

Article I: Effect of Designation

The NMSA authorizes the issuance of such regulations as are necessary and reasonable to implement the designation, including managing and protecting the historical resources and recreational, research, and educational qualities of the Wisconsin-Lake Michigan National Marine Sanctuary (the "Sanctuary"). Section 1 of Article IV of this Designation Document lists those activities that may have to be regulated on the effective date of designation, or at some later date, in order to protect Sanctuary resources and qualities. Listing an activity does not necessarily mean that it will be regulated; however, if an activity is not listed it may not be regulated, except on an emergency basis, unless Section 1 of Article IV is amended by the same procedures by which the original Sanctuary designation was made.

Article II: Description of the Area

The Wisconsin-Lake Michigan National Marine Sanctuary consists of an area of approximately 812 square nautical miles (nmi²) (1,075 sq. mi) of Lake Michigan waters within the state of Wisconsin and the submerged lands thereunder, over, around, and under the submerged underwater cultural resources in Lake Michigan. The eastern boundary of the sanctuary begins approximately 9.5 miles east of the Wisconsin shoreline in Lake Michigan roughly on the border between Manitowoc and Kewaunee County. From this point the boundary continues in Lake Michigan roughly to the SSW until it intersects the border between Ozaukee and Milwaukee County at a point approximately 13 miles east of the shoreline. The southern boundary continues west approximating the border between these same two counties until it intersects the shoreline near Mequon, WI. The western boundary continues north following the shoreline for approximately 90 miles cutting across the mouths of rivers and streams; specifically those of Sauk Creek at Port Washington, the Sheboygan River at Sheboygan, Manitowoc Harbor at Manitowoc, and East Twin River at Two Rivers as well as any other smaller streams and creeks. The western boundary ends at roughly the border between Manitowoc and Kewaunee County along the shoreline near Twin Creeks, WI. The northern boundary continues from the shoreline east approximating the border between these same two counties back to its point of origin 9.5 miles offshore.

Article III: Special Characteristics of the Area

The historic shipwrecks in the Wisconsin-Lake Michigan National Marine Sanctuary are representative of vessels that sailed and steamed the Lake Michigan corridor, carrying grain and raw materials east as other vessels came west loaded with coal, manufactured good, and immigrants. Eighteen of the 37 shipwrecks are listed on the National Register of Historic Places. Many of the shipwrecks in the proposed sanctuary retain an unusual degree of architectural integrity, with 14 vessels virtually intact. Well preserved by Lake Michigan's cold, fresh water, the shipwrecks and related

underwater cultural sites in and around the Wisconsin-Lake Michigan National Marine Sanctuary possess exceptional historical, archaeological and recreational value.

Article IV: Scope of Regulations

Section 1. Activities Subject to Regulation. The following activities are subject to regulation, including prohibition, to the extent necessary and reasonable to ensure the protection and management of the historical resources and recreational, research and educational qualities of the area:

- a. Damaging sanctuary resources.
- b. Using grappling hooks and anchors at shipwreck sites.
- c. Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation issued under the Act.
- d. Reporting shipwreck discoveries and locations to the sanctuary.

Section 2. Emergencies. Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality; or minimize the imminent risk of such destruction, loss, or injury, any activity, including those not listed in Section 1, is subject to immediate temporary regulation. An emergency regulation shall not take effect without the approval of the Governor of Wisconsin or her/his designee or designated agency.

Article V: Relation to Other Regulatory Programs

Section 1. Fishing Regulations, Licenses, and Permits. Fishing in the Sanctuary shall not be regulated as part of the Sanctuary management regime authorized by the Act. However, fishing in the Sanctuary may be regulated by other Federal, State, Tribal and local authorities of competent jurisdiction, and designation of the Sanctuary shall have no effect on any regulation, permit, or license issued thereunder.

Section 2. Other Regulations, Licenses, and Permits. If any valid regulation issued by any Federal, state, Tribal, or local authority of competent jurisdiction, regardless of when issued, conflicts with a Sanctuary regulation, the regulation deemed by the Director of the Office of National Marine Sanctuaries, National Oceanic and Atmospheric Administration, or designee, in consultation with the State of Wisconsin, to be more protective of Sanctuary resources and qualities shall govern. Pursuant to section 304(c)(1) of the Act, 16 U.S.C. 1434(c)(1), no valid lease, permit, license, approval, or other authorization issued by any Federal, State, Tribal, or local authority of competent jurisdiction, or any right of subsistence use or access, may be terminated by the Secretary of Commerce, or designee, as a result of this designation, or as a result of any Sanctuary regulation, if such lease, permit, license, approval, or other authorization, or right of subsistence use or access was issued or in existence as of the effective date of this designation. However, the Secretary of Commerce or designee, in consultation with the State of Wisconsin, may regulate the exercise of such authorization or right consistent with the purposes for which the Sanctuary is designated.

