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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

7 CFR Part 622

[Docket ID NRCS–2023–0020]

RIN 0578–AA72

Tribe or Tribal Organization Sponsor Option for Watershed Projects

AGENCY: Natural Resources Conservation Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: The Natural Resources Conservation Service (NRCS) is amending its regulations for watershed projects to allow Indian Tribes or Tribal organizations to sponsor needed watershed projects. While federally recognized Tribes generally maintain regulatory jurisdiction over their land and can therefore exert eminent domain, Alaska Native Corporations and Tribal organizations do not have eminent domain authority, which has been one of the requirements to be a watershed project sponsor. This rule change will provide an option to better allow federally recognized Tribes, Alaska Native Corporations, or Tribal organizations to become watershed project sponsors.

DATES:

Effective date: August 14, 2024.

Comment date: We will consider comments that we receive by September 13, 2024.

ADDRESSES: We invite you to submit comments in response to this rule. You may submit your comments through one of the following methods below:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov> and search for Docket ID NRCS–2023–0020. Follow the instructions for submitting comments.

All comments received will be made publicly available on <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Ralph Smith; telephone: (202) 819–6587; email: ralph.smith@usda.gov. Individuals who require alternative means for communication should contact the U.S. Department of Agriculture (USDA) Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

Watershed projects are authorized under the Watershed Protection and Flood Prevention Act of 1954 (Pub. L. 83–566, 16 U.S.C. 1001–1008), as amended, and the Flood Control Act of 1944 (Pub. L. 78–534, 33 U.S.C. 701b–1). Public Law 83–566 and Public Law 78–534 authorize the Secretary of Agriculture to cooperate with State and local agencies, federally recognized Tribes, Alaska Native Corporations, and Tribal organizations in the planning and carrying out of works of improvement for flood prevention; for the conservation, development, utilization, and disposal of water; and for the conservation and proper use of land. NRCS administers these authorities for watershed projects for USDA. NRCS provides technical and financial assistance for watershed projects. Participation in watershed projects is voluntary.

NRCS is amending its regulations for watershed projects to allow more Indian Tribes or Tribal organizations to sponsor needed watershed projects.

While federally recognized Tribes generally maintain regulatory jurisdiction over their land and can therefore exert eminent domain, Alaska Native Corporations and Tribal organizations do not have eminent domain authority, which has been one of the requirements to be a watershed project sponsor. This requirement is not necessary when the Tribe or Tribal organization has already acquired the necessary real property interests needed in connection with the works of improvement.

Through the Watershed and Flood Prevention Operations Program, NRCS provides technical and financial assistance to entities of State and local governments, federally recognized Tribes, Alaska Native Corporations, and Tribal Organizations in need of help

with protecting and restoring small watersheds for multiple purposes including, but not limited to, flood prevention, watershed protection, and agricultural water management. These locally sponsored projects are highly coordinated between sponsoring and regulatory agencies and involve detailed studies before design and implementation can begin.

Exemption for Tribes or Tribal Organizations To Become Watershed Project Sponsors

This rule change will provide an option to allow more Indian Tribes, defined under the legislative authorization to include Alaska Native Corporations (25 U.S.C. 5304), or Tribal organizations to become watershed project sponsors.

This rule will modify the sponsorship requirements to increase Indian Tribes or Tribal organizations ability to be a sponsor for watershed projects to:

- (1) Prevent damage from erosion, floodwater, and sediment;
- (2) Further the conservation, development, utilization, and disposal of water; and
- (3) Further the conservation and proper utilization of land.

Specifically, the rule will revise the regulation in 7 CFR 622.10 to add an exemption for applicable Indian Tribes and Tribal organizations from the requirement to have eminent domain in order to be a watershed project sponsor.

NRCS must revise its current regulations to modify the power of eminent domain requirement for watershed project sponsors. While federally recognized Tribes generally maintain regulatory jurisdiction over their land and can therefore exert eminent domain, Alaska Native Corporations and Tribal organizations do not have eminent domain authority. Still, many Indian Tribes and Tribal organizations have expressed the need to sponsor watershed projects. As noted above, the rule change will exempt Indian Tribes or Tribal organizations from that requirement.

NRCS currently has requests from approximately 30 Indian Tribes or Tribal organizations for watershed projects in 9 states.

The change in the regulation will help to ensure that Indian Tribes or Tribal organizations have the opportunity to sponsor watershed projects if there is a need.

Being a sponsor of a watershed project is voluntary. There are no anticipated changes to the current overall watershed project costs or benefits to customers, NRCS or others. The change is relatively minor in the overall scope of the Public Law 83–566 and Public Law 78–534 watershed projects.

Notice and Comment, Effective Date, and Exemptions

The Administrative Procedure Act (5 U.S.C. 553) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts. This rule involves matters relating to financial assistance, which is considered a benefit.

This rule is exempt from the regulatory analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996.

For major rules, the Congressional Review Act requires a delay in the effective date for 60 days from the date of publication to allow for Congressional review. This rule is not a major rule under the Congressional Review Act, as defined by 5 U.S.C. 804(2). Therefore, this rule is effective upon publication in the **Federal Register**.

Executive Orders 12866 and 13563

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review” direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. The assessment should include potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) designated this rule as not significant under Executive Order 12866, “Regulatory Planning and Review,” and therefore, OMB has not reviewed this rule.

Environmental Review

The environmental impacts of this rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347), the

regulations of the Council on Environmental Quality (40 CFR parts 1500 through 1508), and the NRCS regulations for compliance with NEPA (7 CFR parts 1b and 650).

This rule makes a minor discretionary amendment to improve administration of the program and clarify existing program requirements. The discretionary change will not alter any environmental impacts resulting from implementing the change for watershed projects. Accordingly, the discretionary change is covered by the USDA Categorical Exclusion for policy development, planning, and implementation that relates to routine activities (7 CFR 1b.3(a)(1)).

Through this review, NRCS determined that the discretionary change in this rule is within the categorical exclusion listed above. Categorical exclusions apply when no extraordinary circumstances exist (7 CFR 650.6(c)(2)). The amendment will not have an adverse impact on the human environment, individually or cumulatively. Therefore, NRCS will not prepare an environmental assessment or environmental impact statement for this rule.

Executive Order 12988

This rule has been reviewed under E.O. 12988 on “Civil Justice Reform.” This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. This rule will not have a retroactive effect.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, “Consultation and Coordination with Indian Tribal Governments.” E.O. 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that 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.

NRCS developed the rule changes in response to requests from Tribes and Alaska Native Corporations seeking greater flexibility in the administration of USDA programs. Tribes have suggested this change as a means of removing a barrier to their participation in the Watershed and Flood Prevention Operations Program. If a Tribe requests

consultation, the USDA Office of Tribal Relations (OTR) will ensure meaningful consultation is provided where changes, additions, and modifications are not expressly mandated by law.

The Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of \$100 million or more in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in title II of UMRA, for State, local, and Tribal governments, or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Paperwork Reduction Act

This rule has been reviewed in compliance with the Paperwork Reduction Act (44 U.S.C. 3501–3520). This rule does not have any information collection requirements. NRCS neither collects information from the public nor sponsors the collection of information from the public for the watershed programs.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, the USDA, its agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the

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]

BILLING CODE 3410–16–P

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-[(3R,5R,8R,9R,10S,13S,14S,17S)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetradecahydro-1H-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).