

### III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

#### PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 884.5210 to subpart F to read as follows:

##### § 884.5210 Pressure wedge for the reduction of cesarean delivery.

(a) *Identification.* A pressure wedge for the reduction of cesarean delivery is a prescription device that provides external mechanical support to the perianal region during the labor and vaginal delivery process. External mechanical support of the perianal region is intended to help reduce the occurrence of cesarean delivery.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting materials must be evaluated to be biocompatible.

(2) Nonclinical performance data must demonstrate that the device will not break when subjected to the forces it will be exposed to during labor.

(3) Performance data must validate the sterility of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility and package integrity over the labeled shelf life.

(5) Clinical performance data must be provided that characterizes the rate of skin/tissue trauma.

(6) The labeling must include:

(i) Specific instructions regarding the proper placement and use of the device.  
(ii) A shelf life.

Dated: December 22, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 11

[189A2100DD/AAKC001030/A0A501010.999900]

RIN 1076–AF39

#### Addition of the Wind River Indian Reservation to the List of Courts of Indian Offenses

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

**ACTION:** Final rule; confirmation.

**SUMMARY:** The Bureau of Indian Affairs (BIA) is confirming the interim final rule published on October 27, 2016, establishing a Court of Indian Offenses (also known as a CFR Court) for the Wind River Indian Reservation.

**DATES:** This final rule is effective on December 28, 2017.

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

#### SUPPLEMENTARY INFORMATION:

I. Summary of Rule

II. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866)

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 and Departmental Policy)

I. Paperwork Reduction Act

J. National Environmental Policy Act

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

L. Clarity of This Regulation

M. E.O. 13771: Reducing Regulation and Controlling Regulatory Costs

### I. Summary of Rule

Generally, Courts of Indian Offenses operate in those areas of Indian country where Tribes retain jurisdiction over Indians that is exclusive of State jurisdiction, but where Tribal courts have not been established to fully exercise that jurisdiction. The Eastern Shoshone Tribe and the Northern Arapaho Tribe have an equal joint interest in the Wind River Indian Reservation. Since the publication of the Interim Final Rule establishing the Court of Indian Offenses for the Wind River Indian Reservation, the Shoshone & Arapaho Tribal Court has operated without the legal support of the Eastern Shoshone Tribe, and with limited resources. The Bureau has attempted to work with the Northern Arapaho Tribe towards establishing a system of courts with concurrent jurisdiction. However, after nine months of operation, the joint nature of the Wind River Indian Reservation has proven establishing such a system untenable.

Allowing the Bureau of Indian Affairs to constitute a CFR Court will provide all residents on the Wind River Indian Reservation with comprehensive judicial services, and ensure the administration of justice and public safety. To accomplish this, this rule finalizes the revision of a section of 25 CFR part 11 to add the Wind River Indian Reservation in Wyoming to the list of areas in Indian country with established Courts of Indian Offenses (also known as CFR Courts). This rule inserts the Wind River Indian Reservation into a new paragraph (d) in 25 CFR 11.100.

An interim final rule published on October 27, 2016 (81 FR 74675). Comments received on the interim final rule are addressed in Section II.H of this preamble, below.

### II. Procedural Requirements

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

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and

Regulatory Affairs has determined that this rule is not significant.

Executive Order 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 executive order 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

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.*) because the rule affects only the administration of justice on a reservation through a CFR court.

#### C. Small Business Regulatory Enforcement Fairness Act

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

#### 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 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. 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. 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 and Departmental Policy)

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 under the criteria in Executive Order 13175 and have consulted with the affected tribes.

Prior to issuing this regulation, the Department of the Interior and its Agencies, Bureaus, and Offices, communicated repeatedly with the Eastern Shoshone Tribe and the Northern Arapaho Tribe regarding public safety concerns for the residents of the Wind River Indian Reservation. Following the withdrawal of the Northern Arapaho Tribe from the Joint Business Committee, the Shoshone & Arapaho Tribal Court continued to operate with limited resources and only with the support of the Northern Arapaho Tribe. The Northern Arapaho Tribe has established its own Northern Arapaho Tribal Code has retitled the Shoshone & Arapaho Tribal Court as the Northern Arapaho Tribal Court. The Northern Arapaho Tribe and Eastern Shoshone Tribe have responded to the Interim Final Rule. The Northern Arapaho Tribe provided extensive documentation on its right to establish an independent judiciary, without addressing the pragmatic consequences of having multiple courts with concurrent jurisdiction on the Reservation. The Eastern Shoshone

Business Committee expressly requested that the Department establish and operate a Court of Indian Offenses for the Wind River Indian Reservation.

After reviewing these comments, and the operation of the Court of Indian Offenses for the Wind River Indian Reservation over the past nine months, the Department has determined that to ensure public safety, it is necessary to establish a Court of Indian Offenses for the Wind River Indian Reservation.

#### I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### 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", 42 U.S.C. 4321 *et seq.*) is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. (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. E.O. 13771: Reducing Regulation and Controlling Regulatory Costs*

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

#### List of Subjects in 25 CFR Part 11

Courts, Indians—law.

For the reason stated in the preamble the Department of the Interior, Bureau of Indian Affairs amends part 11 in Title 25 of the Code of Federal Regulations as follows:

#### PART 11—COURTS OF INDIAN OFFENSES AND LAW AND ORDER CODE

■ The interim final rule amending 25 CFR part 11 which was published at 81 FR 74675 on October 27, 2016, is adopted as final without change.

