reported with respect to a Fund's Highly Liquid Investment Minimum (Item B.7), derivatives transactions (Item B.8), country of risk and economic exposure (Item C.5.b), delta (Items C.9.f.v, C.11.c.vii, or C.11.g.iv), liquidity classification for portfolio investments (Item C.7), or miscellaneous securities (Part D), or explanatory notes related to any of those topics (Part E) that is identifiable to any particular fund or adviser. However, the SEC may use information reported on this Form in its regulatory programs, including examinations, investigations, and enforcement actions.

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Part B: Information About the Fund

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Item B.2.f. Cash and cash equivalents not reported in Parts C and D.

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Item B.8 Derivatives Transactions. For portfolio investments of open-end management investment companies, provide the percentage of the Fund's Highly Liquid Investments that it has segregated to cover or pledged to satisfy margin requirements in connection with derivatives transactions that are classified among the following categories as specified in rule 22e–4 [17 CFR 270.22e–4]:

1. Moderately Liquid Investments
2. Less Liquid Investments
3. Illiquid Investments

* * * * *

Part C: Schedule of Portfolio Investments

* * * * *

Item C.7.a Liquidity classification information.

For portfolio investments of open-end management investment companies, provide the liquidity classification(s) for each portfolio investment among the following categories as specified in rule 22e–4 [17 CFR 270.22e–4]. For portfolio investments with multiple liquidity classifications, indicate the percentage amount attributable to each classification.

i. Highly Liquid Investments
ii. Moderately Liquid Investments
iii. Less Liquid Investments
iv. Illiquid Investments

Item C.7.b. If attributing multiple classification categories to the holding, indicate which of the three circumstances listed in the Instructions to Item C.7 is applicable.

Instructions to Item C. 7 Funds may choose to indicate the percentage amount of a holding attributable to multiple classification categories only in the following circumstances: (1) If portions of the position have differing liquidity features that justify treating the portions separately; (2) if a fund has multiple sub-advisers with differing liquidity views; or (3) if the fund chooses to classify the position through evaluation of how long it would take to liquidate the entire position (rather than basing it on the sizes it would reasonably anticipated trading). In (1) and (2), a fund would classify using the reasonably anticipated trade size for each portion of the position.

* * * * *

Part F: Exhibits

For reports filed for the end of the first and third quarters of the Fund's fiscal year, attach no later than 60 days after the end of the reporting period the Fund's complete portfolio holdings as of the close of the period covered by the report. These portfolio holdings must be presented in accordance with the schedules set forth in §§ 210.12–12—210.12–14 of Regulation S–X [17 CFR 210.12–12—210.12–14].

* * * * *

By the Commission.

Dated: June 28, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–14366 Filed 7–9–18; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–479]

Schedules of Controlled Substances: Temporary Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cannabinoids, Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial name: NM2201; CBL2201); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA); 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial name: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78); methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA); and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA), and their optical, positional, and geometric isomers, salts, and salts of isomers in schedule I. This action is based on a finding by the Acting Administrator that the placement of these synthetic cannabinoids in schedule I of the Controlled Substances Act 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, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

DATES: This temporary scheduling order is effective July 10, 2018, until July 10, 2020. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, 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. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling [1] 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,

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

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). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated March 9, 2018. The Assistant Secretary responded to this notice by letter dated March 27, 2018, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no active investigational new drug applications or approved new drug applications for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in 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). NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA or 5F-CUMYL-P7AICA under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA was published in the **Federal Register** on May 30, 2018. 83 FR 24696.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 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 NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA, summarized below, indicate that these synthetic cannabinoids (SCs) have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's March 27, 2018 letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov* under FDMS Docket ID: DEA–2018–0010–0001 (Docket Number DEA–479).

Synthetic Cannabinoids

The illicit use of the synthetic cannabinoids (SCs) has continued throughout the United States, resulting in severe adverse effects, overdoses and deaths. While new SCs continue to emerge on the illicit market, some substances identified at their peak in previous years have continued to be abused by the user population.

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 on the designer drug market in several European countries as ''herbal incense'' before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. From 2009 to the present, misuse of SCs has increased in the United States with law enforcement encounters describing SCs applied onto plant material and in other designer drug products intended for human consumption. Hospital reports, scientific publications and/or law enforcement reports demonstrate that NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA and their associated designer drug products are abused for their psychoactive properties. As with many generations of SCs encountered since 2009, the abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA is impacting or will negatively impact communities.

As observed by the DEA and CBP, SCs originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters, 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).

