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

Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Background

On June 17, 2019, the Drug Enforcement Administration (DEA) published an interim final rule to make brexanolone (including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible) a schedule IV controlled substance. 84 FR 27938. The interim final rule provided an opportunity for interested persons to submit comments, as well as file a request for hearing or waiver of hearing, on or before July 17, 2019.

Comments Received

The DEA received three comments in response to the interim final rule to control brexanolone as a schedule IV substance of the Controlled Substances Act (CSA). Two of the three commenters were in support of the interim final rule to place brexanolone in schedule IV of the CSA, and one commenter was opposed to the placement of brexanolone in schedule IV of the CSA. The DEA did not receive any requests for hearing or waiver of hearing.

Support of the Interim Final Rule

Two commenters supported controlling brexanolone as a schedule IV controlled substance. These commenters indicated support for scheduling brexanolone under the CSA due to its similarity to other schedule IV sedatives including midazolam and alprazolam.

DEA Response. The DEA appreciates the support for this rulemaking.

Opposition to the Interim Final Rule

A commenter opposed the interim final rule to control brexanolone as a schedule IV substance. Although the commenter did not state if or where brexanolone should be scheduled, the commenter expressed concerns about brexanolone's adverse health effects such as exposure of an antidepressant to infants through breastmilk, potential for ''hidden side effects,'' and drug-associated dizziness and somnolence affecting the maternal care of the infant.

DEA Response. The commenter's concerns about adverse health effects of brexanolone are related to the Food and Drug Administration's (FDA) approval process (such as weighing the benefits versus risks) and outside of the scope of this rulemaking. The FDA approved a new drug application (NDA) for Zulresso (brexanolone)—a substance identified as having abuse potential pursuant to 21 U.S.C. 811(f)—and provided the DEA with a scheduling recommendation for control of brexanolone in schedule IV of the CSA. As provided in 21 U.S.C. 811(j), the scheduling recommendation by the Department of Health and Human Services (HHS) and the FDA approval of the NDA necessitated the DEA review and scheduling action. The DEA made the findings required under 21 U.S.C. 812(b)(4) for the placement of brexanolone in schedule IV. The scheduling determination was based on a comprehensive evaluation of all available data as related to the eight-factor analysis pursuant to 21 U.S.C. 811(c), but not by a single metric such as adverse health effects as expressed by this commenter. As stated in the interim final rule, after careful consideration of data from preclinical and clinical studies, the DEA concurred with the HHS recommendation that brexanolone has abuse potential comparable to other schedule IV benzodiazepines such as midazolam and alprazolam, and therefore, supported and continues to support through the promulgation of this final rule placement of brexanolone in schedule IV under the CSA. None of the commenter's concerns about brexanolone's potential health effects undermine any aspect of the interim final rule's analysis.

Based on the rationale set forth in the interim final rule, the DEA adopts the interim final rule without change.

Requirements for Handling Brexanolone

As indicated above, brexanolone has been a schedule IV substance by virtue of the interim final rule issued by DEA in June 2019. Therefore, this final rule does not alter the regulatory requirements applicable to handlers of brexanolone that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Brexanolone is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) brexanolone, or who desires to handle brexanolone, must 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. Any person who intends to handle brexanolone and is not registered with the DEA must submit an application for registration and may not handle brexanolone, unless the DEA approves that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle brexanolone, but who subsequently does not desire or is not able to maintain such registration, must surrender all quantities of brexanolone or may transfer all quantities of brexanolone to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Brexanolone is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of brexanolone must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of brexanolone was required to keep an inventory of all stocks of brexanolone on hand, as of June 17, 2019, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for brexanolone, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for brexanolone or products containing brexanolone must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of brexanolone may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act and the CSA.

9. *Importation and Exportation.* All importation and exportation of

brexanolone must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving brexanolone 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

Administrative Procedure Act

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811 provides that in cases where a new drug is (1) approved by the HHS and (2) HHS recommends control in CSA schedule II–V, the DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause. The DEA issued an interim final rule on June 17, 2019 and solicited public comments on that rule. Section 811 further states that after giving interested persons the opportunity to comment and to request a hearing, ''the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 812 (b) of'' the CSA. 21 U.S.C. 811(j)(3). The DEA is now responding to the comments submitted by the public and issuing the final rule, in conformity with the APA and the procedure required by 21 U.S.C. 811.

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) and (j), this 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 procedures and 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 is not an Executive Order 13771 regulatory action pursuant to Executive Order 12866 and OMB guidance.[1]

Executive Order 12988, Civil Justice Reform

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, Federalism

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), the DEA was not required to publish a general notice of proposed rulemaking prior to this final rule. Consequently, the RFA does not apply.

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 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 requirement 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 final 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 U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA is submitting 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.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim final rule amending 21 CFR part 1308, which published on June 17, 2019 (84 FR 27938), is adopted as a final rule without change.

Dated: January 3, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–00669 Filed 1–23–20; 8:45 am]

BILLING CODE 4410–09–P

[1] Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled ''Reducing Regulation and Controlling Regulatory Costs'' (Feb. 2, 2017).

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 10930]

RIN 1400–AE96

Visas: Temporary Visitors for Business or Pleasure

AGENCY: Department of State.