Dated: December 19, 2017.

**John Tahsuda,**

*Principal Deputy Assistant Secretary—Indian Affairs, Exercising the Authority of the Assistant Secretary—Indian Affairs.*

[FR Doc. 2017–28063 Filed 12–27–17; 8:45 am]

**BILLING CODE 4337–15–P**

#### DEPARTMENT OF THE INTERIOR

##### Bureau of Indian Affairs

#### 25 CFR Part 11

[189A2100DD/AAKC001030/A0A501010.999900]

#### Court of Indian Offenses Serving the Wind River Indian Reservation

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

**ACTION:** Waiver of certain regulations.

**SUMMARY:** This document accompanies the final rule establishing a Court of Indian Offenses (also known as a CFR Court) for the Wind River Indian Reservation published today and waives the application of certain regulations for the Court of Indian Offenses serving the Wind River Indian Reservation.

**DATES:** This waiver is applicable on December 28, 2017.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative

Action—Indian Affairs, (202) 273–4680; *elizabeth.appel@bia.gov*.

**SUPPLEMENTARY INFORMATION:** Generally, Courts of Indian Offenses operate in those areas of Indian country where Tribes retain jurisdiction over Indians exclusive of State jurisdiction, but where Tribal courts have not been established to fully exercise that jurisdiction. The Eastern Shoshone Tribe and the Northern Arapaho Tribe have an equal joint interest in the Wind River Indian Reservation. However, since October of 2016, the former Shoshone & Arapaho Tribal Court has operated only with the support of the Northern Arapaho Tribe. The Bureau of Indian Affairs (BIA) is taking the next step to provide all residents on the Wind River Indian Reservation with comprehensive judicial services, and ensure the permanent administration of justice and public safety.

Therefore, the Secretary has determined, in his discretion under 5 U.S.C. 301, 25 U.S.C. 2 and 9, that it is necessary to waive 25 CFR 11.104(a), (b) and 11.201(a), (e), and (f), as well as a portion of 25 CFR 11.108, as applied to the Wind River Indian Reservation. This waiver will ensure that a BIA Court of Indian Offenses can effectively operate and serve all of the residents of the Wind River Indian Reservation.

The Secretary has determined that, for the Wind River Reservation, it is necessary to waive 25 CFR 11.201(a), (e), and (f)—requirements that a magistrate must be confirmed by a tribal governing body, or, in the case of multi-tribal courts, confirmation by a majority of the tribal governing bodies; and requirements regarding training or other qualifications for CFR Court Magistrates—to ensure that the Bureau has the ability to hire and staff the Court with qualified employees efficiently.

Additionally, 25 CFR 11.104, which provides that the regulations in part 11 continue to apply until either: (1) The BIA and the tribe enter into a contract or compact for the tribe to provide judicial services; or (2) [t]he tribe has put into effect a law-and-order code that establishes a court system, is waived in part as applied to the Wind River Indian Reservation. Due to the shared nature of the Wind River Indian Reservation, the practical consequences of separate courts with overlapping jurisdiction will be further confusion about the authority of each court and exponentially increase the difficulty of maintaining law and order on the Reservation. While the Tribes are free to operate judicial systems independently, the Department will not acknowledge or enforce acts of those judicial systems

entered after the publication of this waiver, with the exception that the Department will acknowledge any emergency restraining or protective issued by the Northern Arapaho Court within ten (10) days of the publication of this waiver, until such time as both tribes jointly petition under 25 CFR 11.104.

Finally, 25 CFR 11.108 is waived to the extent necessary for the Court of Indian Offenses for the Wind River Indian Reservation to enforce Titles II, III, V, VII, VIII, IX, Title XI Chapters 3 and 4, Title XII Chapter 2, Titles XIV, and XVI of the Shoshone and Arapaho Law and Order Code as it existed on October 1, 2016. To the extent that the Shoshone and Arapaho Law and Order Code, as written, requires an action of the Joint Business Committee as a predicate for a criminal offense or the regulation of an action, *e.g.* the determination of the hunting season, that authority is hereby vested in the BIA Superintendent of the Wind River Agency.

The authority for publication of this document is: 5 U.S.C. 301; R.S. 463, 25 U.S.C. 2; R.S. 465, 25 U.S.C. 9; 42 Stat. 208, 25 U.S.C. 13; 38 Stat. 586, 25 U.S.C. 200.

Dated: December 5, 2017.

**John Tahsuda,**

*Principal Deputy Assistant Secretary—Indian Affairs, Exercising the Authority of the Assistant Secretary—Indian Affairs.*

[FR Doc. 2017–28062 Filed 12–27–17; 8:45 am]

**BILLING CODE 4337–15–P**

#### DEPARTMENT OF THE TREASURY

##### Office of Foreign Assets Control

#### 31 CFR Part 576

#### Iraq Stabilization and Insurgency Sanctions Regulations

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending the Iraq Stabilization and Insurgency Sanctions Regulations to implement Executive Order (E.O.) 13668 of May 27, 2014 ("Ending Immunities Granted to the Development Fund for Iraq and Certain Other Iraqi Property and Interests in Property Pursuant to Executive Order 13303, as Amended"). These amendments also implement certain technical and conforming changes.

**DATES:** *Effective:* December 28, 2017.