statement is made: ''Comments to FAA Docket No. FAA–2018–1028; Airspace Docket No. 17–ASO–6.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018 and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to modify the description of VOR Federal airway V–18, in the vicinity of Talladega, AL, due to the planned decommissioning of the Talladega, AL, VOR/DME. The proposed route change is described below.

V–18: V–18 currently extends between the Guthrie, TX, VORTAC and the Charleston, SC, VORTAC. The FAA proposes to remove the airway segments between the Vulcan, AL, VORTAC and the Colliers, SC, VORTAC. This would result in a gap in the airway between Vulcan, AL, and Colliers, SC. Therefore, proposed amended V–18 route would consist of two separate sections: First, between the Guthrie, TX, VORTAC and the Vulcan, AL, VORTAC; and second, after the gap, the airway would resume between the Colliers, SC, VORTAC and the Charleston, SC, VORTAC.

Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document would be subsequently published in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 proposed rule, when promulgated, will 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 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 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–18 [Amended]

From Guthrie, TX, via INT Guthrie 156° and Millsap, TX, 274° radials; Millsap; Glen Rose, TX; Cedar Creek, TX; Quitman, TX; Belcher, LA; Monroe, LA; Magnolia, MS; Meridian, MS; Crimson, AL; to Vulcan, AL. From Colliers, SC; to Charleston, SC.

* * * * *

Issued in Washington, DC, on December 17, 2018.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2018–28107 Filed 12–27–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–491]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic cannabinoids (SCs), ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial name: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)

methanone (trivial name: FUB-144), in schedule I. This action is based on a finding by the Acting Administrator that the placement of these SCs in schedule I of the Controlled Substances Act (CSA) is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose regulatory requirements under the CSA on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of these SCs, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such requirements or otherwise violate the CSA with respect to these substances.

DATES: December 28, 2018.

FOR FURTHER INFORMATION CONTACT: Kathy L. Federico, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: This 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) placing 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I of the Controlled Substances Act (CSA).[1] The temporary scheduling order will be published in the **Federal Register** on or after January 28, 2019.

Legal Authority

Section 201 of the CSA provides the Attorney General 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 permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General 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 section 202 of the CSA,[4] 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).[5] The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA.[6]

Background

Section 201(h)(4) of the CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[7] The Acting Administrator transmitted notice of his intent to place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated August 24, 2018. The Assistant Secretary responded to this notice of intent by letter dated September 6, 2018, 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 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144. The Assistant Secretary also stated that HHS has no objection to the temporary placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 in schedule I of the CSA. 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 under section 505 of the FDCA.[8]

In order to place a substance temporarily in schedule I of the CSA 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): (1) The substance's history and current pattern of abuse; (2) the scope, duration and significance of abuse; and (3) what, if any, risk there is to the public health.[9] Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.[10]

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[11] Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use for treatment in the United States, and a lack of accepted safety for use under medical supervision.[12]

Synthetic Cannabinoids

The illicit use of SCs continues to cause severe adverse effects, overdoses and deaths in the United States. SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. SCs were introduced to 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, misuse 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. Recent hospital reports, scientific publications, and/or law enforcement reports demonstrate that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, FUB-144, and their associated designer drug products are being abused for their psychoactive properties (*see* DEA 3-Factor Analysis). As with many generations of SCs encountered since 2009, the abuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 is negatively impacting communities in the United States.

As noted 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,

[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.

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

[3] *Id.* at 811(h)(2).

[4] 21 U.S.C. 812.

[5] 21 U.S.C. 811(h)(1); 21 CFR part 1308(h).

[6] 28 CFR 0.100.

[7] 21 U.S.C. 811(h)(4); As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the 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).

[8] 21 U.S.C. 355.

[9] 21 U.S.C. 811(h)(3).

[10] *Id.*

[11] 21 U.S.C. 811(h)(1).

[12] 21 U.S.C. 812(b)(1).

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).

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have no accepted medical use in the United States. Use of 5F-MDMB-PICA, 5F-EDMB-PINACA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 has been reported to result in adverse effects in humans in the United States (*see* DEA 3-Factor Analysis). In addition, there have been multiple law enforcement seizures of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in the United States. Use of other SCs has resulted in signs of addiction and withdrawal. Based on the pharmacological similarities between 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 and other SCs, these five SCs are likely to produce signs of addiction and withdrawal similar to those produced by other SCs.

