''EXPEDITED REVIEW REQUESTED UNDER 17 CFR 270.0–5(d)'',

(2) Exhibits with marked copies of the application showing changes from the final versions of the two applications identified as substantially identical under paragraph (e)(3) of this section, and

(3) An accompanying cover letter, signed, on behalf of the applicant, by the person executing the application,

(i) Identifying two substantially identical applications; and

(ii) Certifying that that the applicant believes the application meets the requirements of paragraph (d) of this section and that the marked copies required by paragraph (e)(2) of this section are complete and accurate.

(f)(1) No later than 45 days from the date of filing of an application for which expedited review is requested:

(i) Notice of an application will be issued in accordance with paragraph (a) of this section, or

(ii) The applicant will be notified that the application is not eligible for expedited review because it does not meet the criteria set forth in paragraph (d) of this section or because additional time is necessary for appropriate consideration of the application;

(2) For purposes of paragraph (f)(1) of this section:

(i) The 45 day period will restart upon the filing of any unsolicited amendment.

(ii) The 45 day period will stop running upon:

(A) Any request for modification of an application and will resume running on the 14th day after the applicant has filed an amended application responsive to such request, including a marked copy showing any changes made and a certification signed by the person executing the application that such marked copy is complete and accurate; and

(B) Any irregular closure of the Commission's Washington, DC office to the public for normal business, including, but not limited to, closure due to a lapse in federal appropriations, national emergency, inclement weather, or ad hoc federal holiday, and will resume upon the reopening of the Commission's Washington, DC office to the public for normal business.

(iii) If the applicant does not file an amendment responsive to any request for modification within 30 days of receiving such request, including a marked copy showing any changes made and a certification signed by the person executing the application that such marked copy is complete and accurate, the application will be deemed withdrawn.

(g) If an applicant has not responded in writing to any request for clarification or modification of an application filed under this section, other than an application that is under expedited review under paragraphs (d) through (e) of this section, within 120 days after the request, the application will be deemed withdrawn.

By the Commission.

Dated: October 18, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23082 Filed 10–29–19; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–472]

Schedules of Controlled Substances: Placement of FUB-AMB in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle FUB-AMB.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Comments must be submitted electronically or postmarked on or before November 29, 2019. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before November 29, 2019.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–472'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

FOR FURTHER INFORMATION CONTACT: Scott Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–8209.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

Request for Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

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

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of the HHS (Assistant Secretary) and an evaluation of all other relevant data by the DEA. If finalized, this action would continue [2] to impose the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle FUB-AMB.

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] FUB-AMB is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 82 FR 51154, Nov. 3, 2017.

Background

On November 3, 2017, the DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 82 FR 51154. That temporary scheduling order was effective on the date of publication, and was based on findings by the Acting Administrator of the DEA (Acting Administrator) that the temporary scheduling of this synthetic cannabinoid (SC) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), requires that the temporary control of this substance expire two years from the effective date of the scheduling order, which is November 3, 2019. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling of that substance could be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,[3] or on the petition of any interested party. An extension of the temporary order is being ordered by the Acting Administrator in a separate action, and is published elsewhere in this issue of the **Federal Register**.

The Acting Administrator, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule FUB-AMB. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for this synthetic cannabinoid. On March 9, 2018, the Acting Administrator submitted a request to the Assistant Secretary to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for FUB-AMB, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on September 19,

[3] Because the Secretary of HHS has delegated to the Assistant Secretary the authority to make domestic drug scheduling recommendations, for purposes of this proposed rulemaking, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

2019, the Assistant Secretary submitted to the Acting Administrator HHS's scientific and medical evaluations for this substance. Upon receipt of the scientific and medical evaluation and scheduling recommendation from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of FUB-AMB in accordance with 21 U.S.C. 811(c).

Proposed Determination to Schedule FUB-AMB

As discussed in the background section, the Acting Administrator initiated proceedings, pursuant to 21 U.S.C. 811(a)(1), to add FUB-AMB permanently to schedule I. The DEA has reviewed the scientific and medical evaluations and scheduling recommendation, received from HHS, and all other relevant data and conducted its own eight-factor analysis of the abuse potential of FUB-AMB pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its proposed scheduling action. Please note that both the DEA 8-Factor and HHS 8-Factor analyses and the Assistant Secretary's September 19, 2019, letter, are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *http://www.regulations.gov,* under Docket Number ''DEA–472.''

