



BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-385]

**Schedules of Controlled Substances: Temporary Placement of Four Synthetic
Cannabinoids Into Schedule I**

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule four synthetic cannabinoids into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA).

The substances are: quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids and their optical, positional, and geometric isomers, salts and salts of isomers into schedule I of the CSA is necessary to avoid an 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 will be imposed on persons who handle (manufacture, distribute, import, export,

engage in research, conduct instructional activities, and possess), or propose to handle these synthetic cannabinoids.

DATES: This final order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 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. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. 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, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the 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 he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). 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 his authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, Appendix to Subpart R of Part 0, Sec. 12.

Background

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.¹ The Deputy Administrator

¹ Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.” As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within the HHS in carrying out the Assistant Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

transmitted notice of his intent to place PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into schedule I on a temporary basis to the Assistant Secretary by letter dated November 7, 2013. The Assistant Secretary responded to this notice by letter dated January 27, 2014, and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into schedule I of the CSA.

The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). As PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA under section 505 of the FDCA , 21 U.S.C. 355, the conditions of 21 U.S.C. 811(h)(1) have been satisfied. As required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule these four synthetic cannabinoids was published in the Federal Register on January 10, 2014. 79 FR 1776.

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 Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 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 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). Available data and information for PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA indicate that these four synthetic cannabinoids 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

Synthetic cannabinoids are a large family of compounds that are functionally (biologically) similar to delta9-tetrahydrocannabinol (THC), the main active ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory. Two of the synthetic cannabinoids currently controlled (CP-47,497 and cannabicyclohexanol) were first synthesized in the early 1980's for research purposes in the investigation of the cannabinoid system. JWH-018, JWH-073, and JWH-200 (temporarily scheduled on March 1, 2011, at 76 FR 11075 and permanently scheduled on July 9, 2012, by Section 1152 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112-144) were synthesized in the mid-1990s and studied to further advance the understanding of drug-receptor interactions regarding the cannabinoid system. Synthesized as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids.

According to forensic laboratory reports, the initial appearance of synthetic cannabinoids in herbal incense products in the United States occurred in November 2008

when U.S. Customs and Border Protection (CBP) first encountered products using brand names such as “Spice.” Prior to appearing on the U.S. market, synthetic cannabinoids were marketed in herbal incense products in several European countries. After experiencing numerous health-related incidents, some European countries banned these products/chemicals. According to CBP, a number of the synthetic cannabinoids appeared to originate from foreign sources.

Detailed chemical analyses by DEA and other agencies have found synthetic cannabinoids applied on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the type of synthetic cannabinoid and the amount of the substance found on the plant material.

The vast majority of cannabinoids are manufactured in Asia by individuals who are not bound by any manufacturing requirements or quality control standards. The bulk products are smuggled into the United States typically as misbranded imports. These chemicals are generally found in powder form or are dissolved in solvents, such as acetone, before being applied to the plant material comprising the “herbal incense” products. After local distributors apply the drug to the leafy material, they package it for retail distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of drug in each package. According to Internet discussion boards and law enforcement encounters, spraying or mixing the synthetic cannabinoids on plant material provides a vehicle for the most common route of administration- smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers). They are sold under hundreds of different brand names, including “Spice,” “K2,” “Blaze,” “Red X Dawn,”

“Paradise,” “Demon,” “Black Magic,” “Spike,” “Mr. Nice Guy,” “Ninja,” “Zohai,” “Dream,” “Genie,” “Sence,” “Smoke,” “Skunk,” “Serenity,” “Yucatan,” “Fire,” and “Crazy Clown.”

Law enforcement personnel have encountered dosage form and packaging operations in residential neighborhoods, garages, and warehouses. Throughout this process, there is no concern for preventing contamination of the product, consistent dosage, or the adverse health consequences that may occur from ingesting the drug. As proposed in the scientific literature, the risk of adverse health effects is further increased by the fact that similarly labeled products vary in the composition and concentration of synthetic cannabinoids applied on the plant material.

