SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and two abbreviated new animal drug applications (ANADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is applicable February 3, 2020.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234, has requested that FDA withdraw approval of NADA 010–005 for use of WAZINE (dipiperazine sulfate and piperazine hydrochloride) Soluble Powders because the product is no longer manufactured or marketed.

Also, Halocarbon Products Corp., 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092, has requested that FDA withdraw approval of ANADA 200–200 for use of Halothane USP (halothane) because the product is no longer manufactured or marketed.

Lastly, Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103, has requested that FDA withdraw approval of ANADA 200–472 for use of Fomepizole Injection because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 010–005 and ANADAs 200–200 and 200–472, and all supplements and amendments thereto, is hereby withdrawn, effective February 3, 2020.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00422 Filed 1–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–446]

Schedules of Controlled Substances: Placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their 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. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA.

DATES: Effective: January 24, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

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 action was initiated on the Attorney General's own motion, as delegated to the Administrator of the DEA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS and an evaluation of all relevant data by the DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

Background

On April 10, 2017, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the six synthetic cannabinoids (SCs) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 82 FR 17119. That temporary scheduling order was effective on the date of publication, and was based on findings by the former Acting Administrator of the DEA (Acting Administrator) that the temporary scheduling of these six SCs 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

[1] As set forth 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 Department of Health and Human Services (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.

the CSA, 21 U.S.C. 811(h)(2), requires that the temporary control of these substances expire two years from the issuance date of the scheduling order, on or before April 9, 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. Accordingly, on April 8, 2019, DEA extended the temporary scheduling of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA by one year, or until April 9, 2020. 84 FR 13796. Also, on April 8, 2019, DEA published a notice of proposed rulemaking (NPRM) to permanently control 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA in schedule I of the CSA. 84 FR 13848. Specifically, DEA proposed to add these six SCs to the hallucinogenic substances list under 21 CFR 1308.11(d).

DEA and HHS Eight Factor Analyses

On March 21, 2019, HHS provided DEA with a scientific and medical evaluation document prepared by the Food and Drug Administration (FDA) entitled ''Basis for the Recommendation to Place Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide [ADB-FUBINACA]; Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA], Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] and their Salts in Schedule I of the Controlled Substances Act.'' After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary of HHS recommended that 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA be controlled in schedule I of the CSA. In response, DEA conducted its own eight factor analysis of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA. The DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–446) at *http://www.regulations.gov* under ''Supporting Documents.''

Determination to Schedule 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendations from HHS, DEA published a NPRM entitled ''Schedules of Controlled Substances: Placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA in Schedule I.'' This NPRM proposed to control 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA, and their salts, isomers, and salts of isomers in schedule I of the CSA. 84 FR 13848, April 8, 2019. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before May 8, 2019. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before May 8, 2019.

Comments Received

The DEA received three comments on the proposed rule to control 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA in schedule I of the CSA.

Support for rulemaking: Two commenters recognized the dangers and public health risks, and supported the rulemaking to permanently place these substances in schedule I.

DEA Response: The DEA appreciates the comments in support of this rulemaking.

Dissent for rulemaking: One commenter stated that while SCs, in general, could pose a public health risk, are more harmful than ''traditional cannabis,'' and have no known legitimate medical use, this individual disagreed with the permanent control of these specific six substances. This commenter also questioned the appropriateness and effectiveness of current drug control policy and mentioned use of alternative approaches such as investing in treatment of current SC users, education about harmful effects of SCs, removal of cannabis from schedule I, and additional research into the substances at issue in this rulemaking. In addition, the commenter discussed the increased cost associated with regulatory, administrative, and enforcement activities involving scheduled drugs and concern over potential tribal implications.

DEA response: DEA's mission is to enforce the controlled substance laws and regulations of the United States. The CSA contains specific mandates pertaining to the scheduling of controlled substances. DEA has followed all of those mandates regarding the scheduling of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA, including receiving from the Secretary of HHS a scientific and medical evaluation, and recommendation, regarding control (21 U.S.C. 811(b)); considering the factors enumerated in 21 U.S.C. 811(c); determining, based on the above, appropriate scheduling for these SCs (21 U.S.C. 812(b)); and conducting a formal rulemaking to schedule these SCs (21 U.S.C. 811(a)). These SCs satisfy the CSA's criteria for placement in schedule I by virtue of their high potential for abuse, the fact that these substances have no currently accepted medical use in treatment in the United States, and their lack of accepted safety for use of the substance under medical supervision. 21 U.S.C. 812(b)(1).

As per the commenter's views regarding the appropriateness and effectiveness of current drug control policy, use of alternative approaches such as investing in treatment, education about harmful effects of SCs, and removal of cannabis from schedule I, these are outside the scope of the current scheduling action.

