

the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule V controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of lasmiditan 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 lasmiditan 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 lasmiditan 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 affirms the amendment made by the interim final rule that is already in effect with a minor change in placement ordering of lasmiditan as discussed above. 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(j) provides that in cases where a certain new drug is: (1) Approved by HHS and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause. DEA issued an interim final rule on January 31, 2020, which provided notice and an opportunity for a hearing on the record and solicited public comments on that rule. Subsection (j) further states 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). DEA is now responding to the comments submitted by the public and issuing the final rule in accordance with subsection (j).

### *Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

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 (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

### *Executive Order 12988, Civil Justice Reform*

This regulation 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 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.

### *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 was not required to publish a general notice of proposed rulemaking. 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.*, 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 million 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.

### *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. However, DEA is submitting the required reports to the Government Accountability Office, the House, and the Senate under the CRA.

### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

■ Accordingly, the interim final rule amending 21 CFR part 1308, which was published at 85 FR 5557 on January 31, 2020, and as subsequently amended at 85 FR 13741 and 85 FR 51340, is adopted as a final rule without change.

### D. Christopher Evans,

*Acting Administrator.*

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## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 224

[212D0102DR/DS5A300000/  
DR.5A311.IA000118]

RIN 1076–AF65

#### Tribal Energy Resource Agreements

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Interim final rule.

**SUMMARY:** On December 18, 2019, the Bureau of Indian Affairs (BIA) amended its regulations governing Tribal Energy

Resource Agreements (TERAs) between the Secretary of the Interior (Secretary) and Indian Tribes. That document inadvertently failed to include the statutory requirement that any application for a Tribal Energy Development Organization (TEDO) be submitted by the Tribe, rather than the TEDO itself, and incorrectly listed three cross-references. This interim final rule would correct that omission and cross-references.

**DATES:** This rule is effective May 24, 2021. Submit comments by June 23, 2021.

**ADDRESSES:** You may submit comments by any of the following methods:

- Federal rulemaking portal [www.regulations.gov](http://www.regulations.gov). The rule is listed under the agency name “Bureau of Indian Affairs.”

- *Email: comments@bia.gov.*

- We cannot ensure that comments received after the close of the comment period (see **DATES**) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed above will not be included in the docket for this rulemaking.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, (202) 273-4680; [elizabeth.appel@bia.gov](mailto:elizabeth.appel@bia.gov).

**SUPPLEMENTARY INFORMATION:**

I. Background

II. Corrections to Final Rule

III. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866, 13563, and 13771)

B. Regulatory Flexibility Act

C. Small Business Regulatory Enforcement Fairness Act

D. Unfunded Mandates Reform Act

E. Takings (E.O. 12630)

F. Federalism (E.O. 13132)

G. Civil Justice Reform (E.O. 12988)

H. Consultation With Indian Tribes (E.O. 13175)

I. Paperwork Reduction Act

J. National Environmental Policy Act

K. Effects on the Energy Supply (E.O. 13211)

## I. Background

On December 18, 2019, BIA updated its TERA regulations under the authority of the Indian Tribal Energy Development and Self-Determination Act of 2005, as amended by the Indian Tribal Energy Development and Self-Determination Act Amendments of 2017, 25 U.S.C. 3501–3504, Public Law 115–325, and 25 U.S.C. 2 and 9. The rule addressed the requirements of the Indian Tribal Energy Development and Self-Determination Act Amendments of 2017 (2017 Amendments), including establishing a process and criteria for

TEDOs to obtain certification from the Secretary so that they may enter into leases, business agreements, and rights-of-way with Tribes on Tribal land without Secretarial approval. See Section 103(b) of the 2017 Amendments.

## II. Corrections to Final Rule

The 2019 regulation stated at § 224.202 that a TEDO must submit an application. The statute, however, states that the Tribe submits the application for certification of a TEDO. See 25 U.S.C. 3504(h)(1). For that reason, the regulation at § 224.202 must be corrected to provide that a Tribe must submit the application.

Additionally, Indian Affairs identified typographical errors in the cross-references to paragraphs in § 224.53, which should be corrected as follows:

- In paragraph (a)(3), the cross-reference should be to paragraph (b), rather than paragraph (c);
- In paragraph (a)(5), the cross-reference should be to paragraph (c) rather than paragraph (d); and
- In paragraph (b), the cross reference should be to paragraph (a)(3) rather than paragraph (a)(6).

