further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018 and effective September 15, 2018, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–18 [Amended]

From Millsap, TX; Glen Rose, TX; Cedar Creek, TX; Quitman, TX; Belcher, LA; Monroe, LA; Magnolia, MS; Meridian, MS; Crimson, AL; Vulcan, AL; Talladega, AL; Atlanta, GA; Colliers, SC; to Charleston, SC.

* * * * *

V–102 [Amended]

From Salt Flat, TX; Carlsbad, NM; Hobbs, NM; to Lubbock, TX.

* * * * *

V–278 [Amended]

From Texico, NM; to Plainview, TX. From Bowie, TX; Bonham, TX; Paris, TX; Texarkana, AR; Monticello, AR; Greenville, MS; Sidon, MS; Bigbee, MS; to Vulcan, AL.

Issued in Washington, DC, on June 5, 2019.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2019–12623 Filed 6–14–19; 8:45 am]

BILLING CODE 4910–13–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: Interim final rule, with request for comments.

SUMMARY: On March 19, 2019, the U.S. Food and Drug Administration (FDA) approved a new drug application for Zulresso (brexanolone). Brexanolone is chemically known as 3α-hydroxy-5α-pregnan-20-one and is also referred to as allopregnanolone. The Department of Health and Human Services (HHS) provided the Drug Enforcement Administration (DEA) with a recommendation that brexanolone be placed in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing brexanolone (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 CSA.

DATES: The effective date of this rulemaking is June 17, 2019. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before July 17, 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 may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before July 17, 2019.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–503'' on all 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 and are discouraged. 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/DPW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for 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 also 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/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received 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 and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying 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, including the complete Department of Health and Human Services and Drug Enforcement Administration eight-factor analyses, to this interim final 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 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).

All requests for a hearing and waivers of participation must be sent to the DEA using the address information provided above.

Legal Authority

Under the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), which was signed into law on November 25, 2015, the Drug Enforcement Administration (DEA) is required to commence an expedited scheduling action with respect to certain new drugs approved by the FDA. As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (Secretary of HHS or the Secretary) has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and, (2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, the DEA is required to issue an interim final rule controlling the drug within 90 days.

The law further states that the 90-day timeframe starts the later of (1) the date DEA receives the HHS scientific and medical evaluation/scheduling recommendation or (2) the date DEA receives notice of the NDA approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause therefor. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

Background

Brexanolone (3α-hydroxy-5α-pregnan-20-one), also known as allopregnanolone, is a new molecular entity with central nervous system (CNS) depressant properties. Brexanolone is an inhibitory neurosteroidal substance structurally related to progesterone. Brexanolone shares a pharmacological mechanism of action with schedule IV substances such as diazepam and alprazolam and is a positive allosteric modulator of the gamma-aminobutyric acid type A (GABA–A) receptors.

On April 19, 2018, Sage Therapeutics (Sponsor) submitted an NDA for brexanolone to the FDA. On March 19, 2019, the DEA received notification that HHS/FDA approved, on that date, the NDA for Zulresso (brexanolone) injection, for intravenous use, to treat postpartum depression (PPD) in adult women. Zulresso is approved with a Risk Evaluation and Mitigation Strategy (REMS) and is available to patients through a restricted distribution program where a healthcare professional can only administer the drug in a certified healthcare facility.

Determination To Schedule Brexanolone

On March 19, 2019, the DEA received from the HHS a scientific and medical evaluation document (dated March 08, 2019) prepared by the FDA entitled ''Basis for the Recommendation to Control Brexanolone and its Salts in schedule IV of the Controlled Substances Act.'' Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of brexanolone, along with the HHS's recommendation to control brexanolone under schedule IV of the CSA.

In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that brexanolone met the 21 U.S.C.

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on the HHS recommendation, NDA approvals by HHS/FDA, and the DEA's determination, the DEA is issuing this interim final rule to schedule brexanolone as a schedule IV controlled substance under the CSA.

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 scheduling action. Please note that both the DEA and the HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this interim final rule at *http://www.regulations.gov,* under Docket Number ''DEA–503.'' Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. *Its Actual or Relative Potential for Abuse:* Brexanolone is a new molecular entity and is not currently available or marketed in any country; evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is lacking. However, as stated by the HHS, brexanolone is related in action to schedule IV sedatives such as midazolam and alprazolam. It is thus reasonable to assume that brexanolone may be diverted from legitimate channels, used contrary to or without medical advice, and otherwise abused so as to create hazards to the users and to the safety of the community to an extent similar to that of schedule IV sedatives.