Regarding the increased costs associated with regulatory, administrative, and enforcement activities involving scheduled drugs, these issues are not unique to the substances that are currently being controlled by this final rule.

Regarding the commenter's concern that the scheduling of these SCs will have tribal implications, DEA has analyzed the expected impact of this final rule, and has determined that it will 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. As evidence, the commenter cites the incarceration rates of Native Americans and native youths relative to the national average; however, does not explain how this data is relevant to the substances being permanently scheduled in this final rule.

As per the comment related to additional research into the substances at issue in this rulemaking, DEA has utilized funding of its own to conduct pharmacological research studies into all these six substances. The data generated from these studies have been utilized in evaluating these substances for control under the CSA. HHS, upon conducting scientific and medical evaluation of these and all available data, recommended schedule I controls for these substances. DEA conducted its own review of HHS scientific and medical evaluation and all other relevant data and determined that these substances warrant control as schedule I substances under the CSA. Additional information about these substances can be viewed in the public docket for this rule (Docket Number DEA–446) at *http://www.regulations.gov* under ''Supporting Documents.''

Scheduling Conclusion

After consideration of the relevant matter presented as a result of public comments, the scientific and medical evaluations and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA. As such, DEA is permanently scheduling 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA as controlled substances under the CSA.

Determination of Appropriate Schedule

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

(1) Methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9-THC) and JWH-018;

(2) Methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA will continue [2] 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, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA must be registered with 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.* 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA 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 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Every DEA registrant who possesses any quantity of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA was required to

[2] 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 82 FR 17119, April 10, 2017.

keep an inventory of all stocks of these substances on hand as of April 10, 2017, 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 must maintain records and submit reports with respect to 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and/or MDMB-FUBINACA, 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 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA must continue 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 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA must continue to 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 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this final 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.

This final rule does not meet the definition of an Executive Order 13771 regulatory action. 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.

Executive Order 12988

This 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 rulemaking does not have federalism implications warranting the application of Executive Order 13132. The 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 rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On April 10, 2017, DEA published an order to temporarily place these six substances in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle these substances have already established and implemented the systems and processes required to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA. There are currently 33 registrations authorized to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and/or MDMB-FUBINACA specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 33 registrations represent 28 entities, of which 22 are small entities. Therefore, DEA estimates 22 small entities are affected by this rule.

A review of the 33 registrations indicates that all entities that currently handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, or MDMB-FUBINACA. Therefore, DEA anticipates that this 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 22 affected small entities. Therefore, DEA has concluded that this 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.,* 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 annually for inflation) in any 1 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.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

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, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11,

■ a. Add paragraphs (d)(73) through (78); and

■ b. Remove and reserve paragraphs (h)(6) through (11);

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(73) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other names: 5F-ADB; 5F-MDMB-PINACA)	7034
(74) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (Other names: 5F-AMB)	7033
(75) *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (Other names: 5F-APINACA, 5F-AKB48)	7049
(76) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (Other names: ADB-FUBINACA)	7010
(77) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (Other names: MDMB-CHMICA, MMB-CHMINACA)	7042
(78) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other names: MDMB-FUBINACA)	7020

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Dated: January 3, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–00665 Filed 1–23–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–492]

Schedules of Controlled Substances: Removal of 6β-Naltrexol From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Administrator of the Drug Enforcement Administration removes (5α,6β)-17-(cyclopropylmethyl)-4,5-epoxymorphinan-3,6,14-triol (6β-naltrexol) and its salts from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, 6β-naltrexol was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle 6β-naltrexol.

DATES: *Effective Date:* January 24, 2020.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, ''remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Acting Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on 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 action was initiated by two citizen petitions to remove 6β-naltrexol from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary of the HHS and an evaluation of all relevant data by the DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle 6β-naltrexol.

Background

6β-Naltrexol is the major metabolite of naltrexone. Naltrexone and 6β-naltrexol are reversible opioid receptor antagonists. Opioid receptor antagonists are commonly used in the treatment of opioid addiction and overdose. On December 24, 1974, naloxone, an opioid receptor antagonist that works similarly to naltrexone, was removed from all schedules for control under the CSA. Effective on March 6, 1975, title 21 of the Code of Federal Regulations was amended to remove naltrexone from all schedules for control under the CSA. The Administrator of the DEA found that both naltrexone and naloxone and their salts have an accepted medical use for treatment in the United States and that they do not have a potential for abuse to justify continued control in any schedule under the CSA. In June 2003 and April 2008, the DEA received two separate citizen petitions to initiate proceedings to amend 21 CFR 1308.12(b)(1) to decontrol 6β-naltrexol from schedule II of the CSA. These petitions complied with the requirements of 21 CFR 1308.44(b) and were accepted for filing. Both petitioners argue that 6β-naltrexol has been characterized as an opioid receptor

[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.