Background

The FAA published an NPRM in the **Federal Register** for FAA–2020–0707 (85 FR 49985; August 17, 2020) to establish Class E airspace at the Benton Field Airport for the purpose of containing the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 16 approach and the RNAV (GPS) RWY 34 approach. Following the above NPRM publication, the two procedures were modified and renamed. The RNAV (GPS) RWY 16 approach was modified to become a circling only approach and was renamed as the RNAV GPS–A approach. The RNAV (GPS) RWY 34 approach was modified to become a circling only approach and was renamed as the RNAV GPS–B approach. These revised procedures have generated the need for additional modifications to the airspace dimensions to appropriately contain the procedures at Benton Field Airport, CA. This supplemental SNPRM reflects those changes.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace, extending upward from 700 feet above the surface, at Benton Field Airport. This area is designed to accommodate arriving IFR operations below 1,500 feet above the surface and departing IFR operations until they reach 1,200 feet above the surface. The proposed airspace is described in relation to the airport reference point and is within a 3.3-mile radius of the airport, and within 4 miles east and 2.3 miles west of the 002° bearing from the airport, extending from 3.3-miles radius to 12.4 miles north of the airport, and within 3.1 miles each side of the 179° bearing from the airport, extending from the 3.3-mile radius to 8.8 miles south of the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and is unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More above the Surface of the Earth.

* * * * *

AWP CA E5 Redding, CA [New]

Benton Field Airport, CA
(Lat. 40°34′25″ N, long. 122°24′26″ W)

That airspace extending upward from 700 feet above the surface within a 3.3-mile radius of the airport, and within 4 miles east and 2.3 miles west of the 002° bearing from the airport, extending from 3.3-miles radius to 12.4 miles north of the airport, and within 3.1 miles each side of the 179° bearing from the airport, extending from the 3.3-mile radius to 8.8 miles south of Benton Field Airport.

* * * * *

Issued in Seattle, Washington, on March 27, 2023.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2023–06886 Filed 4–3–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1006]

Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule six synthetic cannabinoids and their optical and geometric isomers, salts, and salts of isomers, whenever the existence of such isomers and salts is possible, in schedule I under the Controlled Substances Act. When it is issued, the temporary scheduling order will impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle these six specified controlled substances.

DATES: This notice of intent is effective April 4, 2023.

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

SUPPLEMENTARY INFORMATION: The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) to add the following six substances, including their optical, positional, and geometric isomers, salts, and salts of isomers whenever the existence of such isomers and salts is possible, to schedule I under the Controlled Substances Act (CSA): [1]

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

- Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate (Other name: MDMB-4en-PINACA),
- Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (Other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA),
- *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide (Other name: ADB-4en-PINACA),
- 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (Other name: CUMYL-PEGACLONE; SGT-151),
- Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (Other names: 5F-EDMB-PICA; 5F-EDMB-2201),
- Methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (Other name: MMB-FUBICA)

The temporary scheduling order will be published in the **Federal Register** on or after May 4, 2023.

Legal Authority

The CSA provides the Attorney General (as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100) with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety.[2] In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Administrator may extend the temporary scheduling for up to one year.[3]

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.,* to issue a temporary scheduling order).[4] The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary)[5] by letter dated January 24, 2022 regarding MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA. The Assistant Secretary responded to this notice by letter dated March 7, 2022, and advised that based on a review by the Food and Drug Administration, there are currently no approved new drug applications or investigational new drug applications for MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, or MMB-FUBICA. The Assistant Secretary also stated that HHS has no objection to the temporary placement of these substances in schedule I of the CSA. MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, or MMB-FUBICA currently are not listed in any schedule under the CSA, and no exemptions or approvals under 21 U.S.C. 355 are in effect for these six substances.

Under 21 U.S.C. 811(h)(3), to find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. This consideration includes any information indicating actual abuse; diversion from legitimate channels; and clandestine importation, manufacture, or distribution of these substances.