There is an incorrect assumption that these products are safe. Numerous states, local jurisdictions, and the international community have controlled many synthetic cannabinoids. These substances have no accepted medical use in the United States and have been reported to produce adverse health effects in those who abuse them.

PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA are synthetic cannabinoids that have pharmacological effects similar to the schedule I hallucinogen delta-9-tetrahydrocannabinol (THC). PB-22 and 5F-PB-22 were not reported in the scientific literature prior to their appearance on the illicit drug market. First appearing in a 2009 patent filed by the pharmaceutical manufacturer Pfizer, AB-FUBINACA was most recently reported in the scientific literature as a component of so-called “herbal products” purchased via the Internet in July 2012. ADB-PINACA was first encountered by law enforcement following reports of serious adverse events in Georgia and Colorado in August and September 2013, respectively.

From January through December 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE)² there were 211 reports involving PB-22, 168 reports involving 5F-PB-22, and 74 reports involving AB-FUBINACA (Queried on January 22, 2014). From January through December 2013, the National Forensic Laboratory Information System (NFLIS)³ registered 1,318 reports containing PB-22 in 29 states, 1,294 reports containing 5F-PB-22 in 29 states, 822 reports containing AB-FUBINACA in 21 states and 40 reports containing ADB-PINACA in three states (Queried on January 22, 2014). No reports in NFLIS or STRIDE were identified for PB-22 or 5F-PB-22 prior to January 2013. No reports in NFLIS or STRIDE were identified for AB-FUBINACA prior to June 2013 or for ADB-PINACA prior to August 2013.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed over the last 30 years as tools for investigating the cannabinoid system. Synthetic cannabinoids intended for illicit use were first reported in the United States in a November 2008 encounter, where a shipment of “Spice” was seized and analyzed by CBP in Dayton, Ohio. Additionally around the same time, in December 2008, JWH-018 and cannabicyclohexanol (CP-47,497 C8 homologue) were identified by German forensic laboratories. Since the initial identification of JWH-018, many additional synthetic cannabinoids have been found applied on plant material and encountered as designer drug products. The majority of the substances encountered on the illicit market have not been tested beyond preliminary pre-clinical laboratory screens before clandestine operators apply them on plant material.

² 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 local law enforcement agencies.

³ NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country.

JWH-018 was the first synthetic cannabinoid to be identified as a product adulterant in Germany in 2008. This substance was initially synthesized as a research tool to investigate the cannabinoid system. Since then, numerous other synthetic cannabinoids have been identified as product adulterants and law enforcement has seized bulk amounts of these substances. The first synthetic cannabinoids identified as being abused included JWH-018, JWH-200, JWH-073, CP-47,497 and CP-47,497 C8 homologue, followed shortly thereafter by new generations of synthetic cannabinoids that included AM2201 and others, and eventually UR-144, XLR11 and AKB48. JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 were temporarily scheduled on March 1, 2011 (76 FR 11075), and later permanently placed in schedule I by Section 1152 of FDASIA on July 9, 2012. Section 1152 of FDASIA amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 synthetic phenethylamines of the 2C-series) in schedule I. UR-144, XLR11 and AKB48 were temporarily scheduled on May 16, 2013 (78 FR 28735). The most recent synthetic cannabinoids emerging as drugs of abuse include PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. These four synthetic cannabinoids, along with UR-144, XLR11 and AKB48, were not included among the 15 specific named synthetic cannabinoids, and do not fall under the definition of cannabimimetic agents, under FDASIA.

Synthetic cannabinoid products are marketed directly to adolescents and youth who appear to be the primary abusers of synthetic cannabinoids and synthetic cannabinoid-containing products. This is supported by law enforcement encounters and reports from emergency rooms; however, all age groups have been reported by media as abusing these substances and related products.