1. *The Drug's Actual or Relative Potential for Abuse:* The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests that the DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse: [4]

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

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

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

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

Epidemiological data reviewed by HHS has concluded that individuals are taking FUB-AMB in sufficient amounts as to create a hazard to the health and safety of both the individual users and others within the community. Adverse effects observed following the ingestion of FUB-AMB include nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness and cardiotoxicity. SCs like FUB-AMB are easily accessible and difficult to detect in standard urine drug screens, which contributes to their popularity and high rates of abuse.

The HHS stated in their letter dated June 9, 2017 that there are currently no approved new drug applications or active investigational new drug applications for FUB-AMB. In addition, HHS stated that since FUB-AMB is not a Food and Drug Administration (FDA)-approved drug product for treatment in the United States and there appear to be no legitimate sources for FUB-AMB as a marketed drug or as a subject of scientific investigations, this characteristic of abuse potential is not applicable.

HHS has determined that since FUB-AMB is not approved for medical use and is not formulated or available for clinical use, the human use of this substance is assumed to be on an individual's own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer drugs. Further, published scientific and medical literature and law enforcement reports indicate that individuals are taking FUB-AMB on their own initiative, rather than on the basis of medical advice of a licensed practitioner.

As stated by HHS, in vitro and in vivo data for FUB-AMB indicate that it has a pharmacological profile similar to other schedule I SCs of various structural classes, including tetrahydrocannabinols (such as Δ9-THC), bicyclic cannabinoid analogs (*e.g.,* CP55, 940), aminoalkylindoles (*e.g.,* WIN55, 212-2), and other indole- and pyrol-derived cannabinoids (*e.g.,* JWH-018, schedule I) (see Factor 2 DEA 8-Factor Analysis). In in vitro receptor binding and functional assays, FUB-AMB, similar to JWH-018 and WIN 55,212-2, acts as a CB1 receptor agonist. In drug discrimination studies sponsored by the National Institute on Drug Abuse (NIDA), FUB-AMB, similar to other schedule I SCs (*e.g.,* JWH-018; AM2201; ADB-PINACA, AB-FUBINACA etc.), fully substitutes for THC in animals trained to discriminate THC from vehicle control (see Factor 2 DEA 8-Factor Analysis). Based on these pharmacological similarities, HHS stated that FUB-AMB would present with an abuse potential similar to these and other cannabinoids. HHS further stated that in terms of overall potency, FUB-AMB appears to be more potent than JWH-018 and WIN 55,212-2.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* As described by HHS, receptor binding and drug discrimination studies with FUB-AMB demonstrate findings that are consistent with findings from the testing of other schedule I SCs. In vitro receptor binding and functional assays and in vivo drug discrimination studies were conducted with FUB-AMB. These results indicate that FUB-AMB, similar to other schedule I SCs, binds to CB1 receptors and acts as an agonist at CB1 receptors. Treatment with FUB-AMB (0.1—1 mg/kg), similar to THC, resulted in time- and dose-dependent depression of locomotor activity. Depressant effects of 0.1 to 0.5 mg/kg FUB-AMB occurred within 10 minutes following intraperitoneal (i.p.) injection and lasted 40 to 100 minutes. Also, tremors were seen 30 minutes following 1 mg/kg FUB-AMB in 3 of 8 mice. The drug discrimination assay is a well-accepted animal model used to predict subjective effects of substances in humans. In the drug discrimination assay, FUB-AMB similar to other schedule I SCs (*e.g.,* JWH-018; AM2201; ADB-PINACA, AB-FUBINACA etc.), substituted fully for the discriminative stimulus effects produced by THC.

Based on data from CB1 receptor binding (Ki), CB1 receptor functional assays, drug discrimination, and locomotor studies, HHS stated that FUB-AMB is a full cannabinoid agonist with no antagonist activity, and is more potent than Δ9-THC, the principal psychoactive constituent in marijuana (schedule I).

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* FUB-AMB is a potent cannabinoid receptor agonist that is pharmacologically similar to THC. Emerging in the early 1980's, SCs were originally designed to investigate structure activity relationships (SAR) based on the potent substance, 9-nor-9β-hydroxyhexahydrocannabinol (HHC).

