(r)(1)(iii) of this AD, if those actions were performed before the effective date of this AD using Messier-Dowty Service Bulletin A33/34–32–284, including Appendix A, dated May 11, 2010, which is not incorporated by reference in this AD.

(9) This paragraph provides credit for the corresponding actions required by paragraphs (n)(1) and (r)(1)(ii) of this AD, if those actions were performed before the effective date of this AD using Messier-Dowty Service Bulletin A33/34–32–278, including Appendixes A and B, dated February 17, 2010, which is not incorporated by reference in this AD.

(q) Clarification of Inspection Compliance Times

After accomplishment of the one-time detailed inspection required by paragraph (h) of this AD, the repetitive actions required by paragraph (g) of this AD remain applicable, and must be done within the compliance times specified in paragraph (g) of this AD.

(r) Parts Installation Limitations

(1) After modification of an airplane, as required by paragraph (k) of this AD, or as specified in paragraphs (n)(1) and (n)(2) of this AD, do not install an MLG bogie beam on any airplane unless it is done in compliance with the requirements of paragraph (r)(1)(i), (r)(1)(ii), or (r)(1)(iii) of this AD.

(i) The MLG bogie beam has been modified and re-identified in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–32–3237 or A340–32–4279, both Revision 1, both dated October 14, 2011, as applicable.

(ii) The MLG bogie beam has been inspected and all applicable corrective actions have been done in accordance with the Accomplishment Instructions of Messier-Dowty Service Bulletin A33/34–32–278, Revision 1, dated August 24, 2011; and modified in accordance with the Accomplishment Instructions of Messier-Dowty Service Bulletin A33/34–32–283 or A33/34–32–284, both Revision 1, both dated July 10, 2012.

(iii) The MLG bogie beam has a serial number listed in Appendix A of Messier-Dowty Service Bulletin A33/34–32–283 or A33/34–32–284, both Revision 1, both dated July 10, 2012.

(2) As of the effective date of this AD, except as specified in paragraph (r)(1) of this AD, installation of an MLG bogie beam on an airplane is allowed, provided that following the installation it is inspected and all applicable repairs and corrective actions have been done in accordance with the requirements of this AD.

(s) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) AD 2013–0267R1, dated March 4, 2014, corrected March 8, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0828.

(2) For Airbus service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.*

(3) For Messier-Dowty service information identified in this AD, contact Messier-Dowty: Messier Services Americas, Customer Support Center, 45360 Severn Way, Sterling, VA 20166–8910; telephone 703–450–8233; fax 703–404–1621; Internet *https://techpubs.services/messier-dowty.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 27, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–02161 Filed 2–4–16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–433]

Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 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), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This proposed scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Comments must be submitted electronically or postmarked on or before March 7, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before March 7, 2016.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–433'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement

Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).'' 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing held in relation to this rulemaking is restricted to: ''(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.'' All requests for hearing and waivers participation must be sent to the DEA using the address information provided above.

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), 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, 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 scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal

[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 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.

sanctions of schedule I controlled substances on any person who handles or proposes to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

Background

On February 10, 2014, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place 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) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 7577. That final order, which became effective on the date of publication, was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these four synthetic cannabinoids (SCs) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). At the time the final order took effect, section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), required that the temporary scheduling of a substance expire at the end of two years from the date of issuance of the scheduling order, and it provided that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance could be extended for up to 1 year. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of PB-22; QUPIC, 5F-PB-22, AB-FUBINACA, and ADB-PINACA expires on February 9, 2016, unless extended. An extension of the temporary order is being ordered by the DEA Administrator in a separate action.

These four SCs have not been investigated for medical use nor are they intended for human use. With no known legitimate use and safety information, manufacturers are surreptitiously adulterating plant material with these SCs and distributors are selling the associated products which pose potentially dangerous consequences to the consumer.

The Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) has advised that there are no exemptions or approvals in effect for PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA under section 505 (21 U.S.C. 355) of the Federal Food, Drug, and Cosmetic Act. As stated by the HHS, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA have no known accepted medical use. They are not the subject of any approved new drug applications (NDAs) or investigational new drug applications (INDs), and are not currently marketed as approved drug products. The HHS recommends that PB-22, 5F-PB-22, AB-FUBINACA, ADB-PINACA, and their salts be placed into schedule I of the Controlled Substances Act (CSA).