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[6] Substances in schedule I have a high potential for abuse, no currently accepted medical use for treatment in the United States, and no accepted safety for use under medical supervision.[7]

Synthetic Cannabinoids

Synthetic cannabinoids (SCs) are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC, schedule I), the main psychoactive ingredient in marijuana (schedule I). SCs were introduced to the designer drug market in several European countries as ''herbal incense'' before the initial encounter in the United States by the United States Customs and Border Protection (CBP) in November 2008. From 2009, abuse of SCs has escalated in the United States as evidenced by large numbers of law enforcement encounters of SCs applied onto plant material and in other designer drug products intended for human consumption.[8] Recent hospital reports, scientific publications and/or law enforcement reports demonstrate that MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA, and their associated designer drug products, are being abused for their psychoactive properties (see Factors 5 and 6). As with many generations of SCs encountered since 2009, the abuse of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA is negatively impacting communities in the United States.

As noted by DEA and CBP, SCs originate from foreign sources, such as China. Substances in bulk powder form are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters, spraying or mixing the SCs with plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-laced plant material in cigarette papers).

MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA have no accepted medical use in treatment in the United States.[9] Emergency department

[2] 21 U.S.C. 811(h)(1).

[3] 21 U.S.C. 811(h)(2).

[4] 21 U.S.C. 811(h)(4).

[5] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[6] 21 U.S.C. 811(h)(1).

[7] 21 U.S.C. 812(b)(1).

[8] While law enforcement data are not direct evidence of abuse, they can lead to an inference that drugs have been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[9] Although there is no evidence suggesting that MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA have 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 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, Mar. 26, 1992, pet. for rev. denied, *Alliance*

Continued

presentations involving MDMB-4en-PINACA or CUMYL-PEGACLONE have included seizures, sudden collapse, involuntary muscle spasms, jerking movements, catatonia, and increased violence. Multiple deaths have been reported involving MDMB-4en-PINACA, 4F-MDMB-BUTICA and CUMYL-PEGACLONE. In addition, all six SCs have been seized by law enforcement in the United States. Use of other schedule I SCs (*e.g.,* JWH-018, AB-FUBINACA) has resulted in signs of addiction and withdrawal. Based on the pharmacological similarities between MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA and other schedule I SCs (*e.g.,* JWH-018, AB-FUBINACA), these six SCs are likely to produce signs of addiction and withdrawal similar to those produced by other schedule I SCs (*e.g.,* JWH-018, AB-FUBINACA).

MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA are SCs that have pharmacological effects similar to the schedule I hallucinogen THC and other temporarily and permanently controlled schedule I SCs. With no approved medical use and limited safety or toxicological information, MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA have emerged in the designer drug market, and the abuse of these substances for their psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

SCs have been developed by researchers over the last 30 years as tools for investigating the endocannabinoid system (*e.g.,* determining CB1 and CB2 receptor activity). The first encounter of SCs intended for illicit use within the United States occurred in November 2008 by CBP. Since then, the popularity of SCs as product adulterants and objects of abuse has increased as evidenced by law enforcement seizures, public health information, and media reports.

Research and clinical reports have demonstrated that SCs are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive ''high,'' believed to be similar to marijuana. The adulterated products are marketed as ''legal'' alternatives to marijuana.

The designer drug products laced with SCs, including MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA, are often sold under the guise of ''herbal incense'' or ''potpourri,'' using various product names, and are routinely labeled ''not for human consumption.'' Additionally, these products are marketed as a ''legal high'' or ''legal alternative to marijuana'' and are readily available over the internet, in head shops, or sold in convenience stores. There are incorrect assumptions that these products are safe, that these are synthetic forms of marijuana, and that labeling these products as ''not for human consumption'' is a legal defense to criminal prosecution under the Controlled Substances Analogue Enforcement Act.