Article VI. Alteration of This Designation

The terms of designation may be modified only by the same procedures by which the original designation is made, including public meetings, consultation according to the NMSA.

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-446]

Schedules of Controlled Substances: Temporary Placement of Six Synthetic Cannabinoids (5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA) Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule six synthetic cannabinoids: Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). This action is based on a finding by the Administrator that the placement of these synthetic cannabinoids into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, exportation of, and research and conduct with, instructional activities of these synthetic cannabinoids.

DATES: January 9, 2017.

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION: Any final order will be published in the **Federal Register** and may not be effective prior to February 8, 2017.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 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 section 202 of the CSA, 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 (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of any intention to temporarily place a substance into schedule I of the CSA.¹ The Acting Administrator transmitted notice of his intent to place 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in schedule I on a temporary basis to the Assistant Secretary by letter dated April 22, 2016. The Assistant Secretary responded to this notice by letter dated May 2, 2016, and advised that based on a review by the Food and Drug Administration (FDA), there were no investigational new drug applications or approved new drug applications for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA. The Assistant Secretary also stated that the HHS had no objection to the temporary placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA into schedule I of the CSA. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA are not currently listed in any schedule under the CSA.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to 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. 21 U.S.C. 811(h)(3).

Consideration of these factors includes

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Service (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). 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. 21 U.S.C. 812(b)(1).

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA

Available data and information for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA indicate that these synthetic cannabinoids (SCs) 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.

Synthetic Cannabinoids

SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed that SCs were first introduced on the designer drug market in several European countries as "herbal incense" before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. From 2009 to the present, misuse and abuse of SCs has increased in the United States with law enforcement encounters describing SCs applied onto plant material and in designer drug products intended for human consumption. It has been demonstrated that the substances and the associated designer drug products are abused for their psychoactive properties. With many generations of SCs having been encountered since 2009, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are some of the latest, and the abuse of these substances is negatively impacting communities.

As observed by the DEA and CBP, SCs originate from foreign sources, such as China. Bulk powder substances 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,

applying by 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).

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA have no accepted medical use in the United States. Use of these specific SCs has been reported to result in adverse effects in humans including deaths (see 3-Factor document in “Supporting and Related Material” section). Use of other SCs has resulted in signs of addiction and withdrawal, and based on the similar pharmacological profile of these six substances, it is believed that there will be similar observed adverse effects.

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are SCs that have pharmacological effects similar to the schedule I hallucinogen delta- Δ -tetrahydrocannabinol (THC) and temporarily and permanently controlled schedule I synthetic cannabinoid substances. In addition, the misuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA have been associated with either overdoses requiring emergency medical intervention or death (see factor 6). With no approved medical use and limited safety or toxicological information, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have emerged on the designer drug market, and the abuse of these substances for their psychoactive properties is concerning. The DEA’s analysis is available in its entirety under “Supporting and Related Material” of the public docket for this action at www.regulations.gov under docket number DEA-443.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed 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 within the United States occurred in November 2008 by CBP. Since then the popularity of SCs and their associated products has increased steadily as evidenced by law enforcement seizures, public health information, and media reports. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are SCs that have been recently encountered (see “Supporting and Related Material,” Factor 5). Multiple overdoses involving

emergency medical intervention or deaths have been associated with 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

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/or psychoactive “high,” believed to be similar to marijuana. Data gathered from published studies, supplemented by discussions on Internet discussion Web sites, demonstrate that these products are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as “legal” alternatives to marijuana. In recent overdoses, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have been shown to be applied onto plant material, similar to the SCs that have been previously available.

Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs (including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA) are mixed together, as well as 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 control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the substance(s) during the manufacturing process. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, similar to other SCs, have been encountered in form of dried leaves or herbal blends.

The designer drug products laced with SCs, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, are often sold under the guise of “herbal incense” or “potpourri,” use 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 is an incorrect assumption that these products are safe, that they are a synthetic form of marijuana, and that labeling these products as “not for

human consumption” is a legal defense to criminal prosecution.

A major concern, as reiterated by public health officials and medical professionals, is the targeting and direct marketing of SCs and SC-containing products to adolescents and youth. This is supported by law enforcement encounters and reports from emergency departments; however, all age groups have been reported by media as abusing these substances and related products. Individuals, including minors, are purchasing SCs from Internet Web sites, gas stations, convenience stores, and head shops.

