DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–472]

Schedules of Controlled Substances: Temporary Placement of FUB-AMB Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic cannabinoid, Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], into Schedule I. This action is based on a finding by the Administrator that the placement of this synthetic cannabinoid into Schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to Schedule I controlled substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, exportation of, and research and conduct with, instructional activities of this synthetic cannabinoid.

DATES: September 11, 2017.

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: This notice of intent contained in this document is issued pursuant to the temporary schedule 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) to add FUB-AMB to Schedule I under the Controlled Substances Act.[1] The temporary scheduling order will be published in the **Federal Register**, but will not be issued before October 11, 2017.

[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.

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 into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(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 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 into Schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place FUB-AMB in Schedule I on a temporary basis to the Assistant Secretary for Health by letter dated May 19, 2017. The Assistant Secretary responded to this notice of intent by letter dated June 9, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there were no approved new drug applications or active investigational new drug applications for FUB-AMB. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of FUB-AMB into Schedule I of the CSA. FUB-AMB is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for FUB-AMB under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of FUB-AMB in Schedule I on a temporary basis is necessary to avoid imminent hazard to the public safety.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the 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).

FUB-AMB

The illicit use of the synthetic cannabinoid (SC) methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Street names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) has dramatically increased over the past 12 months posing an imminent threat to public safety. Available data and information for FUB-AMB, summarized below, indicates that this SC has 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 is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–372.

Synthetic Cannabinoids

SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed that SCs were first 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 and abuse of SCs has increased in the United States with law enforcement encounters describing

[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.

SCs applied onto plant material and in designer drug products intended for human consumption. It has been demonstrated that the substances and the associated designer drug products are abused for their psychoactive properties. With many generations of SCs having been encountered since 2009, FUB-AMB is one of the latest, and the abuse of these substances is negatively impacting 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, applying by 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).

FUB-AMB has no accepted medical use in the United States. Use of this specific SC has been reported (see factor 6) to result in adverse effects in humans. Use of other SCs has resulted in signs of addiction and withdrawal and based on the similar pharmacological profile of FUB-AMB, it is believed that there will be similar observed adverse effects.

FUB-AMB is a SC that has pharmacological effects similar to the Schedule I hallucinogen THC and other temporarily and permanently controlled Schedule I synthetic cannabinoid substances. In addition, the misuse of FUB-AMB has been associated with multiple overdoses requiring emergency medical intervention (see factor 6). With no approved medical use and limited safety or toxicological information, FUB-AMB has emerged on the designer drug market, and the abuse of this substance for its 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 within the United States occurred in November 2008 by CBP. Since then, the popularity of SCs in general and their associated products has increased as evidenced by law enforcement seizures, public health information, and media reports. FUB-AMB was originally encountered in 2014, but has since seen a large increase in its illicit use. The misuse of FUB-AMB has been associated with multiple overdoses requiring emergency medical intervention.

Research and clinical reports have demonstrated that SCs are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive ''high,'' believed to be similar to marijuana. Data gathered from a published study, and supplemented by discussions on Internet Web sites, demonstrate that these products are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as ''legal'' alternatives to marijuana. In recent cases of overdoses, FUB-AMB has been encountered in the form of herbal products, similar to the SCs that have been previously available.

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. 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 manufacturer's 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. FUB-AMB, similar to other SCs, has been encountered in the form of dried leave or herbal blends.

The designer drug products laced with SCs, including FUB-AMB, are often sold under the guise of ''herbal incense'' or ''potpourri,'' use various product names, and are routinely labeled ''not for human consumption.'' Additionally, these products are marketed as a ''legal high'' or ''legal alternative to marijuana'' and are readily available over the Internet, in head shops, or sold in convenience stores. There is an incorrect assumption that these products are safe, that they are a synthetic form of marijuana, and that labeling these products as ''not for human consumption'' is a legal defense to criminal prosecution under the Controlled Substances Analogue Enforcement Act.

It is believed most abusers of SCs or SC-related products are smoking the product following application to plant material. Law enforcement has also begun to encounter new variations of SCs in liquid form. It is believed abusers have been applying the liquid to hookahs or ''e-cigarettes,'' which allows the user to administer a vaporized liquid that can be inhaled.

Factor 5. Scope, Duration and Significance of Abuse

SCs including FUB-AMB continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances are encountered each month, differing only by small 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. The threat of serious injury to the individual following the ingestion of FUB-AMB and other SCs persists.

