

## XI. Codification of Orders

Prior to the amendments by FDASIA, section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found substantially equivalent to preamendments devices. Section 515(b) of the FD&C Act, as amended by FDASIA, provides for FDA to require approval of an application for premarket approval for such devices by issuing a final order, following the issuance of a proposed order in the **Federal Register**. FDA will continue to codify the requirement for an application for premarket approval, resulting from changes issued in a final order, in the Code of Federal Regulations (CFR). Therefore, under section 515(b)(1)(A) of the FD&C Act, as amended by FDASIA, in this proposed order, we are proposing to require approval of an application for premarket approval for surgical mesh for transvaginal POP repair and, if this proposed order is finalized, we will make the language in § 884.5980 consistent with the final version of this proposed order.

## XII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## XIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. “FDA Public Health Notification: Serious Complications Associated With Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence”, October 20, 2008, available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/>

*PublicHealthNotifications/ucm061976.htm.*

2. “FDA Safety Communication: UPDATE on Serious Complications Associated With Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse,” July 13, 2011, available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>.
3. “FDA Executive Summary: Surgical Mesh for Treatment of Women With Pelvic Organ Prolapse and Stress Urinary Incontinence, Obstetrics & Gynecological Devices Advisory Committee Meeting”, September 8–9, 2011, available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm262488.htm>.
4. FDA Meeting of the Obstetrics & Gynecological Devices Panel, September 8–9, 2011, available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm262488.htm>.
5. Blue Book Memo #G–95–1 “Use of International Standard ISO–10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,” May 1, 1995, available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm>.

### 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, it is proposed that 21 CFR part 884 be amended as follows:

### PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

- 1. The authority citation for 21 CFR part 884 continues to read as follows:

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

- 2. Add paragraph (c) to § 884.5980, Subpart F, to read as follows:

#### § 884.5980 Surgical mesh for transvaginal pelvic organ prolapse repair.

\* \* \* \* \*

(c) *Date premarket application approval or notice of completion of a product development protocol is required.* A premarket application approval or notice of completion of a product development protocol for a device is required to be filed with the Food and Drug Administration on or before [90 DAYS AFTER DATE OF PUBLICATION OF FINAL ORDER FOR PREMARKET APPLICATION OR 30

MONTHS AFTER DATE OF PUBLICATION OF FINAL ORDER RECLASSIFYING INTO CLASS III, WHICHEVER IS LATER], for any surgical mesh described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before [90 DAYS AFTER DATE OF PUBLICATION OF FINAL ORDER FOR PREMARKET APPROVAL APPLICATIONS OR 30 MONTHS AFTER DATE OF PUBLICATION OF FINAL ORDER RECLASSIFYING INTO CLASS III, WHICHEVER IS LATER] been found substantially equivalent to a surgical mesh described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other surgical mesh intended for transvaginal pelvic organ prolapse repair shall have an approved premarket application or declared completed product development protocol in effect before being placed in commercial distribution.

Dated: April 25, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–09909 Filed 4–29–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 151

[Docket ID: BIA 2014–0002; K00103 12/13 A3A10; 134D0102DR–DS5A300000–DR.5A311.IA000113]

**RIN 1076–AF23**

#### Land Acquisitions in the State of Alaska

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would delete a provision in the Department of the Interior’s land-into-trust regulations that excludes from the scope of the regulations, with one exception, land acquisitions in trust in the State of Alaska.

**DATES:** Comments on this proposed rule must be received by June 30, 2014. *Comments on the information collections contained in this proposed regulation are separate from those on the substance of the rule.* Comments on the information collection burden should be received by June 2, 2014 to ensure consideration, but must be received no later than June 30, 2014.

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

—*Federal rulemaking portal:* <http://www.regulations.gov>. The rule is listed under the agency name “Bureau of Indian Affairs.” The rule has been assigned Docket ID: BIA–2014–0002.

—*Email:* [consultation@bia.gov](mailto:consultation@bia.gov). Include the number 1076–AF23 in the subject line of the message.

—*Mail:* Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1849 C Street NW., Washington, DC 20240. Include the number 1076–AF23 in the submission.

—*Hand delivery:* Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1849 C Street NW., Washington, DC 20240. Include the number 1076–AF23 in the submission.

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.

