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

* * * * *

Dated: January 3, 2020.

Uttam Dhillon,

Acting Administrator.

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

BILLING CODE 4410–09–P

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.

antagonist, a class of drugs with no abuse potential.

DEA and HHS Eight Factor Analyses

Pursuant to 21 U.S.C. 811(b), the DEA gathered the necessary data on 6β-naltrexol and forwarded the data, the sponsors' petitions, and a request for scheduling recommendation on 6β-naltrexol to HHS on August 11, 2009.

On July 21, 2017, HHS provided to DEA a scientific and medical evaluation entitled ''Basis for the Recommendation to Remove (5α,6β)-17-(cyclopropylmethyl)-4,5-epoxymorphinan-3,6,14-triol (6β-naltrexol) and Its Salts from All Schedules of Control Under the Controlled Substances Act'' and a scheduling recommendation. Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that 6β-naltrexol and its salts be removed from all schedules of control of the CSA.

In response, DEA conducted its own eight factor analysis of 6β-naltrexol pursuant to 21 U.S.C. 811(c). Both the DEA and HHS analyses are available in their entirety in the public docket of this rule (Docket Number DEA–492) at *http://www.regulations.gov* under ''Supporting and Related Material.''

Determination To Decontrol 6β-Naltrexol

After a review of the available data, including the scientific and medical evaluation and the recommendation to decontrol 6β-naltrexol from HHS, the Acting Administrator of DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Removal of 6β-naltrexol from Control'' which proposed removal of 6β-naltrexol and its salts from the schedules of the CSA. 84 FR 43530, August 21, 2019. The proposed rule provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by September 20, 2019. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before September 20, 2019.

Comments Received

DEA received four comments on the proposed rule to remove 6β-naltrexol from control. Two commenters supported decontrol of 6β-naltrexol. Two commenters submitted comments not related to the proposed action.

Support

One commenter supported decontrolling 6β-naltrexol and expressed agreement with DEA's findings that 6β-naltrexol does not possess abuse or dependence potential. Another commenter was also in support of this decontrol action although the commenter mentioned the drug names as ''6-naltrexol'' and ''naltrexone'' and appears to have used these two names interchangeably. DEA assumes that the commenter's reference to ''naltrexone'' or ''6-naltrexol'' is actually in reference to 6β-naltrexol.

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

Unrelated Comments

One commenter stated that DEA should spend more time in combating drugs that are readily available to public and are highly prescribed by physicians rather than putting efforts on drugs with no abuse potential and are limited to research labs.

DEA Response: DEA's mission is to enforce the controlled substance laws and regulations. The CSA contains specific mandates pertaining to the scheduling of controlled substances. Pursuant to 21 U.S.C. 811(a)(2), the Attorney General through formal rulemaking may remove any drug or other substance from the schedules if it is found that the drug or other substance does not meet the requirement for inclusion in any schedule under the CSA. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party. DEA, under authority delegated by the Attorney General, has initiated the current scheduling action in response to two petitions requesting decontrol of 6β-naltrexol. Pursuant to CSA, DEA has followed all of those mandates regarding the current decontrol of 6β-naltrexol, 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 6β-naltrexol (21 U.S.C. 812(b)); and conducting a formal rulemaking to decontrol 6β-naltrexol (21 U.S.C. 811(a)(2)). 6β-Naltrexol satisfies the CSA's criteria for removal from controls.

Another commenter mentioned that a majority of states have legalized the use of cannabis for medical and recreational purposes and there are reports of medical benefits for cannabis. This commenter further stated that ''removing cannabis from being Schedule I drug is long over due . . .''

DEA Response: Because the current rule involves 6β-naltrexol, but not cannabis, this comment is unrelated and is outside the scope of the current scheduling action.

Scheduling Conclusion

Based on the consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, the Acting Administrator finds that these facts and all relevant data demonstrate that 6β-naltrexol does not meet the requirements for inclusion in any schedule, and will be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''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 regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform 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 Federal 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. This rule 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 (5 U.S.C. 601–612) (RFA), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove 6β-naltrexol from the list of schedules of the CSA. This action removes regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of 6β-naltrexol. Accordingly, it has the potential for some economic impact in the form of cost savings.

This rule will affect all persons who would handle, or propose to handle, 6β-naltrexol. 6β-Naltrexol is the major metabolite of naltrexone and is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of 6β-naltrexol, DEA is unable to determine the number of entities and small entities which might handle 6β-naltrexol. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, the DEA does not have a basis to estimate whether 6β-naltrexol is expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, the DEA is unable to estimate the number of entities and small entities who plan to handle 6β-naltrexol.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. Any person planning to handle 6β-naltrexol will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements. Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* 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 provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 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 section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). 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 companies to compete with foreign-based companies 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 to read 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 § 1308.12, revise the introductory text of paragraph (b)(1) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol and naltrexone, and their respective salts, but including the following:

* * * * *

Dated: December 19, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–00664 Filed 1–23–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–503]

Schedules of Controlled Substances: Placement of Brexanolone in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts without change an interim final rule with request for comments published in the **Federal Register** on June 17, 2019. That interim final rule placed the substance brexanolone (3α-hydroxy-5α-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains brexanolone in schedule IV of the Controlled Substances Act.

DATES: Effective January 24, 2020.

FOR FURTHER INFORMATION CONTACT: Scott Brinks, Diversion Control Division, Drug Enforcement