The following information details information obtained through NFLIS [3] (queried on May 16, 2017), including dates of first encounter, exhibits/reports, and locations.

FUB-AMB: NFLIS—6,522 reports, first encountered in June 2014, locations include: Arkansas, Arizona, California, Colorado, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Minnesota, Missouri, Mississippi, North Dakota, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.

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

FUB-AMB has been identified in overdose cases attributed to its abuse. Adverse health effects reported from these incidents involving FUB-AMB have included: Nausea, persistent vomiting, agitation, altered mental

[3] The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

status, seizures, convulsions, loss of consciousness, and cardiotoxicity. By sharing pharmacological similarities with Schedule I substances (Δ9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), SCs pose a risk to the abuser. While these adverse effects have been shown by a variety of SCs, similar concerns remain regarding the welfare of the user as it relates to abuse of products laced with FUB-AMB. The risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of SCs applied on the plant material.

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, importation, exportation, conduct of research and chemical analysis, possession, and abuse of FUB-AMB poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for FUB-AMB 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 FUB-AMB indicate that this SC has 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 Administrator, through a letter dated May 19, 2017, notified the Assistant Secretary of the DEA's intention to temporarily place FUB-AMB in Schedule I.

Conclusion

This notice of intent initiates a temporary scheduling action and 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 Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA] in Schedule I of the CSA, and finds that the placement of FUB-AMB into Schedule I of the CSA on a temporary basis is necessary to avoid an imminent hazard to the public safety.

The temporary placement of FUB-AMB into Schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before October 11, 2017. Because the Administrator hereby finds that it is necessary to temporarily place FUB-AMB into Schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling this substance 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 Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon publication of the temporary order, FUB-AMB will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, 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 an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of 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 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 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 Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

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), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(18) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(18) methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA)	(7021)

Dated: August 14, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–17639 Filed 9–8–17; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0189; FRL–9966–97–Region 6]

Approval and Promulgation of Implementation Plans; Arkansas; Approval of Regional Haze State Implementation Plan Revision and Withdrawal of Federal Implementation Plan for NO_X for Electric Generating Units in Arkansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve a proposed revision to the Arkansas Regional Haze State Implementation Plan (SIP) submitted for parallel processing on July 12, 2017, by the State of Arkansas through the Arkansas Department of Environmental Quality (ADEQ). Specifically, the EPA is proposing to approve the State's proposed SIP revision, which addresses nitrogen oxide (NO_X) requirements for the Arkansas Electric Cooperative Corporation (AECC) Bailey Plant Unit 1; AECC McClellan Plant Unit 1; the American Electric Power/Southwestern Electric Power Company (AEP/SWEPCO) Flint Creek Plant Boiler No. 1; Entergy Arkansas, Inc. (Entergy) Lake Catherine Plant Unit 4; Entergy White Bluff Plant Units 1 and 2 and the Auxiliary Boiler; and Entergy Independence Plant Units 1 and 2. In conjunction with this proposed approval, we are proposing to withdraw federal implementation plan (FIP) emission limits for NO_X that would otherwise apply to the nine aforementioned units.

DATES: Written comments must be received on or before October 11, 2017.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2015–0189, at *http://www.regulations.gov* or via email to *R6AIR_ARHaze@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact Dayana Medina, *medina.dayana@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Dayana Medina, 214–665–7241, *medina.dayana@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Dayana Medina or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

Table of Contents

I. Background

A. The Regional Haze Program

Regional haze is visibility impairment that is produced by a multitude of sources and activities that are located across a broad geographic area and emit fine particulates ($PM_{2.5}$) (*e.g.,* sulfates, nitrates, organic carbon (OC), elemental carbon (EC), and soil dust), and their precursors (*e.g.,* sulfur dioxide (SO_2), NO_X, and in some cases, ammonia (NH_3) and volatile organic compounds (VOCs)). Fine particle precursors react in the atmosphere to form $PM_{2.5}$, which impairs visibility by scattering and absorbing light. Visibility impairment reduces the clarity, color, and visible distance that can be seen. $PM_{2.5}$ can also cause serious adverse health effects and mortality in humans; it also contributes to environmental effects such as acid deposition and eutrophication.

Section 169A of the CAA directs states to evaluate the use of retrofit controls at certain larger, often under-controlled, older stationary sources in order to address visibility impacts from