ASO AL D Fort Novosel (Ozark), AL [Amended]

Cairns Army Air Field (Fort Novosel), AL
(Lat. 31°16′33″ N, long. 85°42′48″ W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 5-mile radius of lat. 31°18′30″ N, long. 85°42′20″ W. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

ASO GA D Columbus, GA [Amended]

Columbus Airport, GA
(Lat. 32°30′59″ N, long. 84°56′20″ W)
Lawson AAF (Fort Moore)
(Lat. 32°19′54″ N, long. 84°59′14″ W)

That airspace extending upward from the surface to and including 2,900 feet MSL within a 4.4-mile radius of the Columbus Airport, and that airspace extending upward from the surface to and including 2,700 feet MSL within a 5.2-mile radius of Lawson Army Airfield (Ft. Moore) and that airspace within 1 mile each side of the 145° bearing from the AAF extending from the 5.2-mile radius to 6.8 miles southeast of the AAF. This Class D airspace is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6002 Class E Surface Airspace.

* * * * *

ASO AL E2 Fort Novosel (Ozark), AL [Amended]

Columbus Airport, GA
(Lat. 32°30′59″ N, long. 84°56′20″ W)
Lawson AAF (Fort Moore)
(Lat. 32°19′54″ N, long. 84°59′14″ W)

That airspace extending upward from the surface to and including 2,900 feet MSL within a 4.4-mile radius of the Columbus Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

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

* * * * *

ASO MS E5 Columbus, MS [Amended]

Columbus AFB, MS
(Lat. 33°38′43″ N, long. 88°26′45″ W)
Monroe County Airport
(Lat. 33°52′26″ N, long. 88°29′23″ W)
Columbus-Lowndes County Airport
(Lat. 33°27′55″ N, long. 88°22′51″ W)
Golden Triangle Regional Airport
(Lat. 33°26′54″ N, long. 88°35′29″ W)
Oktibbeha Airport
(Lat. 33°29′52″ N, long. 88°4′53″ W)
McCharen Field
(Lat. 33°35′03″ N, long. 88°40′00″ W)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of Columbus AFB, a 16-mile radius of Monroe County Airport, and within a 6.4-mile radius of Columbus-Lowndes County Airport, and within a 6.6-mile radius of Golden Triangle Regional Airport, and within a 6.2-mile radius of Oktibbeha Airport, and a 6.3-mile radius of McCharen Field.

* * * * *

Issued in College Park, Georgia, on December 6, 2023.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2023–27195 Filed 12–11–23; 8:45 am]

BILLING CODE 4910–13–P

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 into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this 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. This action is based on a finding by the Administrator that the placement of these six substances in schedule I is necessary to avoid imminent hazard to the public safety. As a result of this order, 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 temporary scheduling order is effective December 12, 2023, until December 12, 2025. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) issues a temporary scheduling order [1] (in the form of a temporary amendment) to add the following six substances, including their optical 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):

- 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), and
- Methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (Other name: MMB–FUBICA).

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 the Administrator 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]

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

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

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

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.[4]

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).[5] The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[6] 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 (FDA), 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, and 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.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). DEA has found that the control of these six synthetic cannabinoids (SCs) in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety. MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and 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.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent (NOI) to temporarily schedule MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA on April 4, 2023.[7] That NOI discussed findings from DEA's three-factor analysis dated April 2023, which DEA made available on *www.regulations.gov.*

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. Consideration of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances.[8]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[9] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States, and no accepted safety for use under medical supervision.[10]

The DEA's three-factor analysis and the Assistant Secretary's March 7, 2022, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov.*

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 U.S. 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.[11] 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 in DEA's three-factor analysis). 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.[12] Emergency department 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

[4] 21 U.S.C. 811(h)(1); 21 CFR part 1308.

[5] 21 U.S.C. 811(h)(4).

[6] 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.

[7] 88 FR 19896.

[8] 21 U.S.C. 811(h)(3).

[9] 21 U.S.C. 811(h)(1).

[10] 21 U.S.C. 812(b)(1).

[11] 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.

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

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 the substance's 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.[13] 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 Factor 6 in DEA's three-factor analysis).

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 evidence 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

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

(NFLIS),[14] along with additional data, may be found in DEA's three-factor analysis. According to NFLIS data,[15] 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 Factors 5 and 6 in DEA's 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.

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.

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, Massachusetts, 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 phencyclidine (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 Factor 6 in DEA's 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/or abuse of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA 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.

[14] 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.

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

As required by 21 U.S.C. 811(h)(4), the Administrator transmitted to the Assistant Secretary for Health, via a letter dated January 24, 2022, notice of her intent to place MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I.

DEA subsequently published a NOI in the **Federal Register** on April 4, 2023.[16]

Conclusion

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 place 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 safety.