Comments on the information collections contained in this proposed regulation are separate from those on the substance of the rule. Send comments on the information collection burden to OMB by facsimile to (202) 395–5806 or email to the OMB Desk Officer for the Department of the Interior at [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov). Please send a copy of your comments to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

**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. Executive Summary of Rule**

Section 5 of the Indian Reorganization Act (IRA), as amended, authorizes the Secretary of the Interior (Secretary) to acquire land in trust for individual Indians and Indian tribes in the continental United States and Alaska. 25 U.S.C. 465; 25 U.S.C. 473a. For several decades, the Department’s regulations at 25 CFR part 151, which establish the process for taking land into trust, have included a provision stating that the regulations in part 151 do not cover the acquisition of land in trust status in the State of Alaska, except acquisitions for the Metlakatla Indian Community of the Annette Island Reserve or its members (the “Alaska

Exception”). 25 CFR 151.1. This rule would delete the Alaska Exception, thereby allowing applications for land to be taken into trust in Alaska to proceed under part 151. The decision to take land into trust is a decision made on a case-by-case basis. Thus, even with the deletion, the Department would retain its usual discretion to grant or deny land-into-trust applications.

**II. Background and Explanation**

The Alaska Exception in 25 CFR 151.1 was promulgated in 1980, and it has remained the subject of debate since its creation. A number of recent actions, including a pending lawsuit, have caused the Department to look carefully at this issue again. Upon careful review, the Department proposes removal of the Alaska Exception. The acquisition of land in trust is one of the most significant functions that this Department undertakes on behalf of Indian tribes. Placing land into trust secures tribal homelands, which in turn advances economic development, promotes the health and welfare of tribal communities, and helps to protect tribal culture and traditional ways of life. These benefits of taking land into trust are equally as important to federally recognized Alaska Natives as well, and elimination of the Alaska Exception is thus important and warranted.

*History of the Alaska Exclusion and Its Interpretation*

The Alaska Exception was promulgated as part of the Department’s land-into-trust regulations in 1980, but a brief historical overview of the United States’ laws and policies governing the land claims of Alaska Natives is helpful to put its meaning into context.

Although the United States acquired Alaska from Russia in 1867, 15 Stat. 539, the aboriginal land claims of Alaska Natives remained largely unresolved for more than a century. A reservation was established by Congress in 1891 for the Metlakatla Indians, who had recently moved to Alaska from British Columbia. *See Metlakatla Indians v. Egan*, 369 U.S. 45, 48 (1962). Other reserves for Alaska Natives were established by executive order, as authorized by the IRA, 49 Stat. 1250 c. 254, section 2 May 1, 1936 (repealed). *See Cohen’s Handbook of Federal Indian Law* section 4.07[3][b][iii], at 337–38 (Nell Jessup Newton ed., 2012) (discussing the history of reservation policy in Alaska). Congress made provision for individual Alaska Natives to acquire title to land through the Alaska Native Allotment Act of May 17, 1906, 34 Stat. 197, as amended, 43

U.S.C. 270–1 *et seq.* (repealed 1976), and the Alaska Native Townsite Act, Act of May 25, 1926, Ch. 379, 44 Stat. 629, as amended, 43 U.S.C. 733 *et seq.* (repealed 1976). The title that Alaska Natives received under these statutes was not held in trust but was subject to restrictions on alienation. *United States v. Atlantic Richfield Co.*, 435 F. Supp. 1009, 1015 (D. Alaska 1977), *aff’d* 612 F.2d 1132 (9th Cir. 1980).

In 1934, Congress enacted the IRA to “establish machinery whereby Indian tribes would be able to assume a greater degree of self-government, both politically and economically.” *Morton v. Mancari*, 417 U.S. 535, 542 (1974). Section 5 of the IRA, described as the “capstone” of the land-related provisions in the IRA, authorizes the Secretary, in her discretion, to acquire land in trust on behalf of Indian tribes or individual Indians. 25 U.S.C. 465; *Cohen’s Handbook of Federal Indian Law* section 15.07[1][a], at 1040. Section 5 was not among the provisions of the IRA, as originally enacted, that applied in Alaska. Two years later, however, Congress expressly extended this provision to the Territory of Alaska. Act of May 1, 1936, Public Law 74–538, section 1, 49 Stat. 1250 (codified at 25 U.S.C. 473a). The 1936 Act also authorized the Secretary to designate reservations on certain Alaska lands, *id.* section 2, 49 Stat. 1250–51, and seven reservations were established under that authority, *see Cohen’s Handbook of Federal Indian Law* section 4.07[3][b][iii], at 338.

