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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: Proposed amendment; notice of intent.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic cannabinoids, 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. 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 (CSA) is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose regulatory requirements under the CSA on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of these synthetic cannabinoids, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such requirements or otherwise violate the CSA with respect to these substances.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION: This notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) placing NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I of the Controlled Substances Act.¹ The temporary scheduling order will be published in the *Federal Register* on or after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Legal Authority

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

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 permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of 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

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.

temporary basis to the Assistant Secretary for Health of HHS by letter dated March 9, 2018. The Assistant Secretary responded to this notice of intent by letter dated March 27, 2018, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no approved new drug applications or active investigational 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. 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 and 5F-CUMYL-P7AICA under section 505 of the FDCA, 21 U.S.C. 355.

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 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).

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, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA and MMB-CHMICA have been seized by law enforcement in the United States. Use of 5F-CUMYL-P7AICA has not been documented in the United States yet, but 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.

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), Pub. L. 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) and most recently 4-CN-CUMYL BUTINACA (January, 2016). While 5F-CUMYL-P7AICA has not been encountered within the U.S. yet, the use of this substance and resulting adverse events have been documented in Europe. Based on the similarity between trafficking patterns, distribution and use of 5F-CUMYL-P7AICA versus other illicit SCs, 5F-CUMYL-P7AICA poses significant risk for emergence in illicit drug markets in the United States. 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. 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.

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 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 and 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: 2,705 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: 1,141 NFLIS reports from 36 states since 2013, 188 STRIDE/STARLiMS reports from 17 states plus DC and Guam since 2013.

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, 2017 data were still reporting.

4-CN-CUMYL-BUTINACA: 59 NFLIS reports from 3 states since 2016.

MMB-CHMICA: 201 NFLIS reports from 17 states since 2015, 96 STARLiMS reports from 8 states plus DC since 2015.

5F-CUMYL-P7AICA: currently international seizures only.

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 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. 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.

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 and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA, resulting from the lack of control of these substances, pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for 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.

Conclusion

This notice of intent provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h), of the DEA's intent to issue a temporary scheduling order. 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, herein set 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, and finds that placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-

BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I of the CSA on a temporary basis is necessary to avoid an imminent hazard to the public safety.

The temporary placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Because the Acting Administrator hereby finds that it is 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, the temporary order scheduling these substances will be effective on the date that order is published in the *Federal Register* and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Acting Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this notice. Upon publication of the 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, research, conduct of instructional activities and chemical analysis, and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done “on the record after opportunity for a hearing” conducted pursuant to the

provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the

public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to section 811(h)(4).

Further, the DEA believes that this temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

- 2. In § 1308.11, add paragraphs (h)(31) through (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)

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