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

Interest in various structural classes was generated by the mouse vas deferens (MVD) and prostaglandin synthetase activity of pravadoline and subsequent finding of its affinity to the cannabinoid receptor.

Neither the DEA nor HHS is aware of any currently accepted medical use for FUB-AMB. A letter, dated May 19, 2017, was sent from the DEA Acting Administrator to the Assistant Secretary for Health of the HHS as notification of intent to temporarily place FUB-AMB in schedule I and solicited comments, including whether there is an exemption or approval in effect for the substance in question under the Federal Food, Drug and Cosmetic Act. The Assistant Secretary for Health responded on June 9, 2017 that there are currently no approved new drug applications or active investigational new drug applications for FUB-AMB and that HHS has no objection regarding the temporary placement of FUB-AMB in schedule 1 of the CSA. Also, HHS is not aware of any reports of clinical studies or claims of an accepted medical use in the United States. HHS concluded without further consideration that FUB-AMB has no currently accepted medical use in the United States.

HHS stated in its recommendation that information collected by the World Health Organization indicates that FUB-AMB is most commonly ingested following inhalation either via smoking an adulterated plant material or by manipulating the substance into a liquid form for vaporization via an electronic smoking device.

4. *Its History and Current Pattern of Abuse:* As described by HHS, SCs 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 U.S. Customs and Border Protection. 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 first identified in June 2014, in seized drug evidence. Up until its temporary control in November, 2017, there had been a large increase in its encounters by law enforcement (see Factor 5 DEA 8-Factor Analysis). The misuse of FUB-AMB has been associated with multiple overdoses requiring emergency medical intervention (see Factor 6 DEA 8-Factor Analysis). 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 (see Factor 6 DEA 8-Factor Analysis).

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 in convenience stores.

There are incorrect assumptions 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.

Presentations at emergency departments directly linked to the abuse of FUB-AMB have resulted in similar symptoms, including nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, cardio toxicity and/or death (see Factor 6 DEA 8-Factor Analysis). Law enforcement has had numerous encounters of FUB-AMB and has documented the abuse of this substance (see Factor 5 DEA 8-Factor Analysis). SCs and their associated products are available over the internet and sold in gas stations, convenience stores, and tobacco and head shops. FUB-AMB, similar to the previously scheduled SCs, have been seized alone and/or laced on products that are marketed under the guise of ''herbal incense'' and promoted as a ''legal'' alternative to marijuana.

5. *The Scope, Duration, and Significance of Abuse:* As described by HHS, 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 SC substances continue to be encountered, differing from controlled SCs only by small chemical structural modifications intended to avoid prosecution while maintaining the pharmacological effects.

HHS stated that based on FUB-AMB's pharmacological properties, it is reasonable to assume that, if uncontrolled, the scope, duration, and significance of FUB-AMB abuse would be similar to Δ9-THC and other SCs that are listed in schedule I. The threat of serious injury to the individual following the ingestion of FUB-AMB and other SCs persists.

From June 2014 to the present, the National Forensic Laboratory Information System (NFLIS) has documented over 21,000 reports involving FUB-AMB across the District of Columbia, Puerto Rico, and the following states: Alabama, Arizona, California, Colorado, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Hampshire, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin and Wyoming.

6. *What, if Any, Risk There is to the Public Health:* As shown by HHS, 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 status, seizures, convulsions, loss of consciousness, cardiotoxicity and death (see DEA and HHS 8-Factor Analyses in docket folder).

7. *Its Psychic or Physiological Dependence Liability:* As stated by HHS, the pharmacologic and chemical profile of FUB-AMB strongly suggests that it possesses a physiological and psychological dependence liability that is similar to that of Δ9-THC (schedule I) and JWH-018 (schedule I). Although there are no clinical studies evaluating dependence liabilities specific for FUB-AMB, the pharmacological profile of this substance strongly suggests that it possesses dependence liabilities that are qualitatively similar to, and potentially stronger than, THC (schedule I) or marijuana (schedule I).

