

these 28 registrations represent 22 entities. Some of these entities are likely to be large entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 22 entities are small entities. Therefore, DEA conservatively estimates as many as 22 small entities are affected by this proposed rule.

A review of the 28 registrations indicates that all entities that currently handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. Therefore, 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 22 affected small entities. Therefore, 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.,* 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 million 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.

**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 proposes to amend 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. In § 1308.11,

■ a. Add paragraphs (d)(87) through (d)(91); and

■ b. Remove and reserve paragraphs (h)(37) through (41).

The additions to read as follows:

**§ 1308.11 Schedule I.**

* * * * *

(d) * * *

| | |
|---|---|
| (87) ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA) | 7036 |
| (88) methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA) | 7041 |
| (89) *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)) | 7047 |
| (90) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25) | 7083 |
| (91) (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144) | 7014 |

* * * * *

**D. Christopher Evans,**

*Acting Administrator.*

[FR Doc. 2021–06553 Filed 3–29–21; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### 21 CFR Part 1310

**[Docket No. DEA–678]**

## Designation of Methyl alpha-phenylacetoacetate, a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration is proposing the control of the chemical methyl *alpha*-phenylacetoacetate (also known as MAPA; methyl 3-oxo-2-phenylbutanoate; methyl 2-phenylacetoacetate; α-acetyl-benzeneacetic acid, methyl ester; and CAS Number: 16648–44–5) and its optical isomers as a list I chemical under the Controlled Substances Act (CSA). Methyl *alpha*-phenylacetoacetate is used in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone or P2P), methamphetamine, and amphetamine and is important to the manufacture of these controlled substances. If finalized, this action would subject handlers of methyl *alpha*-phenylacetoacetate to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of methyl *alpha*-phenylacetoacetate. As such, all transactions of chemical mixtures containing methyl *alpha*-phenylacetoacetate would be regulated at any concentration and would be subject to control under the CSA.

**DATES:** Comments must be submitted electronically or postmarked on or before June 1, 2021. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference ''Docket No. DEA–678'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) 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