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA have no accepted medical use in the United States. Use of NM2201, 5F-AB-PINACA and 4-CN-CUMYL-BUTINACA has been reported to result in adverse effects in humans in the United States. In addition, within the United States, there have been numerous law enforcement seizures of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, and MMB-CHMICA during 2013 to 2018, as well as one law enforcement seizure of 5F-CUMYL-P7AICA in 2018. There have been multiple international seizures of 5F-CUMYL-P7AICA, and its use has been reported to result in serious adverse events, including death, in other countries. Use of other SCs has resulted in signs of addiction and withdrawal. Based on the pharmacological similarities between NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA and other SCs, they are likely to produce signs of addiction and withdrawal similar to those produced by other SCs.

[2] 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.

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA 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 NM2201, 5F-AB-PINACA and 4-CN-CUMYL-BUTINACA has been associated with multiple overdoses requiring emergency medical intervention in the United States. With no approved medical use and limited safety or toxicological information, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA have emerged on the designer drug market, and the abuse or trafficking of these substances for their psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids 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 included within schedule I, 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 in 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, 79 FR 7577), another generation of SCs appeared, including AB-CHMINACA, AB-PINACA, and THJ-2201. These substances were also temporarily, and then permanently, scheduled in schedule I (80 FR 5042, 82 FR 8593).

NM2201 was first identified in November 2012 in seized drug evidence, followed by 5F-AB-PINACA (August, 2013), MMB-CHMICA (December, 2015), 4-CN-CUMYL BUTINACA (January, 2016) and most recently 5F-CUMYL-P7AICA (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 the US. European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) reported that 50 kg's of 4-CN-CUMYL-BUTINACA were seized in Europe in 2016. While the National Forensic Laboratory Information System (NFLIS) (see factor 5) reported the first US encounter of 4-CN-CUMYL-BUTINACA in January 2016, the recent increase in encounters did not occur until later in 2017. Similarly, prior to the first US encounter of 5F-CUMYL-P7AICA in February 2018, the use of this substance has resulted in adverse events that have been documented in Europe (See factor 6). These data further support that based upon trends, SCs originate in China before being abused in countries including those in Europe often before being trafficked in the US. Based upon the similarity between the trafficking patterns, distribution and use of 5F-CUMYL-P7AICA versus other illicit SCs, 5F-CUMYL-P7AICA poses significant risk for continued emergence in illicit drug markets in the United States. Recent law enforcement seizures are demonstrating that some SCs whose popularity peaked in 2014 and 2015 have remained popular within the illicit market (*i.e.* NM2201 and 5F-AB-PINACA). The misuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA has been associated with either law enforcement seizures or overdoses requiring emergency medical intervention. Reports of overdoses involving the ingestion of products containing NM2201, 5F-AB-PINACA and 4-CN-CUMYL-BUTINACA, similar to other SCs available on the illicit market, have recently been published in the scientific literature (See factor 4).

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, 4-CN-CUMYL BUTINACA was identified as an adulterant on pieces of paper that were then smuggled into a detention facility and later found partially burned. 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, as well as large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the 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.

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA, 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 NM2201, 5F-AB-PINACA or 4-CN-CUMYL-BUTINACA have resulted in adverse symptoms, including diaphoresis, tachycardia, hypertension, seizures, agitation, violence, nausea and memory impairment.

Factor 5. Scope, Duration and Significance of Abuse

SCs continue to be encountered on the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances (see factor 5 in supporting documentation). 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 the National Institute on Drug Abuse (NIDA), many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity. This is especially true for substances like NM2201 and 5F-

AB-PINACA, SCs that were popular in 2014 and have remained popular on the illicit market. The threat of serious injury to the individual and the imminent threat to public safety following the ingestion of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, 5F-CUMYL-P7AICA and other SCs persist.

Full reports of information obtained through STARLiMS,[3] STRIDE,[4] and NFLIS for the past five years are available under Factor 5 of the DEA 3-Factor Analysis. According to NFLIS data, state and local forensic laboratories have detected the following information about the SCs in question:

NM2201: 2,830 NFLIS reports from 30 states since 2012,[5] 282 STRIDE/STARLiMS reports from 21 states plus DC and Puerto Rico since 2014.

5F-AB-PINACA: 1,180 NFLIS reports from 36 states since 2013, 188 STRIDE/STARLiMS reports from 17 states plus DC and Guam since 2013.

4-CN-CUMYL-BUTINACA: 493 NFLIS reports from 3 states since 2016.

MMB-CHMICA: 254 NFLIS reports from 17 states since 2015, 96 STARLiMS reports from 8 states plus DC since 2015.