According to recent testimony given by the Deputy Director of the Office of National Drug Control Policy (ONDCP) to the United States Senate Caucus on International Narcotics Control (September 25, 2013), current drug testing misses significant populations of synthetic cannabinoid users. This testimony describes a study showing that in a sample of men 30 years old or younger within the District of Columbia parole and probation system, 39 percent of those who cleanly passed a traditional drug screen tested positive for synthetic cannabinoids. The study continued that between one-quarter and one-third of young men who were tested in the Washington, D.C. criminal justice system had positive test results for synthetic cannabinoids, regardless of whether they had failed or passed a traditional drug screen.

Factor 5. Scope, Duration and Significance of Abuse

Recently, increased exposure incidents have been documented by poison control centers in the United States as the abuse of synthetic cannabinoids has been associated with both acute and long-term public health and safety concerns. From January through December 2013, according to STRIDE there were 211 reports involving PB-22; 168 reports involving 5F-PB-22; and 74 reports involving AB-FUBINACA (Queried on January 22, 2014). From January through December 2013, NFLIS registered 1,318 reports containing PB-22 in 29 states (Arkansas, Arizona, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, Wisconsin and Wyoming); 1,294 reports containing 5F-PB-22 in 29 states (Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota,

Missouri, North Dakota, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming); 822 reports containing AB-FUBINACA in 21 states (Arizona, Colorado, Connecticut, Florida, Georgia, Iowa, Indiana, Kansas, Louisiana, Minnesota, Missouri, North Dakota, New Hampshire, New Jersey, Nevada, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas and Wisconsin); and 40 reports containing ADB-PINACA in three states (Colorado, Georgia and Wisconsin) (Queried on January 22, 2014). No reports in NFLIS or STRIDE were identified for PB-22 or 5F-PB-22 prior to January 2013. No reports in NFLIS or STRIDE were identified for AB-FUBINACA prior to June 2013 or for ADB-PINACA prior to August 2013.

ADB-PINACA was first encountered in the United States following reports of serious adverse events in Georgia on August 23, 2013. Reports of ADB-PINACA were not found in the scientific literature prior to its emergence on the designer drug market. The Georgia Bureau of Investigation (GBI) reported on September 12, 2013, that ADB-PINACA was detected in “herbal incense” products sold under the brand name “Crazy Clown.” It was later confirmed by the Centers for Disease Control and Prevention (CDC) as the substance responsible for severe adverse events in at least 22 persons who consumed the product. In addition, on August 30, 2013, the Colorado Department of Public Health and Environment (CDPHE) was notified by several hospitals of an increase in the number of patients visiting their emergency departments (EDs) with altered mental status after using “synthetic marijuana.” CDC 2013. On September 8, 2013, CDPHE, with the assistance of CDC, began an epidemiologic investigation whereby 221 cases of severe illness due to ingestion of a synthetic cannabinoid were identified. Those that presented at emergency rooms in the

Denver, Colorado area around September 1, 2013, had symptoms similar to those found in the August 2013 Georgia incident. Laboratory analysis of samples from the Colorado incident confirmed that the substance abused in the “herbal incense” products was ADB-PINACA.

The American Association of Poison Control Centers (AAPCC) reported receiving over 2,639 calls from January to December 2013, regarding exposures to products purportedly containing synthetic cannabinoids, although the data provided does not generally include biological sample testing that would confirm to which cannabinoids the user was exposed. A majority of these exposure incidents resulted in individuals seeking medical attention at health care facilities.

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

The earliest reported encounter of PB-22 was by Finnish Customs (Tulli) in Helsinki who intercepted a consignment of 54 kilograms en route from China to Russia on October 27, 2012. From January through November 2013, CBP shared information related to synthetic cannabinoid shipments encountered at United States Ports of Entry and intended for destinations within the United States: PB-22 – 25 encounters involving 69.6 kg; 5F-PB-22 – 23 encounters involving 32.9 kg; and AB-FUBINACA – 9 encounters involving 16.1 kg. The DEA has reported multiple encounters of large quantities of PB-22, 5F-PB-22 and/or AB-FUBINACA that have been confirmed by forensic laboratories (STRIDE).