Proposed Determination To Schedule PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by the Attorney General, or her delegate, the DEA Administrator. On December 30, 2014, the DEA requested scientific and medical evaluations and scheduling recommendations from the Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) for PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA pursuant to 21 U.S.C. 811(b). Upon receipt of the scientific and medical evaluations and scheduling recommendations from the HHS dated January 19, 2016, the DEA reviewed the documents and all other relevant data and conducted its own eight-factor analysis of the abuse potential of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its proposed scheduling action. Please note that both the DEA 8-Factor and HHS 8-Factor analyses and the Assistant Secretary's January 19, 2016, letter, are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *http://www.regulations.gov,* under Docket Number ''DEA–433.''

1. *The Drug's Actual or Relative Potential for Abuse:* The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests that the DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse [2]:

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Review of scientific and medical literature indicates that the ingestion of synthetic cannabinoids leads to adverse health effects. Specifically, adverse effects following ingestion have included: Seizures, neurotoxicity and death for PB-22; respiratory failure, organ failure, and death for 5F-PB-22; diaphoresis, nausea, confusion, tachycardia and death for AB-FUBINACA; and anxiety, delirium, psychosis, aggression, seizures and death for ADB-PINACA.

The American Association of Poison Control Centers (AAPCC) has reported 7,779 exposures to SCs from January 1 through December 31, 2015. The significance of this value is based upon reporting of human exposures to SCs since 2011. While 2012–2014 saw a reduction in exposure calls to the AAPCC, 2015 records demonstrate resurgence in calls to poison centers regarding SCs. In addition, the largest monthly tally ever recorded by AAPCC in reference to SCs occurred in April 2015, with 1,511 calls.

The HHS stated that there are no FDA-approved drug products containing PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in the United States and there appear to be no legitimate sources for these substances as marketed drugs. According to the HHS, because PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA are not approved for medical use and are not formulated or available for clinical use, the human use of these substances is assumed to be on an individual's own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer drugs. Further, AAPCC reports, published scientific and medical literature, and law enforcement reports indicate that individuals are

[2] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

taking these SCs on their own initiative, rather than on the medical advice of a licensed practitioner. As noted by the HHS, pharmacological studies sponsored by NIDA have demonstrated that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are similar to other schedule I SCs. All four of these substances, similar to other schedule I SCs, display high affinity binding and potent agonist functional activity at the cannabinoid (CB1) receptor, while drug discrimination studies have demonstrated the ability of all four substances to substitute for delta-9-tetrahydrocannabinol (THC) (see Factor 2). The results supporting CB1 agonist activity of PB-22 and 5F-PB-22 are consistent with the similar findings reported in published literature.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* In vitro receptor binding and functional assays were conducted with PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. In addition, drug discrimination assays using Sprague Dawley rats were performed to identify drugs with similar subjective effects to THC. These results indicate that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA, similar to other schedule I SCs, bind to CB1 receptors with high affinity and act as agonists at CB1 receptors.

Based on results from the receptor binding (Ki), CB1 functional assay, and drug discrimination studies, the HHS concluded that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA act as full psychoactive cannabinoid agonists with no antagonist activity and that these four substances are more potent than THC, the principal psychoactive chemical in marijuana (schedule I), and are similar in activity to JWH-018 (schedule I).

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* The DEA is not aware of any currently accepted medical uses for PB-22, 5F-PB-22, AB-FUBINACA or ADB-PINACA. A letter dated November 7, 2013 was sent from the DEA Deputy Administrator to the Assistant Secretary for Health of the Department for Health and Human Services as notification of intent to temporarily place these four substances in schedule I and solicited information, including whether there was an exemption or approval in effect for the substances in question under the Federal Food, Drug and Cosmetic Act. The Assistant Secretary of Health responded that there were no current INDs or NDAs for these synthetic cannabinoids in a letter to the DEA Assistant Administrator dated January 27, 2014. The scientific and medical evaluations provided by the HHS also stated that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA have no currently accepted medical use. These SCs are not the subject of an approved NDAs or INDs, and are not currently marketed as approved drug products. In recent overdoses, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA have been found to be laced on green plant material, similar to the SCs that have been previously encountered.

