responsible agency or the USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

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List of Subjects in 7 CFR Part 622

Flood control, Grant programs—natural resources, Loan programs—natural resources, Soil conservation, Technical assistance, Watersheds.

For the reasons discussed above, NRCS amends 7 CFR part 622 as follows:

PART 622—WATERSHED PROJECTS

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1001–1012a, and 33 U.S.C. 701b–1.

Subpart B—Qualifications

■ 2. In § 622.10, revise paragraph (a) to read as follows.

§ 622.10 Sponsors.

(a) Watershed projects are sponsored by one or more local organizations qualifying as sponsors. All watershed plans must be sponsored by entities legally organized under State law or by any Indian Tribe or Tribal organization having the authority to carry out, operate, and maintain works of improvement.

(1) *In General.* Those plans that incorporate the use of nonstructural or structural measures must be sponsored by organizations that, individually or collectively, have:

(i) The power of eminent domain, except as provided in paragraph (a)(2) of this section; and

(ii) The authority to levy taxes or use other adequate funding sources, to finance their share of the watershed project cost and all operation and maintenance costs.

(2) *Exception.* Paragraph (a)(1)(i) of this section does not apply to Indian Tribes or Tribal organizations.

* * * * *

Terry Cosby,

Chief, Natural Resources Conservation Service.

[FR Doc. 2024–17819 Filed 8–13–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1258]

Schedules of Controlled Substances: Placement of Zuranolone 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 October 31, 2023, placing zuranolone (chemically known as 1-[2-[(3*R*,5*R*,8*R*,9*R*,10*S*,13*S*,14*S*,17*S*)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetradecahydro-1*H*-cyclopenta[*a*]phenanthren-17-yl]-2-oxoethyl]pyrazole-4-carbonitrile) and its salts in schedule IV of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains zuranolone, including its salts, in schedule IV of the Controlled Substances Act.

DATES: Effective September 13, 2024.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Chief, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule (IFR), with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and subsequently to issue a final rule.[1] When controlling a drug pursuant to subsection 811(j), DEA must apply the scheduling criteria of 21 U.S.C. 811(b) through (d), and 812(b).[2]

On August 4, 2023, the U.S. Food and Drug Administration (FDA) approved the New Drug Application (commonly referred to as NDA) for zuranolone to be marketed as a prescription drug (ZURZUVAE, capsule) for the treatment of post-partum depression. DEA received notification that FDA approved the NDA on the same date. Pursuant to its FDA-approved prescription drug labeling, ZURZUVAE, 50 mg, is to be administered orally once in the evening with fat-consuming food for 14 days. The dose may be reduced for patients who cannot tolerate 50 mg. In addition, on July 12, 2023, HHS recommended that DEA place zuranolone and its salts in schedule IV of the CSA.

On October 31, 2023, DEA, pursuant to 21 U.S.C. 811(j), published an IFR in the **Federal Register** to make zuranolone (including its salts) a schedule IV controlled substance.[3] The IFR provided an opportunity for interested persons to submit comments, as well as file a request for a hearing or waiver of a hearing, on or before November 30, 2023. DEA did not receive any requests for a hearing or waiver of a hearing.

Comment Received

DEA received one comment on the IFR to control zuranolone in schedule IV of the CSA. The commenter briefly expressed that schedule IV was the appropriate schedule for zuranolone based on the similarity of this substance to substances in schedule IV and requested information on what surveillance and reporting systems exist to ensure proper use of zuranolone due to its documented abuse potential.

DEA Response: DEA determined in the IFR, and re-affirms in this final rule, that zuranolone meets the criteria under 21 U.S.C. 812(b)(4) for schedule IV control. As described by HHS, and in DEA's September 2023 eight-factor analysis, zuranolone demonstrated abuse potential similar to schedule IV

[1] 21 U.S.C. 811(j).

[2] 21 U.S.C. 811(j)(3).

[3] *Schedules of Controlled Substances: Placement of Zuranolone in Schedule IV,* 88 FR 74347 (Oct. 31, 2023).

depressants. DEA appreciates the support for this rulemaking.

In response to the request of information regarding surveillance and reporting systems in place, DEA notes that diversion and illicit trafficking of zuranolone will be monitored by DEA's National Forensic Laboratory Information System (NFLIS)-Drug.[4] NFLIS-Drug 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.