This temporary order scheduling these substances will be effective on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[17]

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent 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.[18] The permanent 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.[19] Temporary scheduling orders are not subject to judicial review.[20]

Requirements for Handling

Upon the effective date of this temporary order, MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with), or desires to handle, MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, or MMB–FUBICA must be registered with the 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, as of December 12, 2023. Any person who currently handles MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, or MMB–FUBICA, and is not registered with the DEA, must submit an application for registration and may not continue to handle MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA as of December 12, 2023, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after December 12, 2023 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, or MMB–FUBICA must surrender all currently held quantities of these six substances.

3. *Security.* MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93, as of December 12, 2023.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA must comply with 21 U.S.C. 825 and 958(e), and 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from December 12, 2023 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA on the effective date of this order must take an inventory of all stocks of these substances on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants will have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA) on hand on a biennial basis pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, 1317 and section 1307.11. Current DEA registrants authorized to handle these six substances shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants must submit reports with respect to MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of December 12, 2023. Manufacturers and distributors must also submit reports regarding these six substances 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.

8. *Order Forms.* All DEA registrants who distribute MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA must

[16] 88 FR 19896.

[17] 21 U.S.C. 811(h)(1) and (2).

[18] 21 U.S.C. 811.

[19] 21 U.S.C. 877.

[20] 21 U.S.C. 811(h)(6).

comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of December 12, 2023.

9. *Importation and Exportation.* All importation and exportation of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of December 12, 2023.

10. *Quota.* Only DEA registered manufacturers may manufacture MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303, as of December 12, 2023.

11. *Liability.* Any activity involving MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA not authorized by, or in violation of the CSA, occurring as of December 12, 2023, is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

The CSA provides for expedited temporary scheduling actions where necessary to avoid imminent hazards to the public safety. Under 21 U.S.C. 811(h), the Administrator, as delegated by the Attorney General, may, by order, temporarily schedule substances in schedule I. Such orders 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.[21]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this temporary scheduling order. The APA expressly differentiates between orders and rules, 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.*''[22] The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Alternatively, even if this action was subject to section 553 of the APA, the Administrator finds that there is good cause to forgo its notice-and-comment requirements, as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid imminent hazards to public safety.

Although DEA believes this 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 notices that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action 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) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

In accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14094, this action 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, sec. 3(f), as amended by E.O. 14094, sec. 1(b), provides the definition of a ''significant regulatory action,'' requiring review by the Office of Management and Budget. 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 (Federalism), 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 December 7, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(62) to (h)(67) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

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

[22] 5 U.S.C. 551(6) (emphasis added).

* * * * * * *

(62) 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
(63) Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, its optical and geometric isomers, salts and salts of isomers (Other names: 4F–MDMB–BUTICA; 4F–MDMB–BICA) 7091
(64) *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
(65) 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
(66) Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, its optical and geometric isomers, salts and salts of isomers (Other names: 5F–EDMB–PICA; 5F–EDMB–2201) 7094
(67) 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

[FR Doc. 2023–27243 Filed 12–11–23; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0949]

RIN 1625–AA00

Safety Zone; Kaneohe Bay, Oahu, HI—Navy P8 Aircraft Salvage Operations

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 0.5 nautical mile radius temporary safety zone for navigable waters in Kaneohe Bay, HI encompassing the partially submerged Navy P8 aircraft. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by salvage operations of the Navy P8 aircraft. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Honolulu.

DATES: This rule is effective without actual notice from December 12, 2023 through December 10, 2023. For the purposes of enforcement, actual notice will be used from December 2, 2023. This rule will be enforced each day it is in effect from 7 a.m. to 6 p.m. December 12, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0949 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Chief Petty Officer Bradley Lindsey, Waterways Management Division, U.S. Coast Guard Sector Honolulu; telephone 808–541–4363, *bradley.w.lindsey@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable and contrary to the public interest. The Coast Guard was unable to publish an NPRM and hold a reasonable comment period for this rulemaking due to the emergent nature and logistical coordination of salvage operations. It is impracticable to publish an NPRM because we must establish this safety zone by December 2, 2023.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to remove the existing threat to the environment and safeguard against future potential threat to the environment as well as safety hazards associated with emergency salvage operations of the Navy P8 aircraft.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Honolulu (COTP) has determined that potential hazards associated with emergency salvage operations starting December 2, 2023, will be a safety concern for anyone within a 0.5 nautical mile radius of the Navy P8 aircraft. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while salvage operations take place.

IV. Discussion of the Rule

This rule establishes a safety zone from 7 a.m. until 6 p.m. on December 2, 2023, through December 10, 2023. The Coast Guard is establishing a 0.5 nautical mile radius temporary safety zone for navigable waters in Kaneohe Bay, HI encompassing the partially submerged Navy P8 aircraft. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the aircraft is being salvaged. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review).