Pre-clinical and clinical studies show that brexanolone produces effects that are similar to schedule IV sedative-hypnotics, such as midazolam and alprazolam. Data obtained from general behavioral studies demonstrate that brexanolone produced a sedative effect. In a drug discrimination study in rats, brexanolone mimicked stimulus effects of midazolam at certain dosages. Brexanolone produced positive subjective responses and euphoria-related adverse events (AEs) similar to that of alprazolam (schedule IV) in nondependent and healthy humans with a history of recreational use of CNS depressants. Thus, brexanolone likely has abuse potential similar to that of schedule IV sedatives, such as midazolam and alprazolam, and it is likely to be abused for its sedative effects contrary to medical advice.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* Brexanolone, an inhibitory neurosteroid, shares a similar pharmacological profile to another inhibitory neurosteroid (alfaxalone, a schedule IV controlled substance) and schedule IV benzodiazepines such as alprazolam and midazolam. Brexanolone, a metabolite of progesterone, acts on GABA–A receptors and enhances the effects of GABA. GABA is the major inhibitory neurotransmitter in the CNS. The GABA–A receptor is a ligand-gated chloride ion channel consisting of five subunits and a central chloride channel. Benzodiazepines and other GABAergic substances enhance the opening of the ligand-gated chloride channel and the influx of chloride. Brexanolone's ability to bind to GABA-related sites is consistent with the action of other related neurosteroids, such as alfaxalone.

Brexanolone, like schedule IV benzodiazepines, has sedative activity in animals. Acute and chronic administration of brexanolone to male and female rats and dogs elicited dose-dependent behaviors indicative of the sedative and muscle relaxation properties of the drug. In a drug discrimination study using male rats previously trained to discriminate midazolam, brexanolone produced interoceptive cues that are similar to those of midazolam. In human abuse potential studies, brexanolone produced subjective responses similar to that of alprazolam and may have a reinforcing effect at a higher infusion rate. The abuse-related neuropharmacology profile of brexanolone is similar to that of schedule IV substances (alprazolam and midazolam) and consistent with its mechanism of action as a positive allosteric modulator of the GABA–A receptors.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Brexanolone is a new molecular entity. It is the established name for allopregnanolone, chemically known as 5α-pregnan-3α-ol-20-one (also known as 3α-hydroxy-5α-pregnan-20-one). It is insoluble in water, very slightly soluble in *n*-heptane, sparingly soluble in ethyl acetate, slightly soluble in methanol, soluble in 2-methyl-tetrahydrofuran, and freely soluble in tetrahydrofuran. Brexanolone drug product is formulated as a sterile, clear, colorless solution intended for dilution followed by intravenous infusion; and it contains brexanolone, Betadex Sulfobutyl Ether Sodium USP/NF (Captisol) as a solubilizer, citric acid and sodium citrate as buffering agents, and water for injection. The pH of the final bulk compounded solution is adjusted to 6.0 using either sodium hydroxide or hydrochloric acid.

4. *Its History and Current Pattern of Abuse:* There is no information on the history and current pattern of abuse for brexanolone, since it has not been marketed, legally or illegally, in any country. The DEA conducted a search on the National Forensic Laboratory Information System (NFLIS) [2] and STARLiMS [3] databases for brexanolone encounters. Consistent with the fact that brexanolone is a new molecular entity, these databases had no records of encounters by law enforcement.

HHS notes that brexanolone produces abuse-related signals and abuse potential similar to that of schedule IV benzodiazepines. In particular, the pharmacological mechanism of action of brexanolone involving a positive allosteric modulation of the GABA–A receptors suggests that its pattern of abuse would be similar to schedule IV sedative-hypnotics with similar mechanisms of action, such as midazolam and diazepam.

5. *The Scope, Duration, and Significance of Abuse:* As noted, brexanolone is not marketed, legally or illegally, in any country. Thus, information about the scope, duration, and significance of abuse for brexanolone is lacking. However, because of brexanolone's pharmacological similarities to certain schedule IV benzodiazepines, brexanolone is likely to be abused when available in the market with a scope, duration, and significance of abuse similar to those of schedule IV benzodiazepines.

6. *What, if any, Risk There Is to the Public Health:* The extent of abuse potential of a drug is an indication of its public health risk. Data from preclinical and clinical studies showed that brexanolone has abuse potential similar to that of certain schedule IV benzodiazepines. Therefore, upon availability for marketing, it is likely to pose a public health risk to a degree similar to schedule IV benzodiazepines. Data from clinical trials showed that brexanolone caused excessive sedation with occasional loss of consciousness and amnesia. In addition, transient apnea occurred in one patient at a supratherapeutic dose. The HHS states that these adverse effects would likely occur in abusers of brexanolone.

[2] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

[3] STARLiMS is a web-based, commercial laboratory information management system that systematically collects results from drug chemistry analyses conducted by the DEA laboratories. On October 1, 2014, STARLiMS replaced the System to Retrieve Information from Drug Evidence (STRIDE) as the DEA laboratory drug evidence data system of record.

The brexanolone prescription product label states that concomitant use of opioids, antidepressants, or other CNS depressants such as benzodiazepines or alcohol may increase the possibility or severity of adverse reactions related to sedation. In addition, because of the risk of excessive sedation or sudden loss of consciousness, brexanolone is only available through a REMS program. A REMS is a drug safety program required by the FDA for certain medications with serious safety concerns to ensure the benefits of the medication outweighs its risks and is designed to reinforce medication use behaviors and actions that support the safe use of the medication.[4]

The abuse of brexanolone may present risks to the public health at a level similar to those associated with the abuse of schedule IV benzodiazepines, such as midazolam and alprazolam.