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* FUB-AMB is not an immediate precursor of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS's scheduling recommendation, and the DEA's own eight-factor analysis, the DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of FUB-AMB. As such, the DEA hereby proposes to permanently schedule FUB-AMB as a schedule I controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA

also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. FUB-AMB has a high potential for abuse;

2. FUB-AMB has no currently accepted medical use in treatment in the United States; [5] and

3. There is a lack of accepted safety for use of FUB-AMB under medical supervision.

Based on these findings, the Acting Administrator of the DEA concludes that methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling FUB-AMB

If this rule is finalized as proposed, FUB-AMB would continue [6] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) FUB-AMB, or who desires to handle FUB-AMB, is required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* FUB-AMB is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823 and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of FUB-AMB must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture FUB-AMB in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with the DEA to handle FUB-AMB must have an initial inventory of all stocks of controlled substances (including FUB-AMB) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

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

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to FUB-AMB, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes FUB-AMB is required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of FUB-AMB must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving FUB-AMB not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

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

Executive Order 12988

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

Executive Order 13132

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

Executive Order 13175

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

Executive Order 13771

This proposed rule does not meet the definition of an Executive Order 13771 regulatory action, and the repeal and cost offset requirements of Executive Order 13771 have not been triggered. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under Section 3(f) of Executive Order 12866.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On November 3, 2017, the DEA published an order to temporarily place FUB-AMB in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA

[5] Although there is no evidence suggesting that FUB-AMB has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. the drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992).

[6] FUB-AMB is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 82 FR 51154, Nov. 3, 2017.

estimates that all entities handling or planning to handle this substance have already established and implemented the systems and processes required to handle FUB-AMB. There are currently 22 registrations authorized to handle FUB-AMB specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 22 registrations represent 20 entities, of which 12 are small entities. Therefore, the DEA estimates 12 small entities are affected by this proposed rule.

A review of the 22 registrations indicates that all entities that currently handle FUB-AMB also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle FUB-AMB. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 12 affected small entities. Therefore, the DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

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

Paperwork Reduction Act of 1995

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

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11:
■ a. Add paragraph (d)(79); and
■ b. Remove and reserve paragraph (h)(18).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(79) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate, (FUB-AMB, MMB-FUBINACA, AMB-FUBINACA)	(7021)

* * * * *

Dated: October 21, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–23626 Filed 10–29–19; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 380

[Docket No. 19–CRB–0005–WR (2021–2025)]

Determination of Rates and Terms for Digital Performance of Sound Recordings and Making of Ephemeral Copies To Facilitate Those Performances (Web V)

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Proposed rule related to noncommercial educational webcasters.

SUMMARY: The Copyright Royalty Judges are publishing for comment proposed regulations governing the rates and terms for the digital performance of sound recordings by noncommercial educational webcasters and for the making of ephemeral recordings necessary for the facilitation of such transmissions for the period commencing January 1, 2021, and ending on December 31, 2025.

DATES: Comments and objections, if any, are due no later than November 20, 2019.

ADDRESSES: You may submit comments and proposals, identified by docket number 19–CRB–0005–WR (2021–2025), by any of the following methods:

CRB's electronic filing application: Submit comments and proposals online in eCRB at *https://app.crb.gov/.*

U.S. mail: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE, Washington, DC 20559–6000. Deliver to: Congressional Courier Acceptance Site, 2nd Street NE and D Street NE, Washington, DC; or

Hand delivery: Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE, Washington, DC 20559–6000.

Instructions: Parties unable to use eCRB must submit an original, two paper copies, and an electronic version on a CD. All submissions must include the Copyright Royalty Board name and docket number (19–CRB–0005–WR (2021–2025)), as well as the **Federal Register** citation for this proposed rule. All submissions received will be posted without change on eCRB at *https://app.crb.gov/* including any personal information provided.

Docket: For access to the docket to read submitted background documents or comments, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at *https://app.crb.gov/* and search for docket number 19–CRB–0005–WR (2021–2025).

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, by telephone at (202) 707–7658 or email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: On September 23, 2019, the Copyright Royalty Judges (Judges) received a joint motion from SoundExchange, Inc., (''SoundExchange'') and College Broadcasters, Inc., (''CBI'') to adopt a partial settlement of their interests regarding Web V rates and terms for 2021–2025.[1] Joint Motion to Adopt Partial Settlement, Docket No. 19–CRB–0005–WR (2021–2025). Their interests concern the rule setting copyright royalty minimum fees and terms that the Judges will establish for compulsory copyright licenses for certain internet transmissions of sound recordings by college radio stations and other noncommercial educational webcasters for the period from January 1, 2021,

[1] Web V is short for Webcasting V. This proceeding is the fifth since the compulsory license for webcasting was established.