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. Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs are mixed together, or in large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any quality control mechanisms to prevent contamination or to ensure a uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the drug during the manufacturing process. The failure to adhere to any manufacturing standards with regard to amounts, the substance(s) included, purity, or contamination may further increase the risk of adverse events. However, it is important to note that adherence to manufacturing standards would not eliminate their potential to produce adverse effects because the toxicity and safety profiles of these SCs have not been studied. MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA, similar to other schedule I SCs (*e.g.,* JWH-018, AB-FUBINACA), have been found in powder form or mixed with dried leaves or herbal blends that were marketed for human use.

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. Law enforcement in the United States has encountered MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA and has documented the abuse of these substances. SCs and their associated products are available over the internet and sold in gas stations, convenience stores, and tobacco and head shops. MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA, similar to the previously scheduled SCs, have been seized alone and/or laced on products that are marketed under the guise of ''herbal incense'' and promoted as a ''legal'' alternative to marijuana.

CUMYL-PEGACLONE was detailed in a patent published in 2014, was first reported as an adulterated plant material in Germany in December 2016, and appeared in the United States in September 2018. These data further support the trend that SCs often appear in the illicit drug markets of other countries including those in Europe before being reported in the United States. Law enforcement has seized CUMYL-PEGACLONE and its abuse has been associated with overdoses requiring emergency medical intervention. Adverse effects reported following the abuse of CUMYL-PEGACLONE have included seizures followed by collapse and deaths. CUMYL-PEGACLONE has also been encountered laced onto paper in attempts to be smuggled inside of prison facilities.

Users abuse SCs by smoking for the purpose of achieving intoxication, which has resulted in numerous emergency department visits and calls to poison centers. As reported by the American Association of Poison Control Centers (AAPCC), severe, life-threatening health effects including severe agitation and anxiety, nausea, vomiting, seizures, and hallucinations can occur following ingestion of SCs. The AAPCC has specifically noted that SCs are made specifically to be abused.[10] Emergency department presentations involving MDMB-4en-PINACA or CUMYL-PEGACLONE have included seizures, sudden collapse, involuntary muscle spasms, jerking movements, catatonia, or increased violence. Multiple deaths have been reported involving MDMB-4en-PINACA, 4F-MDMB-BUTICA, and CUMYL-PEGACLONE (See DEA Factor 6 in Three Factor Analysis).

for Cannabis Therapeutics v. *DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994).*

[10] *https://aapcc.org/track/synthetic-cannabinoids.*

Factor 5. Scope, Duration, and Significance of Abuse

Novel SCs substances, differing only by small chemical structural modifications intended to avoid prosecution while maintaining the pharmacological effects, continue to be sold on the illicit drug market as evidenced by law enforcement encounters of these substances. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products. The threat of serious injury to the individual and the imminent threat to public safety following the ingestion of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, MMB-FUBICA, and other SCs persist.

Additional information obtained through the National Forensic Laboratory Information System (NFLIS) [11] along with additional data may be found in DEA's Three Factor Analysis. According to NFLIS data,[12] state and local forensic laboratories have detected the following information about the SCs in question:

- MDMB-4en-PINACA was identified in 9,566 NFLIS reports since 2019. In addition, MDMB-4en-PINACA was identified in five exhibits mixed with heroin and/or fentanyl and packaged for sale as suspected heroin.
- 4F-MDMB-BUTICA was identified in 385 NFLIS reports since 2020. 4F-MDMB-BUTICA was also identified in one exhibit in a pill form, mixed with methamphetamine and a synthetic cathinone known as eutylone.
- CUMYL-PEGACLONE was identified in two CBP drug seizures in 2018 and 2021, respectively.
- 5F-EDMB-PICA was identified in 106 NFLIS reports since 2020.
- MMB-FUBICA was identified in 397 NFLIS reports since 2016.