In 1971, Congress enacted the Alaska Native Claims Settlement Act (ANCSA), Public Law 92–203, 85 Stat. 688 (codified as amended at 43 U.S.C. 1601 *et seq.*), “a comprehensive statute designed to settle all land claims by Alaska Natives.” *Alaska v. Native Village of Venetie Tribal Government*, 522 U.S. 520, 523 (1998). The Act revoked all but one of the existing Native reserves, repealed the authority for new allotment applications, and set forth a broad declaration of policy to settle land claims. *See* 43 U.S.C. 1618(a), 1617(d) and 1601(b). It did not, however, revoke the Secretary’s authority, under Section 5 of the IRA, to take Alaska land in trust for Alaska Natives.

Notwithstanding the law’s failure to withdraw authority previously given by Congress to the Secretary, the passage of ANCSA sparked discussion as to the continued wisdom of using Section 5 of the IRA to acquire land in trust for Alaska Natives. The debate became focused in the mid-1970s when the Native Village of Venetie Tribal Government requested that the lands of

its former reserve, which had been revoked by ANCSA and conveyed to ANCSA village corporations in fee simple, be taken back into trust status. In a 1978 opinion, the then-Associate Solicitor for Indian Affairs concluded that in enacting ANCSA, Congress had evinced an “unmistakable” intent to “permanently remove all Native lands in Alaska from trust status.” “Trust Land for the Natives of Venetie and Arctic Village,” Memorandum to Assistant Secretary—Indian Affairs from Associate Solicitor—Indian Affairs, Thomas W. Fredericks, at 1 (Sept. 15, 1978). The memorandum determined that “it would . . . be an abuse of the Secretary’s discretion to attempt to use Section 5 of the IRA . . . to restore the former Venetie Reserve to trust status.” *Id.* at 3. The memorandum concluded that Congress in ANCSA intended not to create a trusteeship or a reservation system, and therefore, it would be an abuse of discretion for the Secretary to acquire lands in trust in Alaska. *Id.*

A few months before the 1978 legal opinion was issued, the Secretary proposed a regulation to govern the taking of land into trust. The proposed rule made no special mention of Alaska. *See* 43 FR 32311 (July 19, 1978). However, when the final regulation was published in 1980, it contained the Alaska Exception found in 25 CFR 151.1. The preamble explained the change by relying on the same rationale used in the 1978 Opinion, stating that during the notice-and-comment period, “[i]t was . . . pointed out that the Alaska Native Claims Settlement Act does not contemplate the further acquisition of land in trust status, or the holding of land in such status, in the State of Alaska, with the exception of acquisitions for the Metlakatla Indian Community.” 45 FR 62034 (Sept. 18, 1980). Consequently, a sentence was added “to specify that the regulations do not apply, except for Metlakatla, in the State of Alaska.” *Id.*

In 1995, the Department invited public comment on a petition by three Native groups in Alaska requesting the Department to initiate a rulemaking that would remove the prohibition in the regulations on taking Alaska land in trust. *See* 60 FR 1956 (Jan. 5, 1995). Later, in 1999, the Department issued a proposed rule to amend the land into trust regulations. 64 FR 17574 (Apr. 12, 1999). Although the proposed rule retained the bar on taking land into trust in Alaska, *id.* at 17578, the Department recognized that the Alaska Exception was “predicated” on the 1978 legal opinion and stated that “[a]lthough that opinion has not been withdrawn or overruled, we recognize that there is a

credible legal argument that ANCSA did not supersede the Secretary’s authority to take land into trust in Alaska under the IRA.” *Id.* at 17577–78. Accordingly, the Department invited “comment on the continued validity of the Associate Solicitor’s opinion and issues raised by the petition noticed at 60 FR 1956 (1995).” *Id.* at 17578.