Factor 5. Scope, Duration and Significance of Abuse

SCs, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Numerous substances are encountered each month, differing only by small modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report abuse of these substances and their associated products.

As described by the National Institute on Drug Abuse (NIDA), many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity.

The threat of serious injury to the individual following the ingestion of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA and other SCs persists. Numerous calls have been received by poison centers regarding the abuse of products potentially laced with SCs that have resulted in visits to emergency departments. Law enforcement continues to encounter novel SCs on the illicit market, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA (see factor 5 in “Supporting and Related Material”).

The following information details information obtained through NFLIS² (queried on November 7, 2016),

² The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

including dates of first encounter, exhibits/reports, and locations.

5F-ADB: NFLIS—2,311 reports, first encountered in September 2014, locations include: Arizona, Arkansas, California, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Missouri, New Jersey, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, Virginia, and Wisconsin.

5F-AMB: NFLIS—3,349 reports, first encountered in January 2014, locations include: Arizona, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.

5F-APINACA: NFLIS—1,936 reports, first encountered in August 2012, locations include: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, West Virginia, Wisconsin, and Wyoming.

ADB-FUBINACA: NFLIS—942 reports, first encountered in March 2014, locations include: Arkansas, California, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Missouri, New Jersey, New Mexico, New York, North Dakota, Ohio, Pennsylvania, Texas, Utah, Virginia, and Wyoming.

MDMB-CHMICA: NFLIS—227 reports, first encountered in March 2015, locations include: Arkansas, Georgia, Indiana, Kentucky, Louisiana, Nevada, Ohio, Oklahoma, South Carolina, and Texas.

MDMB-FUBINACA: NFLIS—507 reports, first encountered in July 2015, locations include: Arkansas, California, Colorado, Connecticut, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Wisconsin, and West Virginia.

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

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have all been

identified in overdose and/or cases involving death attributed to their abuse. Adverse health effects reported from these incidents involving 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA have included: nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness and/or cardio toxicity. Large clusters of overdoses requiring medical care have been reported involving 5F-AMB, MDMB-FUBINACA, MDMB-CHMICA and 5F-ADB. Reported deaths involving these SCs have included 5F-ADB (8); 5F-AMB (6); 5F-APINACA (1); ADB-FUBINACA (2); MDMB-CHMICA (4), European Monitoring Centre for Drugs and Drug Addiction has reported an additional 12 deaths involving MDMB-CHMICA; and MDMB-FUBINACA (1) (see factor 6 in “Supporting and Related Material”).

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 continued uncontrolled manufacture, distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA pose an imminent hazard to the public safety. The 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, 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 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA indicate that these SCs 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 section 201(h)(4) of the CSA, 21 U.S.C.

811(h)(4), the Administrator, through a letter dated April 22, 2016, notified the Assistant Secretary of the DEA’s intention to temporarily place these six substances in schedule I.

Conclusion

This notice of intent initiates a temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] in schedule I of the CSA, and finds that the placement of these substances into schedule I of the CSA on a temporary basis is necessary to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place these SCs into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication 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. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, research, conduct of instructional activities, and chemical analysis and possession of a schedule I controlled substance.

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. 21 U.S.C. 811. 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. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, 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 intention 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. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that 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. 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 the 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, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the 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 (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined

by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

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 Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 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), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(23) through (28) to read as follows:

§ 1308.11 Schedule I

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(h) * * *

(23) methyl 2-(1-(5-fluoropentyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-ADB; 5F-MDMB-PINACA)	(7034)
(24) methyl 2-(1-(5-fluoropentyl)-1 <i>H</i> -indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-AMB)	(7033)
(25) <i>N</i> -(adamantan-1-yl)-1-(5-fluoropentyl)-1 <i>H</i> -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-APINACA, 5F-AKB48)	(7049)
(26) <i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: ADB-FUBINACA)	(7010)
(27) methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MDMB-CHMICA, MMB-CHMINACA)	(7042)
(28) methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MDMB-FUBINACA)	(7020)

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Dated: December 13, 2016.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 57, 70, 72, and 75

[Docket No. MSHA-2014-0031]

RIN 1219-AB86

Exposure of Underground Miners to Diesel Exhaust

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for information; reopening of the comment period.

SUMMARY: In response to requests from the public, the Mine Safety and Health Administration (MSHA) is reopening the proposed rulemaking record for public comment on the Agency's request for information on Exposure of Underground Miners to Diesel Exhaust.

DATES: The comment period for the request for information, published on June 8, 2016 (81 FR 36826), and closed