Factor 6. What, if Any, Risk There is to the Public Health

Since first being identified in the United States in 2008, the ingestion of SCs continues to result in serious adverse effects. Details of these events involving MDMB-4en-PINACA and CUMYL-PEGACLONE are summarized below. (For additional information and citations, see DEA Factors 5 and 6 in Three Factor Analysis.)

1. In October 2017 in France, two 16-year old juveniles were given a cigarette laced with white powder by an unknown individual. Upon arrest of the dealer, he stated the powder was SGT-151. Both juveniles developed seizures followed by collapse. Toxicological analysis of both victim's blood and blood collected from the arrested dealer (who claimed to be a user of the same powder) confirmed the presence of CUMYL-PEGACLONE (SGT-151) and its metabolite, *N*-dealkyl CUMYL-PEGACLONE (SGT-151).

2. Between January and December 2017 in Germany, CUMYL-PEGACLONE was detected in 34 forensic serum/blood samples from fatal and non-fatal cases. Of these cases, six deaths were reported by the Institute of Forensic Medicine in Munich and the Institute of Forensic Medicine in Mainz, respectively. Details of the deaths demonstrated multiple factors in addition to SCs as possible causes of death.

3. Between July 1, 2018 and December 31, 2020 in Northern Australia, CUMYL-PEGACLONE was detected in five deaths. Concurrent alcohol use and underlying cardiovascular disease were considered relevant factors in most cases. Toxicological Significance Scoring (TSS) was carefully considered in all five cases, and in four cases, the presence of CUMYL-PEGACLONE was considered to be highly significant (TSS = 3).

4. In September 2019, the Center for Forensic Science Research and Education released a report detailing the identification of MDMB-4en-PINACA in biological fluids per their toxicology department.

5. In February 2020, local law enforcement in Holyoke, MA, reported serious adverse effects following the abuse of the contents in glassine bags with suspected heroin. Analysis of contents in the bags confirmed the presence of MDMB-4en-PINACA. Per law enforcement witnesses to the overdoses, individuals were experiencing involuntary body/muscle spasms and movements that appeared similar to a seizure, although more violent. Victims were alert and conscious and they appeared to be under the influence of some unknown narcotics at the time, with officers noting that what was observed was nothing like a typical heroin overdose. Victims described it like being under the influence of PCP (schedule II substance) or something similar. In some cases, people were violent and emergency personnel were having a difficult time providing medical attention to these individuals. Emergency personnel also described very high heart rates and blood pressure. Some individuals were acting erratic and running in and out of traffic.

6. In March 2021, a forensic toxicology report from the Defense Health Agency reported the presence of ADB-BUTINACA, ADB-BUTINACA N-butanoic acid (a metabolite of ADB-BUTINACA), and MDMB-4en-PINACA 3,3-dimethylbutanoic acid (a metabolite of MDMB-4en-PINCA) in a submitted urine specimen.

7. MDMB-4en-PINACA and/or its metabolite were detected in 25 forensic investigation cases between August 2019 and March 2020. The first positive sample was collected in May 2019. The majority of cases (n = 16, 64%) were submitted from postmortem investigations, followed by eight cases from suspected clinical toxicology investigations, and one case from an impaired driving investigation.

Because they share pharmacological similarities with schedule I substances (Δ^9-THC, JWH-018, and other temporarily and permanently controlled schedule I SCs), MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA pose serious risks to an abuser. Tolerance to SCs may develop fairly rapidly with larger doses being required to achieve the desired effect. Acute and chronic abuse of SCs in general have been linked to adverse health effects including signs of addiction and withdrawal, numerous reports of emergency department admissions, and overall toxicity and deaths. Psychiatric case reports have been reported in the scientific literature detailing the SC abuse and associated psychoses (See DEA Factor 6 in Three Factor Analysis). As abusers obtain these drugs through unknown sources, the identity and purity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users.

MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA are being encountered on the illicit drug market and have no accepted medical use in the United States. Regardless, these products continue to be easily available and abused by diverse populations.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis with, possession, and

[11] 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.