In 2001, after due consideration of comments and legal arguments submitted by Alaska Native governments and groups and by the State of Alaska and two leaders of the Alaska State Legislature on whether the 1978 Opinion accurately stated the law, *see* 66 FR 3452, 3454 (Jan. 16, 2001), the Solicitor concluded that there was “substantial doubt about the validity of the conclusion reached in the 1978 Opinion” and rescinded it. “Rescinding the September 15, 1978, Opinion of the Associate Solicitor for Indian Affairs entitled ‘Trust Land for the Natives of Venetie and Arctic Village,’” Memorandum to Assistant Secretary—Indian Affairs from Solicitor John D. Leshy, at 1 (Jan. 16, 2001). The Solicitor’s memorandum observed that “[t]he 1978 Opinion gave little weight to the fact that Congress had not repealed section 5 of the IRA, which is the generic authority by which the Secretary takes Indian land into trust, and which Congress expressly extended to Alaska in 1936.” *Id.* The Solicitor explained that the rescission of the 1978 Opinion was made “so as not to encumber future discussions over whether the Secretary can, as a matter of law, and should, as a matter of policy, consider taking Native land in Alaska into trust.” *Id.* at 2.

The Solicitor’s rescission of the 1978 Opinion was made at the same time as the issuance of a final rule amending the part 151 regulations. This 2001 final rule discussed the rescission of the 1978 opinion but nevertheless maintained the existing bar on acquiring land in trust in Alaska. 66 FR 3452, 3454 (Jan. 16, 2001). The preamble to the 2001 final rule explained the retention of the Alaska Exception by stating that “the position of the Department has long been, as a matter of law and policy, that Alaska Native lands ought not to be taken in trust.” *Id.*

But consistent with the 2001 Solicitor’s Opinion questioning the validity of the legal underpinnings of the policy, the Department further provided that the amended regulation “ought to remain in place for a period of three years during which time the Department will consider the legal and policy issues involved in determining whether the Department ought to remove the prohibition on taking Alaska

lands into trust. If the Department determines that the prohibition on taking lands into trust in Alaska should be lifted, notice and comment will be provided.” *Id.* However, later that year, the Department withdrew the entire final rule that would have revised the part 151 regulations. 66 FR 56608, 56609 (Nov. 9, 2001). Thus, the original Alaska Exception has remained in the part 151 regulations.

In 2007, four tribes of Alaska Natives and one individual Alaska Native challenged the Alaska exception in the United States District Court for the District of Columbia. *Akiachak Native Cmty. v. Salazar*, 935 F. Supp. 2d 195, 197 (D.D.C. 2013). During the course of the litigation, the Department clarified its legal position on the effect of ANCSA, informing the Court in 2008 that neither ANCSA nor the Federal Land Policy and Management Act has “removed the Secretary’s discretionary authority to take Indian lands into trust status in the State of Alaska.” Defendants’ Reply Brief, at 1–2 (July 25, 2008). The Department reiterated this position in a court-ordered filing in 2012, informing the Court that “the Secretary has both the authority and discretion to take lands within the State of Alaska into trust for Natives, even though he is not legally obligated to do so.” Defendants’ Supplemental Brief Pursuant to Court Order, at 10 (July 6, 2012).

On March 31, 2013, the district court granted summary judgment in favor of the plaintiffs. *Akiachak*, 935 F. Supp. at 197. Consistent with the Department’s position on the issue, the court held that “ANCSA left intact the Secretary’s authority to take land into trust throughout Alaska” and that “Congress did not explicitly eliminate the grant of authority.” *Id.* at 207–08. The court rejected the argument by Alaska, which had intervened in the case, that ANCSA impliedly repealed the 1936 amendment that authorized the acquisition of land in trust in Alaska under Section 5 of the IRA. *See id.* at 204–05. The court distinguished the settlement of “claims” in ANCSA, which are an assertion of a legal right, from petitions to acquire land into trust, which lies within the Secretary’s discretion. *See id.* at 205–06. The court also noted that Congress expressly repealed the Alaska Native Allotment Act in ANCSA and subsequently repealed the Alaska Native Townsite Act and section 2 of the 1936 Act, and thus understood how to repeal prior enactments, but left Section 5 of the IRA alone. *See id.* at 205, 207. Lastly, the court found no “irreconcilable conflict” between the Secretary’s discretionary authority to

create new trust land and ANCSA, particularly given that while the settlement in ANCSA did not create a trusteeship, it did “not necessarily mean that it prohibits the creation of any trusteeship outside of the settlement.” *Id.* at 207.