## III. Procedural Requirements

### A. Regulatory Planning and Review (E.O. 12866, 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

### B. Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic effect on a

substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

### C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of \$100 million or more;

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises because this rule makes minor corrections.

### D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than \$100 million per year. The rule does not have a monetarily significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

### E. Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630 because this rule does not affect individual property rights protected by the Fifth Amendment or involve a compensable “taking.” A takings implication assessment is not required.

### F. Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement because the rule affects only agreements entered into by Tribes and the Department. A federalism summary impact statement is not required.

### G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule: (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and (b) Meets the criteria of section 3(b)(2) requiring that

all regulations be written in clear language and contain clear legal standards.

*H. Consultation With Indian Tribes (E.O. 13175)*

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it does not have substantial direct effects on federally recognized Indian Tribes because the Department consulted on substantive requirements of the rule that is in effect, and this rule merely makes minor corrections to that substantive rule.

*I. Paperwork Reduction Act*

OMB Control No. 1076–0167 currently authorizes the collections of information contained in 25 CFR part 224. This rule does not affect those collections of information.

*J. National Environmental Policy Act*

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because this is an administrative and procedural regulation. (For further information see 43 CFR 46.210(i)). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

*K. Effects on the Energy Supply (E.O. 13211)*

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

*L. Clarity of This Regulation*

We are required by Executive Orders 12866 (section 1(b)(12)), and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use common, everyday words and clear language rather than jargon;
- (d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you think lists or tables would be useful, etc.

*M. Public Availability of Comments*

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*N. Determination To Issue an Interim Final Rule With Immediate Effective Date*

We are publishing this interim final rule with a request for comment without prior notice and comment, as allowed under 5 U.S.C. 553(b). Under section 553(b) we find that there is good cause to effectuate this rule without prior notice, and comments are unnecessary and would be contrary to the public interest. This rule is necessary to ensure that the regulation is clear in that the Tribe must approve a TEDO application, and correct internal section cross-references.

As allowed under 5 U.S.C. 553(d)(3), the effective date of this rule is the date of publication in the **Federal Register**. Good cause for an immediate effective date exists because the delay in publishing this rule serves no useful purpose as the statute already requires what this interim final rule updates in the regulation and any delay in correcting internal cross-references to sections may cause confusion on the part of potential TEDO applicants. We are requesting comments on this interim final rule. We will review any comments received and, by a future publication in the **Federal Register**, address any comments received.

**List of Subjects in 25 CFR Part 224**

Agreement, Appeals, Application, Business Agreements, Energy Development, Interested Party, Lease, Record keeping requirements, Reporting requirements, Right-of-Way, Tribal Energy Resource Agreements, Tribal

capacity, Tribal lands, Trust, Trust asset.

For the reasons stated in the preamble, the Department of the Interior, Bureau of Indian Affairs, amends part 224 in title 25 of the Code of Federal Regulations as follows:

**PART 224—TRIBAL ENERGY RESOURCE AGREEMENTS UNDER THE INDIAN TRIBAL ENERGY DEVELOPMENT AND SELF DETERMINATION ACT**

■ 1. The authority for part 224 continues to read as follows:

**Authority:** 25 U.S.C. 2 and 9; 25 U.S.C. 3501–3504; Pub. L. 109–58; Pub. L. 115–325.

**§ 224.53 [Amended]**

■ 2. In § 224.53:

- a. Amend paragraph (a)(3) by removing “paragraph (c)” and adding “paragraph (b)” in its place;
  - b. Amend paragraph (a)(5) by removing “paragraph (d)” and adding “paragraph (c)” in its place.
  - c. Amend paragraph (b) introductory text by removing “paragraph (a)(6)” and adding “paragraph (a)(3)” in its place.
- 3. Revise § 224.202 to read as follows:

**§ 224.202 How must a Tribe submit an application for certification of a TEDO?**

A Tribe must submit an application for certification of a TEDO and all supporting documents in a searchable portable document format (PDF) to [TERA@bia.gov](mailto:TERA@bia.gov).

**Bryan Newland,**

*Principal Deputy Assistant Secretary—Indian Affairs.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket Number USCG–2021–0013]

RIN 1625–AA08

**Special Local Regulations; Sector Ohio Valley Annual and Recurring Special Local Regulations, Update**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is amending and updating its special local regulations for recurring marine parades, regattas, and other events that take place in the Coast Guard Sector Ohio Valley area of responsibility