In late August 2013, local law enforcement in Brunswick, Georgia reported that 22 persons ranging in age from 16 to 57 presented to emergency departments with severe adverse reactions after consuming a synthetic product called “Crazy Clown.” Adverse effects included the inability to stand, foaming at the mouth, violence towards police and

paramedics and memory lapse. The substance responsible for these effects was later identified by the GBI as ADB-PINACA. In early September 2013, 221 patients presented to emergency departments in Colorado after having adverse reactions to a synthetic product labeled as “Black Mamba.” Adverse effects included having no gag reflex, inability to breathe on their own, hallucinations and psychotic episodes as described by nurses and attending physicians. The substance in the product consumed was identified as ADB-PINACA. In addition to the incidents in Georgia and Colorado, ADB-PINACA was also identified in exhibits of plant material labeled “10X” and “20X” submitted to a laboratory in Illinois on October 7, 2013.

Health warnings have been issued by numerous state public health departments and poison control centers describing adverse health effects associated with smoking (inhaling) synthetic cannabinoid products including agitation, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations, and non-responsiveness.

Medical examiner and postmortem toxicology reports demonstrate the involvement of 5F-PB-22 in the death of at least five individuals. These reports demonstrated that 5F-PB-22 was qualitatively identified in the blood and/or urine of all five of the deceased individuals. In addition, 5F-PB-22 intoxication was the sole cause of death in one case, while a second case stated that the cause of death was a fatal cardiac arrhythmia and/or fatal seizure in association with the use of 5F-PB-22.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. There are no recognized therapeutic uses of these substances in the United States.

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

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these synthetic cannabinoids in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed into 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 PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA indicate that these four synthetic cannabinoids 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 Deputy Administrator, through a letter dated November 7, 2013, notified the Assistant Secretary of the intention to temporarily place these four synthetic cannabinoids in schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily place four synthetic cannabinoids, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into schedule I of the CSA, and finds that placement of these synthetic cannabinoids into schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into schedule I to avoid an imminent hazard to the public safety, the 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).

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).

Requirements for Handling

Upon the effective date of this final order, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, importing, exporting, research, conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities with, or possesses), or desires to handle,

PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, 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 [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, and is not registered with the DEA, must submit an application for registration and may not continue to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, 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.

2. *Security.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71-1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

3. *Labeling and Packaging.* All labels and labeling for commercial containers of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] to comply with all labeling and packaging requirements.

4. *Inventory.* Every DEA registrant who possesses any quantity of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA on the effective date of this order, must take an inventory of all stocks of these substances on hand as of [INSERT DATE OF

PUBLICATION IN FEDERAL REGISTER], pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Current DEA registrants shall 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 PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA) on hand on a biennial basis, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. *Records.* All DEA registrants must maintain records with respect to PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304, 1307, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants authorized to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

6. *Reports.* All DEA registrants who manufacture or distribute PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

7. *Order Forms.* All registrants who distribute PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Importation and Exportation.* All importation and exportation of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Quota.* Only registered manufacturers may manufacture PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

10. *Criminal Liability.* Any activity involving PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

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 a proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 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 temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Deputy 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. Further, the DEA believes that this temporary scheduling action final order 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 (OMB).

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.

Pursuant to section 808(2) of the Congressional Review Act (CRA), “any rule for which an agency for good cause finds...that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to

schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety from new or designer drugs or abuse of those drugs. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances into schedule I because they pose a threat to public health, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order shall take effect immediately upon its publication.

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, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

2. Amend § 1308.11 by adding paragraphs (h)(15) through (h)(18) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(15) Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers – 7222 (Other names: PB-22; QUPIC)

(16) Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers – 7225 (Other names: 5-fluoro-PB-22; 5F-PB-22)

(17) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers – 7012 (Other names: AB-FUBINACA)

(18) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers – 7035 (Other names: ADB-PINACA)

Dated: February 5, 2014

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2014-02848 Filed 02/07/2014 at 8:45 am; Publication Date: 02/10/2014]