In addition, contrary to the Department’s litigating position in defense of the regulation, the district court found that the Alaska Exception was unlawful because it violates 25 U.S.C. 476(g), one of two “privileges and immunities” provisions added by the 1994 Amendment to the IRA. *See id.* at 208–11. The district court concluded that in providing that the Department will not consider the petitions of Alaska Natives to have land taken into trust, the Alaska Exception impermissibly diminishes their privileges “relative to the privileges . . . available to all other federally recognized tribes by virtue of their status as Indian tribes.” *Id.* at 210–11.

In a subsequent decision addressing how to remedy this violation, the district court concluded that the Alaska Exception was severable from the rest of the Department’s land-into-trust regulations and accordingly vacated and severed the final sentence of 25 CFR 151.1. *See Akiachak Native Cmty. v. Jewell*, 2013 U.S. Dist. LEXIS 141120 (D.D.C. 2013) at \*10–\*16. That case is currently pending on appeal.

#### *Reasons for Eliminating the Alaska Exception*

As the foregoing overview of the development, interpretation, and litigation of the Alaska Exception demonstrates, the Department has ongoing statutory authority to take land into trust in Alaska under Section 5 of the IRA. This authority, explicitly granted by Congress, has never been revoked. Subsequent enactment of ANCSA and the Federal Land Policy and Management Act (FLPMA) have provided additional context for the exercise of such authority, but no legal impediment exists to deleting the Alaska Exception from the land-into-trust regulations. The U.S. District Court for the District of Columbia recently came to the same conclusion concerning the effect of ANCSA and FLPMA.

The categorical exclusion of Alaska from the regulations is particularly unwarranted because, as discussed earlier, it was added to the regulations based on a mistaken legal interpretation of ANCSA, not because of public policy concerns. Congressional policy has remained consistent since 1934 with the enactment of Section 5 of the IRA. By providing authority to take land into trust—an authority that was not revoked

by ANCSA—Congress recognized that restoring tribal lands to trust status was important to tribal self-governance by providing a physical space where tribal governments may exercise sovereign powers to provide for their citizens. Restoring tribal homelands also supports the Federal trust responsibility to Indian nations because it supports the ability of tribal governments to provide for their people, thus making them more self-sufficient. Therefore, given that the authority in Section 5 remains intact for lands in Alaska, it is unnecessary and inappropriate to categorically exclude all Alaska lands from the land-into-trust regulations. Rather, the Department can and should make case-by-case determinations as to whether to take land into trust in Alaska in response to specific requests to do so.

This proposed case-by-case determination is also consistent with the Department’s initiative of acquiring trust land on behalf of federally recognized Indian tribes throughout the country. This initiative was first formally announced by Secretary Ken Salazar in a June 18, 2010 Memorandum to the Assistant Secretary, “Processing Land-Into-Trust Applications for Applications Not Related to Gaming,” available at <http://www.indianaffairs.gov/idc/groups/public/documents/text/idc009901.pdf>. In the memorandum, the Secretary emphasized that “[t]aking land into trust is one of the most important functions that this Department undertakes on behalf of Indian tribes.” *Id.* at 1. He added that “[o]ngoing activities to establish, consolidate and, where appropriate, expand tribal homelands is an essential feature of our Nation’s Indian policy and honoring of principles of tribal self-reliance and self-governance.” *Id.* Most recently, Secretary Sally Jewell reaffirmed this initiative at the Tribal Nations Conference on November 13, 2013. *See* U.S. Dep’t of the Interior, Press Release, 2013 White House Tribal Nations Conference: Promoting Prosperous, Resilient Tribal Nations (Nov. 14, 2013), available at <http://www.doi.gov/news/blog/2013-white-house-tribal-nations-conference-promoting-prosperous-resilient-tribal-nations.cfm>. As part of this initiative, the Department believes that it is important to allow Alaska Native tribes to present land into trust applications.