DEA also notes that the monitoring of adverse effects for any new drug products, including abuse potential, largely falls under the purview of HHS, including FDA. FDA monitors the adverse events for all drugs through a postmarketing pharmacovigilance program.[5]

DEA is aware that in the publicly available NDA letter,[6] FDA noted reporting information under sections ''Reporting Requirements'' and ''Requested Pharmacovigilance.'' Specifically, the sponsor of the zuranolone drug product ZURZUVAE must follow standard reporting guidance as described in 21 CFR 314.80(c)(1) (*e.g.,* 15-day alert reports), submit standard periodic (including quarterly) adverse drug experience reports as described in 21 CFR 314.80(c)(2), and submit standard annual reports as described in 21 CFR 314.81(b)(2). Further, the sponsor must submit additional reports as described in the letter, including ''all serious and nonserious domestic and foreign adverse drug experience reports of Central Nervous System (CNS) depressant effects including adverse sequelae of the CNS depressant effects, such as motor vehicle accidents, falls, loss of consciousness, respiratory depression, or impairment of the ability to care for a child as a 15-day 'Alert report' (described under 21 CFR 314.80(c)(1)), from any source, including information derived from reports in the scientific literature and postmarketing studies (whether or not conducted under an investigational new drug application), through the 5th year following initial U.S. approval.'' DEA notes that additional information about published alerts, as well as the drug labeling and approval process, can be found at ''Drugs@FDA: FDA-Approved Drugs'' on FDA's website.[7] Importantly, drug labeling is used to communicate to both healthcare providers and patients any potential risks associated with the product, including abuse-related risks, if any, and is updated over time.

Additionally, adverse effects can be reported to FDA's Adverse Event Reporting System (FAERS). FDA has a publicly available FAERS dashboard,[8] which states ''[t]he intention of this tool is to expand access of FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.''

Based on the rationale set forth in the IFR, DEA adopts the IFR, without change.

Requirements for Handling Zuranolone

As indicated above, zuranolone has been a schedule IV controlled substance by virtue of an IFR issued by DEA in October 2023. Thus, this final rule does not alter the regulatory requirements applicable to handlers of zuranolone that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Zuranolone is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distributing, dispensing, importing, exporting, research, and conduct of instructional activities, 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) zuranolone 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. These registration requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

2. *Disposal of Stocks.* Any person unwilling or unable to obtain a schedule IV registration must surrender all quantities of currently held zuranolone, or may transfer all quantities of currently held zuranolone to a person registered with DEA. Zuranolone is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Zuranolone is subject to schedule III–V security requirements for DEA registrants and must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling zuranolone must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

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

5. *Inventory.* Since October 31, 2023, every DEA registrant who possesses any quantity of zuranolone must have an initial inventory of all stocks of controlled substances (including zuranolone) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who registers with DEA to handle zuranolone must take an initial inventory of all stocks of controlled substances (including zuranolone) 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(a) and (b).

After the initial inventory, every DEA registrant must take inventory of all controlled substances (including zuranolone) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for zuranolone, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and in accordance with 21 CFR 1301.74(b) and

[4] NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1 million distinct annual state and local drug analysis cases. NFLIS includes drug chemistry results only from completed analyses. Although NFLIS-Drug data are not direct evidence of abuse, they can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330, 77332 (Dec. 12, 2011).

[5] *https://www.fda.gov/drugs/surveillance/postmarketing-adverse-event-reporting-compliance-program.*

[6] *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/217369Orig2s000Corrected_ltr.pdf.*

[7] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

[8] *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.*

(c), and 1301.76(b), and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for zuranolone, or products containing zuranolone, 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 zuranolone 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 (FDCA), as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of zuranolone 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 zuranolone 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 IFR that is already in effect. Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA, and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, subsection 811(j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause. DEA issued an IFR on October 31, 2023, and solicited public comments on that rule. Subsection (j) further provides that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). As stated above, DEA received one comment and no requests for a hearing or waiver of a hearing. DEA is now issuing the final rule in accordance with subsection (j).

Executive Orders 12866, 13563, and 14094, Regulatory Review

In accordance with 21 U.S.C. 811(a), 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 pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 E.O. 13132. The proposed 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 rule does not have tribal implications warranting the application of E.O. 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.

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

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. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this 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.,* DEA has determined and certifies that this proposed 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.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 6, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

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 rule amending 21 CFR part 1308, published October 31, 2023, at 88 FR 74347, is adopted as a final rule without change.

Heather Achbach,

Federal Register Liaison Officer Drug Enforcement Administration.

[FR Doc. 2024–18087 Filed 8–13–24; 8:45 am]

BILLING CODE 4410–09–P