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are SCs that have pharmacological effects similar to the schedule I hallucinogen THC, and other temporarily and permanently controlled schedule I SCs. In addition, the misuse of 5F-CUMYL-PINACA, 5F-EDMB-PINACA and FUB-144 has been associated with multiple overdoses requiring emergency medical intervention (*see* DEA 3-Factor Analysis) while deaths have been reported that involved FUB-AKB48. With no approved medical use and limited safety or toxicological information, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 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.

Numerous SCs have been identified as product adulterants, and law enforcement has seized bulk amounts of these substances. As successive generations of SCs have been identified and controlled as schedule I substances, illicit distributors have developed new SC substances that vary only by slight modifications to their chemical structure while retaining pharmacological effects related to their abuse potential. These substances, and products laced with these substances, are marketed under the guise of ''herbal incense'' and promoted as a ''legal high'' with a disclaimer that they are ''not for human consumption.'' Thus, after section 1152 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, placed cannabimimetic agents and 26 specific substances (15 of these are SCs) into schedule I, law enforcement documented the emergence of new SCs including UR-144, XLR11, AKB48, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. After these substances were temporarily scheduled (78 FR 28735, May 16, 2013; 79 FR 7577, February 10, 2014) other generations of SCs appeared and were temporarily controlled, including AB-CHMINACA, AB-PINACA, THJ-2201 (80 FR 5042, January 30, 2015), MAB-CHMINACA (81 FR 6171, February 5, 2016), 5F-ADB, 5F-AMB, 5F-ABK48, ADB-FUBINACA, MDMB-CHMICA, MDMB-FUBINACA (82 FR 17119, April 10, 2017), FUB-AMB (82 FR 51154, November 3, 2017) NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA (83 FR 31877, July 10, 2018).

FUB-AKB48 was first identified in seized drug evidence in October 2013, followed by FUB-144 (January 2014), 5F-MDMB-PICA (October 2016), 5F-EDMB-PINACA (October 2017) and 5F-CUMYL-PINACA (February 2018). Following their manufacture in China, SCs are often encountered in countries including New Zealand, Australia, and Russia before appearing throughout Europe, and eventually in the United States. 5F-CUMYL-PINACA was first reported in the German and Swiss illicit drug market in 2015 but didn't show up in the United States until February 2018; 5F-EDMB-PINACA was reported in China in 2016 but didn't appear in the United States until October 2017; and 5F-MDMB-PICA was reported in Germany in August 2016 and November 2016 in Belgium, a few months before showing up in the United States. These data further support that based upon trends, SCs appear in the illicit drug markets of other countries including those in Europe, often before being trafficked in the United States. The misuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 has been associated with law enforcement seizures, overdoses requiring emergency medical intervention, or both (*see* DEA 3-Factor Analysis).

The powder form of SCs is typically dissolved in solvents (*e.g.,* acetone) before being applied to plant material, or dissolved in a propellant intended for use in electronic cigarette devices. In addition, 5F-EDMB-PINACA was identified as an adulterant on pieces of paper that were smuggled into a detention facility and later found partially burned (*see* DEA 3- Factor Analysis). 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 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 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 profile of these SCs have not been studied.

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, similar to other SCs, have been found in powder form or mixed with dried leaves or herbal blends that were marketed for human use. Presentations at emergency departments directly linked to the abuse of 5F-EDMB-PINACA and FUB-144 have included seizures, agitation, vomiting, tachycardia and elevated blood pressure (*see* DEA 3-Factor Analysis).

Factor 5. Scope, Duration and Significance of Abuse

SCs continue to be encountered in the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances

(*see* DEA 3-Factor Analysis). Novel substances continue to be encountered, differing only by small chemical structural modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products.

As described by 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 and the imminent threat to public safety following the ingestion of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 and other SCs persist.