5F-CUMYL-P7AICA: 1 NFLIS report from 1 state since 2018. As described previously, based on the similarity between trafficking patterns, distribution and the use of 5F-CUMYL-P7AICA versus other illicit SCs, 5F-CUMYL-P7AICA poses significant risk for continued emergence in illicit drug markets in the United States.

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

Since first being identified in the U.S. in 2008, the ingestion of SCs continues to result in serious adverse effects and encounters. Details of these events in the U.S. and/or abroad involving NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA and 5F-CUMYL-P7AICA are summarized below and detailed in the DEA 3-Factor Analysis. While no adverse event information is currently available for MMB-CHMICA, increasing law enforcement seizures, scientific publications regarding its abuse and the pharmacological similarity of MMB-CHMICA to other currently controlled schedule I SCs with known risks to public health (*i.e.* AB-CHMINACA, AB-FUBINACA, JWH-018) demonstrate an imminent hazard to public safety (see factor 5 in supporting documentation).

1. A previously well 25-year-old man in the United Kingdom presented with agitation, double incontinence and left-sided incoordination. His symptoms started after smoking a synthetic cannabinoid (black mamba) 5 days earlier. Over 48 hours, he developed aphasia, generalized hypertonia, hyper-reflexia and dense left hemiparesis. This progressed to profuse diaphoresis, fever, tachycardia, hypertension and a possible seizure necessitating admission to the intensive care unit. An electroencephalogram showed widespread brain wave slowing, indicating diffuse cerebral dysfunction. Toxicology analysis of the substance confirmed a potent synthetic cannabinoid NM2201.

2. In December 2015, 25–30 people in Ocala, FL who used a synthetic cannabinoid product were taken to local hospitals following episodes of violence, fighting and experiencing seizures. Local laboratory analysis confirmed drug evidence seized from the overdose cluster as NM2201.

3. In June 2014, a 37 year old male in Japan drove a car from a busy downtown street onto a wide sidewalk for 30 meters and hit many pedestrians one after another until it was stopped by collision with a telephone booth. A woman was killed and seven persons were injured. The driver lost consciousness and was drooling. He had no memory of what occurred after smoking. 5F-AMB and AB-CHMINACA were detected in the herbal mixture. In addition, 5F-AB-PINACA was detected in the urine sample.

4. Between December 2017 and January 2018, at least 37 confirmed or suspected cases of intoxication occurred in Utah following ingestion of products labeled either ''CBD Oil'' or ''YOLO.'' The products were liquids intended to be used in a vaping device or directly ingested sublingually. Further testing of these products determined that they contained the synthetic cannabinoid 4-CN-CUMYL-BUTINACA. As per the Utah Department of Health, adverse reactions included altered mental status, hallucinations, seizures, confusion, loss of consciousness, tachycardia or slurred speech.

5. In January 2018, 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. Eight countries within Europe have reported just over 50 detections of 5F-CUMYL-P7AICA to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). 5F-CUMYL-P7AICA was typically detected in plant material or as a powder. The biggest detections included a 5 kg seizure (December 2014) and 7 kg seizure (January 2015) of white powder believed to originate from China.

7. Two deaths with confirmed exposure to 5F-CUMYL-P7AICA (detected along with other substances) have been reported to the EMCDDA. These occurred in November 2016 and December 2016. In one of the cases, 5F-CUMYL-P7AICA was reported as the cause of death.

8. In February 2018, 5F-CUMYL-P7AICA was confirmed in a seizure of powder-material in Bay County, Florida.

Because they share pharmacological similarities with schedule I substances (Δ^9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA pose serious risk 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 resulting from their abuse, 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.

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA are being encountered on the illicit drug market in the US and/or Europe and have no accepted medical use in the United States. Regardless, these products continue to be easily available and abused by diverse populations.

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

In accordance with 21 U.S.C. 811(h)(3), based on the available data

[3] 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 STRIDE as the DEA laboratory drug evidence data system of record.

[4] 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.

[5] At the time of query, 2018 data were still reporting.

and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA indicate that these SCs have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated March 9, 2018, notified the Assistant Secretary of the DEA's intention to temporarily place NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I. A notice of intent was subsequently published in the **Federal Register** on May 30, 2018. 83 FR 24696.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial name: NM2201; CBL2201); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA); 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial name: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78); methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA); and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA) in schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Acting Administrator hereby finds it necessary to temporarily place NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling these substances is effective on the date of publication in the **Federal Register**, and is 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. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent 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 temporary order, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA 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 July 10, 2018. Any person who currently handles NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA, and is not registered with the DEA, must submit an application for registration and may not continue to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA as of July 10, 2018, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after July 10, 2018 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA must surrender all currently held quantities of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

3. *Security.* NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA 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 July 10, 2018.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from July 10, 2018, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants 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 NM2201, 5F-AB-

PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of July 10, 2018.