4. *Its History and Current Pattern of Abuse:* Since the initial identification of JWH-018 (November 2008), many additional synthetic cannabinoids have been found to be applied on plant material and encountered as designer drug products. A major concern, as reiterated by public health officials and medical professionals, remains the targeting and direct marketing of SCs and SC-containing products to adolescents and youth. The Monitoring the Future project, begun in 1975, studies changes in beliefs, attitudes, and behavior of young people in the United States. While the Monitoring the Future survey reported decreases in prevalence amongst 8th, 10th, and 12th grade students over the past two years, AAPCC reports for SCs in 2015 were the highest observed since reporting began in 2011. Reports in 2015 more than doubled compared to those shown for 2011. Smoking mixtures of these substances abused for the purpose of achieving intoxication has resulted in numerous emergency department visits and calls to poison control centers. As reported by the AAPCC, adverse effects including severe agitation, anxiety, racing heartbeat, high blood pressure, nausea, vomiting, seizures, tremors, intense hallucinations, psychotic episodes, suicide, and other harmful thoughts and/or actions can occur following ingestion of SCs. Presentations at emergency departments directly linked to the abuse of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA have resulted in similar symptoms, including severe agitation, seizures, and/or death.

5. *The Scope, Duration, and Significance of Abuse:* PB-22 and 5F-PB-22 are synthetic cannabinoids that have pharmacological effects similar to the schedule I hallucinogen THC. PB-22 and 5F-PB-22 were not reported in the scientific literature prior to their appearance on the illicit drug market. A report from March 2013 identified PB-22 as a component of dried plant material obtained via the Internet between July 2012 and January 2013 in Japan.

AB-FUBINACA is also a synthetic cannabinoid that has pharmacological effects similar to the schedule I hallucinogen THC. First appearing in a 2009 patent filed by the pharmaceutical manufacturer Pfizer, AB-FUBINACA was first 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 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 with altered mental status after using synthetic cannabinoids. On September 8, 2013, the CDPHE, with the assistance of the 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 AAPCC report published on April 23, 2015 showed a marked spike in poison center exposure calls throughout the United States in 2015 related to SCs. The AAPCC reported 1,512 exposure calls in April 2015, representing an almost three-fold increase in exposures to SCs as compared to the previous largest monthly tally (657 exposures in January 2012) since reporting began in 2011. For the first time since reporting began by the AAPCC in 2011, the number of SC cases in 2015 has dramatically risen, more than doubling those reported in 2014. The numbers of SC cases reported in 2015 were the highest ever recorded.

6. *What, if Any, Risk There is to the Public Health:* As stated by the HHS, based solely on their pharmacological similarity to JWH-018 and THC and their potency, the subjective risks to the

public health of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are similar to those of other SCs, which are controlled in schedule I of the CSA. Warnings regarding the dangers associated with abuse of synthetic cannabinoids and their products have been issued by numerous state public health departments and poison control centers and private organizations. Some of the common clinical effects reported in emergency rooms in response to the abuse of synthetic cannabinoids include vomiting, anxiety, agitation, irritability, seizures, hallucinations, tachycardia, elevated blood pressure, and loss of consciousness.

At least ten deaths have been reported involving the four SCs, including at least 3 involving PB-22, 5 involving 5F-PB-22, 1 involving AB-FUBINACA, and 1 involving ADB-PINACA. As mentioned above, there are reported instances of emergency department admissions in association with the abuse of PB-22 and 5F-PB-22. Additional deaths involving a variety of SCs have been reported, along with additional instances of severe toxic effects following ingestion of SCs.