Full reports of information obtained through STARLiMS,[13] STRIDE,[14] and NFLIS [15] for the past five years may be found in the DEA 3-Factor Analysis. According to NFLIS data, state and local forensic laboratories have detected the following information about the SCs in question:

- 5F-EDMB-PINACA was identified in 205 different NFLIS reports from five states since 2017,[16] and 16 STRIDE/STARLiMS reports from one state since 2017.
- 5F-MDMB–PICA was identified in 115 NFLIS reports from 18 states since 2016.
- FUB-AKB48 was identified in 342 NFLIS reports from 20 states since 2014, and 36 STRIDE/STARLiMS reports from eight states since 2013.
- 5F-CUMYL-PINACA was identified in three NFLIS reports from two states since 2018.
- FUB-144 was identified in 346 NFLIS reports from 26 states since 2014, 71 STARLiMS reports from 13 states plus Washington, DC since 2014.

[13] STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories. On October 1, 2014, STARLiMS replaced System to Retrieve Information from Drug Evidence (STRIDE) as the DEA laboratory drug evidence data system of record.

[14] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and some local law enforcement agencies.

[15] The National Forensic Laboratory Information System (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.

[16] At the time of query, 2017 data were still reporting.

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 5F-CUMYL-PINACA, 5F-EDMB-PINACA, FUB-144, FUB-AKB48, and 5F-MDMB-PICA are summarized below.

1. In 2015, in London (United Kingdom), a 34 year-old male was hospitalized after ingesting a synthetic cannabinoid product. Toxicological analysis identified 5F-AKB48 and 5F-CUMYL-PINACA in biological samples.

2. In September 2018, law enforcement in Georgia seized multiple electronic cigarettes with various colored viscous liquids following the reports of overdoses. Laboratory analysis on the seized evidence determined the substance to be 5F-CUMYL-PINACA.

3. In late November and early December 2015, in Jackson, MS, five individuals presented at local emergency facilities following ingestion of a synthetic cannabinoid-containing product. Evidence collected from the individuals tested positive for THC, MAB-CHMINACA and FUB-144. Toxicological analysis of biological samples in all five patients identified THC, MAB-CHMINACA, and FUB-144.

4. In March 2017, in Chaves, NM, a 14 year-old female was found in the bathroom of her home with seizure-like activity. Following transport to a local hospital by family members, she was pronounced dead approximately 20 minutes later. Toxicological analysis upon autopsy identified three SCs: FUB-AKB48, AB-CHMINACA, and ADB-CHMINACA (MAB-CHMINACA). The cause of death was determined to be toxic effects of synthetic cannabinoids (FUB-AKB48, AB-CHMINACA, and ADB-CHMINACA).

5. In January 2018, in Pittsburgh, PA, 13 correctional facility workers were treated for overdose symptoms including diaphoresis, hypertension and tachycardia following ingestion of an airborne substance while conducting cell searches for contraband. In response to the overdose events, evidence retrieved from the searches tested positive for the synthetic cannabinoids 5F-ADB, 5F-EDMB-PINACA, and 4-CN-CUMYL-BUTINACA.

6. In March 2018, in Chicago, IL, a 22 year-old male expired at a local hospital. Toxicological analysis confirmed buprenorphine, brodifacoum, bromadiolone, FUB-AMB and FUB-AKB48 in biological samples of this decedent.

7. In April 2018, in Harrisburg, PA, a 38-year old male presented at a local hospital due to repeated nosebleeds, gastrointestinal bleeding with anemia and bruising on his arms. Toxicological analysis confirmed brodifacoum, FUB-AMB, and FUB-AKB48 in biological samples.

8. In April 2018, in Harrisburg, PA, another patient presented at a local hospital due to significant bleeding and anemia requiring a transfusion. Toxicological analysis confirmed brodifacoum, FUB-AMB, and FUB-AKB48 in biological samples.

9. In June 2018, in Chicago, IL, a 25-year old male expired at a local hospital. Toxicological analysis confirmed brodifacoum, bromadiolone, FUB-AMB and FUB-AKB48 in biological samples of this decedent.

10. In July 2018, in Washington, DC, in excess of 260 overdoses and four deaths were reported following use of a synthetic cannabinoid product. Analysis of drug evidence from the overdose event confirmed the presence of the synthetic cannabinoids FUB-AMB, EMB-FUBINACA and FUB-144.

11. In August 2018, in New Haven, CT, in excess of 47 overdoses were reported following the use of a synthetic cannabinoid product. Analysis of drug evidence from the overdose event confirmed the presence of the synthetic cannabinoids 5F-ADB, FUB-AMB and 5F-MDMB-PICA.