7. *Its Psychic or Physiological Dependence Liability:* The HHS review states that there were no physical dependence studies conducted in animals or humans using brexanolone. Brexanolone is pharmacologically similar to benzodiazepines that are known to produce physical dependence. Sleep disturbances, anxiety, and convulsions can occur upon discontinuation of chronic administration of benzodiazepines. Thus, it is likely brexanolone may have a physical dependence potential similar to that of benzodiazepines. Data from a dog toxicity study demonstrated that discontinuation of chronic administration of brexanolone led to convulsions, similar to the effect from discontinuing benzodiazepines. Because brexanolone produced positive subjective responses and euphoria-related AEs, it is likely to cause psychic dependence.

8. *Whether the Substance Is an Immediate Precursor of a Substance Already Controlled under the CSA:* Brexanolone is not an immediate precursor of any substance already controlled in the CSA.

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS's recommendation, and its own eight-factor analysis, the DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of brexanolone. As such, the DEA hereby schedules brexanolone as a controlled substance under the CSA.

[4] More information may be found at *https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm.*

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) Brexanolone has a low potential for abuse relative to the drugs or other substances in Schedule III.

Brexanolone, a neuroactive steroid, is a positive allosteric modulator of GABA–A receptors and produces sedation in general behavioral studies and locomotion study. In a drug discrimination study in animals, brexanolone was generalized to midazolam (schedule IV) at certain dosages, demonstrating it has GABA–A receptor agonist properties. In a human abuse potential (HAP) study, brexanolone produced positive subjective responses and euphoria-related AEs similar to those of alprazolam (schedule IV) in an HAP study. Furthermore, data from other clinical studies show that brexanolone produced abuse-related AEs, namely somnolence and sedation. Because brexanolone is similar to midazolam and alprazolam (both schedule IV controlled substances) in its abuse potential, brexanolone has a low potential for abuse relative to the drugs or other substances in schedule III.

(2) Brexanolone has a currently accepted medical use in the United States.

The FDA recently approved the NDA for brexanolone as an intravenous treatment of PPD in adult women. Thus, brexanolone has a currently accepted medical use for treatment in the United States.

(3) Abuse of Brexanolone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Brexanolone has a pharmacology profile similar to that of benzodiazepine drugs. Because abrupt discontinuation of benzodiazepines is associated with withdrawal symptoms, it is likely that brexanolone may have the potential to produce physical dependence similar to that produced by benzodiazepines. Data from a dog toxicity study demonstrated that discontinuation of chronic administration of brexanolone led to convulsions, similar to the effect from discontinuing benzodiazepines. In addition, because brexanolone produced positive subjective responses and euphoria-related AEs, it is likely that brexanolone can produce psychic dependence. Thus, abuse of brexanolone may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III.

Based on these findings, the Acting Administrator of the DEA concludes that brexanolone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Brexanolone

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 currently handles or intends to handle brexanolone, and is not registered with the DEA, must submit an application for registration and may not continue to handle brexanolone, unless the DEA has approved 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 does not desire or is not able to maintain a schedule IV registration must surrender all quantities of currently held 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 must take an inventory of all stocks of brexanolone on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA to handle brexanolone must take an initial inventory of all stocks of controlled substances (including brexanolone) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including brexanolone) on hand every two years, 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

As explained above, under 21 U.S.C. 811(j), when a new drug is (1) approved by the Department of Health and Human Services (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. Therefore, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

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 Public Law 114–89, 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 interim final rule is not an Executive Order 13771 regulatory action pursuant to Executive Order 12866 and OMB guidance.[5]

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 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 on the distribution of power and responsibilities among the various levels of government.

[5] 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).

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

In accordance with 5 U.S.C. 603(a), ''[w]henever an agency is required by [5 U.S.C. 553], or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretive rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis.'' As noted in the above discussion regarding applicability of the APA, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action. Consequently, the Regulatory Flexibility Act does not apply to this interim final rule.

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 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 has submitted a copy of this interim 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, the DEA amends 21 CFR part 1308 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), unless otherwise noted.

■ 2. Amend § 1308.14 by:
■ a. Redesignating paragraphs (c)(4) through (c)(55) as (c)(5) through (c)(56);
■ b. Adding new paragraph (c)(4).
The addition reads as follows:

§ 1308.14 Schedule IV.

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(c) * * *

(4) Brexanolone	2400

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Dated: June 10, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–12721 Filed 6–14–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–504]

Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule, with request for comments.

SUMMARY: On March 20, 2019, the U.S. Food and Drug Administration approved a new drug application for SUNOSI, a drug product consisting of solriamfetol ((*R*)-2-amino-3-phenylpropyl carbamate hydrochloride) tablets for oral use. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place solriamfetol in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing solriamfetol, 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 CSA.

DATES: The effective date of this rulemaking is June 17, 2019. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before July 17, 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 may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before July 17, 2019.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–504'' on all 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 and are discouraged. 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/DPW, 8701 Morrissette Drive, Springfield, VA 22152.

• *Hearing requests:* All requests for 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 also 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/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received 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.