[12] At the time of query (March 16, 2022), 2021 and 2022 data were still reporting.

abuse of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, or MMB-FUBICA, resulting from the lack of control of these substances, pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for these substances in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by 21 U.S.C. 811(h)(4), the Administrator, through a letter dated January 24, 2022, notified the Assistant Secretary of DEA's intention to temporarily place MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA in schedule I.

Conclusion

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily schedule MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA in schedule I of the CSA, and finds that placement of these substances in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public's safety.

The temporary placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before May 4, 2023. Because the Administrator hereby finds that it is necessary to temporarily place MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA in schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling these substances will be effective on the date the order is published in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process.[13] It is the intention of the Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon publication of the temporary order, MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA will then be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis with, and possession. The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. Temporary scheduling orders are not subject to judicial review.[14]

Regulatory Analyses

The CSA provides for expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety.[15] As provided in 21 U.S.C. 811(h)(1), the Administrator (as delegated by the Attorney General) may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary for Health of HHS, as delegated by the Secretary of HHS.

Inasmuch as this section directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement of a publication in the **Federal Register** of a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. The APA expressly differentiates between an order and a rule, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' [16] The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in 21 U.S.C. 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice-and-comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this notice of intent is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) only apply when DEA is required, under 5 U.S.C. 553, to issue a

[13] 21 U.S.C. 811(h)(1) and (2).

[14] 21 U.S.C. 811(h)(6). This contrasts with permanent scheduling actions which are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' and final decisions that conclude the scheduling process are subject to judicial review. See 21 U.S.C. 811(a) and 877.

[15] 21 U.S.C. 811(h)(1).

[16] 5 U.S.C. 551(6) (emphasis added).

notice of proposed rulemaking. As discussed above, DEA is issuing this notice of intent pursuant to DEA's authority to issue a temporary scheduling order. See 21 U.S.C. 811(h)(1). Therefore, because DEA believes this temporary scheduling action is not a ''rule,'' DEA is not subject to the requirements of the Regulatory Flexibility Act when issuing this temporary action.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this notice of intent is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866.

This action will 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. Therefore, in accordance with E.O. 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism Assessment.

Signing Authority

This document of the Drug Enforcement Administration was signed on March 29, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

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, add paragraphs (h)(57) through (62) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(57) Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, its optical and geometric isomers, salts and salts of isomers (Other name: MDMB-4en-PINACA) 7090

(58) Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethylbutanoate, its optical and geometric isomers, salts and salts of isomers (Other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA) 7091

(59) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide, its optical and geometric isomers, salts and salts of isomers (Other name: ADB-4en-PINACA) 7092

(60) 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, its optical and geometric isomers, salts and salts of isomers (Other names: CUMYL-PEGACLONE; SGT-151) 7093

(61) Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethylbutanoate, its optical and geometric isomers, salts and salts of isomers (Other names: 5F-EDMB-PICA; 5F-EDMB-2201) 7094

(62) Methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate, its optical and geometric isomers, salts and salts of isomers (Other name: MMB-FUBICA) 7095

* * * * *

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2022–0927; FRL–10657–03–R6]

Determination of Attainment by the Attainment Date but for International Emissions for the 2015 Ozone National Ambient Air Quality Standard; El Paso-Las Cruces, Texas-New Mexico; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for the proposed rule ''Determination of Attainment by the Attainment Date But For International Emissions for the 2015 Ozone National Ambient Air Quality Standard; El Paso-Las Cruces, Texas-New Mexico'' that was published on March 7, 2023. The proposal provided for a public comment period ending April 6, 2023. The EPA received a request from the public to extend this comment period. The EPA is extending the comment period to May 8, 2023.

DATES: The comment period for the proposed rule published March 7, 2023 (88 FR 14095), is extended. Written comments must be received on or before May 8, 2023.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2022–0927, at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be