12. From September 10–16, 2018, in Washington, DC, at least 244 overdoses were reported following use of a synthetic cannabinoid product. Analysis of drug evidence from the overdose event confirmed the presence of the synthetic cannabinoids FUB-AMB and 5F-MDMB-PICA.

Because they share pharmacological similarities with schedule I substances (Δ^9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 pose serious 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. 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.

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 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) and based on the data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144, resulting from the lack of control of these substances, pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in the United States. A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[17] 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.[18] Available data and information for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 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,[19] the Acting Administrator, through a letter dated August 24, 2018, notified the Assistant Secretary for Health of the DEA's intention to temporarily place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in schedule I and considered the Assistant Secretary's response.

Conclusion

This notice of intent provides the 30-day notice, pursuant to section 201(h) of the CSA,[20] of the DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h) of the CSA, the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial name: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone (trivial name: FUB-144) in schedule I of the CSA and finds that placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in schedule I of the CSA on a temporary basis is necessary to avoid an imminent hazard to the public safety.

The temporary placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before January 28, 2019. Because the Acting Administrator hereby finds that it is necessary to temporarily place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling these substances will be effective on the date that 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.[21] It is the intention of the Acting 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, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 will be subject to the 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, 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.[22] 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.[23] Temporary scheduling orders are not subject to judicial review.[24]

Regulatory Matters

Section 201(h) of the CSA provides for a 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 of HHS.[25]

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)[26] 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 Acting 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

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

[18] 21 U.S.C. 812(b)(1).

[19] 21 U.S.C. 811(h)(4).

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

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

[22] 21 U.S.C. 811.

[23] 21 U.S.C. 877.

[24] 21 U.S.C. 811(h)(6).

[25] 21 U.S.C. 811(h)(1).

[26] 5 U.S.C. 553.

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 Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to section 811(h)(4).

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), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(37) through (41) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(37) thyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: 5F-EDMB-PINACA)-(7036)

(38) methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: 5F-MDMB-PICA)-(7041)

(39) *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL))-(7047)

(40) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (trivial names: 5F-CUMYL-PINACA; SGT-25)-(7083)

(41) (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: FUB-144)-(7014)

Dated: December 20, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018–28110 Filed 12–27–18; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–115420–18]

RIN 1545–BP03

Investing in Qualified Opportunity Funds; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains a correction to notice of proposed rulemaking and notice of public hearing (REG–115420–18) that was published in the **Federal Register** on Monday, October 29, 2018. The proposed regulations are providing guidance under new section 1400Z–2 of the Internal Revenue Code relating to gains that may be deferred as a result of a taxpayer's investment in a qualified opportunity fund.

DATES: Written or electronic comments and request for a public hearing for the notice of proposed rulemaking at 83 FR 54279, October 29, 2018, are still being accepted and must be received by December 28, 2018.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Erika C. Reigle of the Office of Associate Chief Counsel (Income Tax and Accounting), (202) 317–7006 and Kyle C. Griffin of the Office of Associate Chief Counsel (Income Tax and Accounting), (202) 317–4718; concerning the submission of comments, the hearing, or to be placed on the building access list to attend the hearing, Regina L. Johnson, (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking and notice of public hearing that is subject of this document is under section 1400Z–2 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking and notice of public hearing (REG–115420–18) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the notice of proposed rulemaking and notice of public hearing, FR Doc. 2018–23382, published at 83 FR 54279, October 29, 2018, is corrected as follows:

1. On page 54285, second column, in the preamble, the twelfth line of the first full paragraph, the language ''1400Z–2(d)](2)(D)). is corrected to read ''1400Z–2(d)(2)(D)).''.

2. On page 54285, second column, in the preamble, the last line of the first full paragraph, the language ''section 1400Z–2(d)(2)(B)(ii)(III).'' is corrected to read ''section 1400Z–2(d)(2)(B)(i)(III) and section 1400Z–2(d)(2)(C)(iii).''.

§ 1.400Z2(e)–1 [Corrected]

3. On page 54296, third column, the eleventh line of paragraph (a)(3)(i), the language ''§ 1.752–3(a)'' is corrected to read ''section 752 and the regulations thereunder,''

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2018–28207 Filed 12–27–18; 8:45 am]

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