7. *Its Psychic or Physiological Dependence Liability:* As stated by the HHS, PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA have pharmacological profiles that are similar to other schedule I SCs. Thus it is reasonable to assume that PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA possess physiological and psychological dependence liability that is similar to that of other schedule I cannabinoids (THC and JWH-018). While PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA are pharmacologically related to JWH-018, no studies regarding the psychic or physiological dependence liability of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA have been identified.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are not considered an immediate precursor of any controlled substance of the CSA.

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS's recommendation, and the DEA's own eight-factor analysis, the DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA. As such, the DEA hereby proposes to schedule PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA have a high potential for abuse that is comparable to other schedule I substances such as delta 9-tetrahydrocannabinol (THC) and JWH-018;

2. PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA have no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA under medical supervision.

Based on these findings, the Administrator of the DEA concludes that 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)-1H-indazole-3-carboxamide (AB-FUBINACA), and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA), including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA

If this rule is finalized as proposed, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA would continue [3] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, or who desires to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, would be required to 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.

2. *Security.* PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823 and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA would need to be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers would be permitted to 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.

5. *Inventory.* Any person who becomes registered with the DEA after the effective date of the final rule must take an initial inventory of all stocks of controlled substances (including PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA would be required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA would need to be in

[3] PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 79 FR 7577, Feb. 10, 2014.

compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On February 10, 2014, the DEA published a final order to temporarily place these four SCs into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA estimates that all entities handling or planning to handle these SCs have already established and implemented the systems and processes required to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA. There are currently 25 registrations authorized to handle PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 25 registrations represent 18 entities, of which 8 are small entities. Therefore, the DEA estimates eight small entities are affected by this proposed rule.

A review of the 25 registrations indicates that all entities that currently handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the eight affected small entities. Therefore, the DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* the DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.11:

■ a. Add new paragraphs (d)(48) through (d)(51); and

■ b. Remove paragraphs (h)(7) through (10); and

■ c. Redesignate paragraphs (h)(11) through (24) as (h)(7) through (20).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(48) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22)	(7222)
(49) quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	(7225)
(50) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	(7012)
(51) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	(7035)

* * * * *

Dated: February 2, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–02305 Filed 2–4–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2015–1055]

RIN 1625–AA08

Special Local Regulation; Charleston Race Week, Charleston Harbor, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation on the waters of Charleston Harbor in Charleston, SC during the Charleston Race Week from April 15, 2016 through April 17, 2016. This special local regulation is necessary to ensure the safety of participants, spectators, and the general public during the event. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before March 7, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2015–1055 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *John.Z.Downing@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code
COTP Captain of the Port

II. Background, Purpose, and Legal Basis

On November 18, 2015, the Charleston Ocean Racing Association notified the Coast Guard that it will be sponsoring a series of sailboat races from 8:30 a.m. to 5 p.m. from April 15, 2016 through April 17, 2016. The legal basis for the proposed rule is the Coast Guard's Authority to establish special local regulations: 33 U.S.C 1233. The purpose of the proposed rule is to ensure safety of life on the navigable water of the United States during the Charleston Race Week.

III. Discussion of Proposed Rule

The COTP proposes to establish a special local regulation on the waters of Charleston Harbor in Charleston, South Carolina during Charleston Race Week. The races are scheduled to take place from Friday, April 15, 2016 through Sunday, April 17, 2016. Approximately 285 sailboats are anticipated to participate in the races, and approximately 30 spectator vessels are expected to attend the event. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and executive orders.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a ''significant regulatory action,'' under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget. This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The economic impact of this proposed rule is not significant for the following reasons: (1) Non-participant persons and vessels may enter, transit through, anchor in, or remain within the regulated area during the enforcement periods if authorized by the Captain of the Port Charleston or a designated representative; (2) vessels not able to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port Charleston or a designated representative may operate in the surrounding areas during the enforcement period; and (3) the Coast Guard will provide advance notification of the special local regulation to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, (5 U.S.C. 601–612), as amended requires Federal agencies to consider the potential impact of regulations on ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. We have considered the impact of this proposed rule on small entities. This rule may affect the following entities, some of which may be small entities: the owner or operators of vessels intending to enter, transit through, anchor in, or remain within the regulated area during the enforcement period. For the reasons discussed in Regulatory Planning and Review section above, this rule will not have a