Recent blue ribbon commissions have emphasized the need for the Department to be able to take land into trust in Alaska. In November of 2013, the Indian Law and Order Commission, a bipartisan commission established by Congress to investigate criminal justice

systems in Indian Country, expressly stated that “a number of strong arguments can be made that [Alaska fee] land may be taken into trust and treated as Indian country” and “[n]othing in ANCSA expressly barred the treatment of these former [Alaska] reservation and other Tribal fee lands as Indian country.” Indian Law and Order Comm’n, “A Roadmap For Making Native America Safer: Report to the President and Congress of the United States,” at 45, 52 (Nov. 2013). The Commission recommended allowing lands to be placed in trust for Alaska Natives. *See id.* at 51–55. The basic thrust of the Indian Law and Order Commission’s recommendation is that the state of public safety for Alaska Natives, especially for Native women who suffer high rates of domestic abuse, sexual violence and other offenses, is unacceptable; providing trust lands in Alaska in appropriate circumstances would provide additional authority for Native governments to be better partners with the State of Alaska to address these problems. In sum, the Commission concludes that trust land in Alaska could help improve the lives of Indian people by creating safer communities.

In December of 2013, the Secretarial Commission on Indian Trust Administration and Reform, established by former Secretary of the Interior Ken Salazar, endorsed these findings and likewise recommended allowing Alaska Native tribes to have tribally owned fee simple land taken into trust. U.S. Dep’t of the Interior, “Report of the Commission on Indian Trust Administration and Reform,” at 65–67 (Dec. 10, 2013). This Commission was motivated by many of the same objectives that motivated the Indian Law and Order Commission; it recommended allowing land owned in fee simple by Alaska Native Tribes to be placed into trust.

In addition to these recommendations, we believe that facts have developed in Alaska that warrant reconsideration of our policy. For more than 25 years, Alaska Native Tribal governments have been at the forefront of Federal policies supporting tribal self-determination and self-governance. The tribal governments in Alaska have made tremendous use of various Federal self-governance policies, thereby increasing self-sufficiency and better quality of life for Alaska Natives. For example, Alaska Native Tribal Governments have a strong record, across a range of programs, of implementing Federal programs thoughtfully and cooperatively, often through consortia.

For all the reasons mentioned above, the Department reconsiders its past approach barring land into trust in Alaska and proposes to amend its regulations by removing the Alaska Exception. Specifically, the Department proposes to eliminate the final sentence in 25 CFR 151.1, which provides that part 151 does not cover the acquisition of land in trust status in the State of Alaska. Deletion of the Alaska Exception would resolve any uncertainty regarding the Department's regulatory authority to take land into trust in Alaska, and would allow for the submission and review of applications.

Applying the part 151 procedures to lands in Alaska would not require the Department to approve applications for trust acquisitions in Alaska. The Secretary would retain full discretion to analyze and determine whether to approve any particular trust application, and such a determination would include consideration of the substantive criteria enumerated in part 151. The Department recognizes, however, that applying those factors in Alaska requires the consideration of unique aspects of Native Alaska Villages and Native land tenure in Alaska, such as the ANCSA-created ownership and governance of land by Regional and Village Corporations. Accordingly, before applying the part 151 procedures in Alaska, the Department intends to engage in further government-to-government consultations on how those procedures are best applied in Alaska. The Department also solicits comments on that issue as part of this rule making.

### III. Procedural Requirements

#### A. Regulatory Planning and Review (E.O. 12866 and 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. This rule is also part of the Department's commitment under the Executive Order to reduce the number and burden of regulations and provide greater notice and clarity to the public.

#### 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. It will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year. The rule's requirements will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Nor will this rule 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 the rule is limited to acquisitions of Indian land.

#### 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)

Under the criteria in E.O. 12630, this rule does not affect individual property rights protected by the Fifth Amendment nor does it involve a compensable "taking." A takings

implication assessment is therefore not required.

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

Under the criteria in E.O. 13132, this rule has no substantial direct effect 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.

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

This rule complies with the requirements of E.O. 12988. Specifically, this rule has been reviewed to eliminate errors and ambiguity and written to minimize litigation; and is written in clear language and contains clear legal standards.

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

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments," E.O. 13175 (59 FR 22951, November 6, 2000), and 512 DM 2, we have evaluated the potential effects on federally recognized Indian tribes and Indian trust assets. During development of this proposed rule, the Department discussed this topic with tribal leaders, and will further consult specifically on the proposed rule during the public comment period.