8. *Order Forms.* All DEA registrants who distribute NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 10, 2018.

9. *Importation and Exportation.* All importation and exportation of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of July 10, 2018.

10. *Quota.* Only DEA registered manufacturers may manufacture NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of July 10, 2018.

11. *Liability.* Any activity involving NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA not authorized by, or in violation of the CSA, occurring as of July 10, 2018, 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 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. 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 the Administrative Procedure Act (APA) at 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 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

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. 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 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.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the 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 to avoid an imminent hazard to the public safety. 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. 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 in schedule I because they pose an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11, add paragraphs (h)(31) to (35) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(31) Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: NM2201; CBL2201) ..... (7221)
(32) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-AB-PINACA) ..... (7025)
(33) 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78) ..... (7089)
(34) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MMB-CHMICA, AMB-CHMICA) ..... (7044)
(35) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-CUMYL-P7AICA) ..... (7085)

Dated: June 30, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–14718 Filed 7–9–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0178]

RIN 1625–AA08

Special Local Regulation; Choptank River, Cambridge, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations for certain waters of the Choptank River. This action is necessary to provide for the safety of life on the navigable waters located in Cambridge, MD, during a power boat racing event on July 28, 2018, and July 29, 2018. This regulation prohibits persons and vessels from entering the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander.

DATES: This rule is effective from 8:30 a.m. on July 28, 2018 through 6:30 p.m. on July 29, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0178 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ronald Houck, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On February 18, 2018, The Kent Narrows Racing Association of Chester, MD, notified the Coast Guard that from 10 a.m. until 6 p.m. on July 28, 2018, and July 29, 2018, it will be conducting power boat races in the Choptank River in a cove located between Hambrooks Bar and the shoreline at Cambridge, MD. Details of the proposed event were provided to the Coast Guard at a meeting on April 10, 2018, where the sponsor changed the start time to 9 a.m. to allow for additional races. In response, on May 21, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Special Local Regulation; Choptank River, Cambridge, MD'' (83 FR 23395). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this high-speed power boat racing event. During the comment period that ended June 20, 2018, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Due to the date of the event, it would be impracticable and contrary to the public interest to make the regulation effective 30 days after publication in the **Federal Register**. The regulation must be in place by June 28th in order to protect the public from the hazards associated with this power boat racing event. Therefore, the Coast Guard is making this rule effective immediately.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port (COTP) Maryland-National Capital Region has determined that potential hazards associated with the power boat racing event will be a safety concern for anyone intending to participate in this event or for vessels that operate within specified waters of the Choptank River at Cambridge, MD. The purpose of this rule is to protect marine event participants, spectators and transiting vessels on specified waters of the Choptank River before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published May 21, 2018. There are no substantive changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a special local regulation to be enforced from 8:30 a.m. until 6:30 p.m. on July 28, 2018 and July 29, 2018. The regulated area covers all navigable waters of the Choptank River and Hambrooks Bay bounded by a line connecting the following coordinates: Commencing at the shoreline at Long Wharf Park, Cambridge, MD, at position latitude 38°34′30″ N, longitude 076°04′16″ W; thence east to latitude 38°34′20″ N, longitude 076°03′46″ W; thence north across the Choptank River along the Senator Frederick C. Malkus, Jr. (US–50) Memorial Bridge, at mile 15.5, to latitude 38°35′30″ N, longitude 076°02′52″ W; thence west along the shoreline to latitude 38°35′38″ N, longitude 076°03′09″ W; thence north and west along the shoreline to latitude 38°36′42″ N, longitude 076°04′15″ W; thence southwest across the Choptank River to latitude 38°35′31″ N, longitude 076°04′57″ W terminating at the Hambrooks Bay breakwall. This rule provides additional information about designated areas within the regulated area, including a ''Race Area,'' ''Spectator Area'' and ''Buffer Zone,'' and the restrictions that apply to mariners. The duration and enforcement of the regulated area is intended to insure the safety of vessels and these navigable waters before, during, and after the scheduled 9 a.m. through 6 p.m. high-speed power boat racing event. Persons and vessels desiring to transit, moor, or anchor within the regulated area must obtain authorization from COTP Maryland-National Capital Region or Coast Guard Patrol