#### I. Paperwork Reduction Act

OMB Control Number: 1076-0100.

Title: Acquisition of Trust Land.

**Brief Description of Collection:** This information collection requires tribes and individual Indians seeking to have land taken into trust status to provide certain information. No specific form is used but respondents supply information so that the Secretary may make an evaluation and determination in accordance with established Federal factors, rules, and policies.

**Type of Review:** Revision of currently approved collection.

**Respondents:** Indian tribes and individuals.

**Number of Respondents:** 1,060 on average (each year).

**Number of Responses:** 1,060 on average (each year).

**Frequency of Response:** On occasion.

**Estimated Time per Response:** (See table below).

**Estimated Total Annual Hour Burden:** 74,400 hours.

| Citation 25 CFR 151                  | Information  | Average number of hours | Average number per year | Estimated annual burden hours |
|--------------------------------------|--|-------------------------|-------------------------|-------------------------------|
| 151.9, 151.10 (On-Res), and 151.13.  | Application .....  | 50                      | 850                     | 42,500                        |
|                                      | Documentation for NEPA—tribe and individual furnish documentation. | 40                      | 120                     | 4,800                         |
|                                      | Documentation for NEPA—Tiering .....                               | 20                      | 200                     | 4,000                         |
| 151.9, 151.11 (Off-Res), and 151.13. | Application .....  | 70                      | 210                     | 14,700                        |
|                                      | Documentation for NEPA—tribe provides documentation .....          | 40                      | 210                     | 8,400                         |

OMB Control No. 1076–0100 currently authorizes the collections of information contained in 25 CFR part 151. If this proposed rule is finalized, the annual burden hours for respondents (entities petitioning for Federal acknowledgment) will increase by approximately 6,600 hours because of the increase in potential respondents.

You may review the information collection request online at <http://www.reginfo.gov>. Follow the instructions to review Department of the Interior collections under review by OMB. We invite comments on the information collection requirements in the proposed rule. You may submit comments to OMB by facsimile to (202) 395–5806 or you may send an email to the attention of the OMB Desk Officer for the Department of the Interior: [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov). Please send a copy of your comments to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. *Note that the request for comments on the rule and the request for comments on the information collection are separate.* To best ensure consideration of your comments on the information collection, we encourage you to submit them by June 2, 2014; while OMB has 60 days from the date of publication to act on the information collection request, OMB may choose to act on or after 30 days. Comments on the information collection should address: (a) the necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents, such as through the use of automated collection techniques or other forms of information technology. Please note that an agency

may not sponsor or request, and an individual need not respond to, a collection of information unless it displays a 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 because it is of an administrative, technical, and procedural nature.

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

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

#### L. Clarity of This Regulation

We are required by E.O. 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- Be logically organized;
- Use the active voice to address readers directly;
- Use clear language rather than jargon;
- Be divided into short sections and sentences; and
- 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 “COMMENTS” 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 are unclearly written, which sections or sentences are too long, the sections where you believe 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.

#### List of Subjects in 25 CFR Part 151

Indians—lands.

For the reasons stated in the preamble, the Department of the Interior, Bureau of Indian Affairs, proposes to amend part 151 in Title 25 of the Code of Federal Regulations as follows:

#### PART 151—LAND ACQUISITIONS

- 1. The authority citation for part 151 continues to read as follows:

**Authority:** R.S. 161: 5 U.S.C. 301. Interpret or apply 46 Stat. 1106, as amended; 46 Stat. 1471, as amended; 48 Stat. 985, as amended; 49 Stat. 1967, as amended, 53 Stat. 1129; 63 Stat. 605; 69 Stat. 392, as amended; 70 Stat. 290, as amended; 70 Stat. 626; 75 Stat. 505; 77 Stat. 349; 78 Stat. 389; 78 Stat. 747; 82 Stat. 174, as amended, 82 Stat. 884; 84 Stat. 120; 84 Stat. 1874; 86 Stat. 216; 86 Stat. 530; 86 Stat. 744; 88 Stat. 78; 88 Stat. 81; 88 Stat. 1716; 88 Stat. 2203; 88 Stat. 2207; 25 U.S.C. 2, 9, 409a, 450h, 451, 464, 465, 487, 488, 489, 501, 502, 573, 574, 576, 608, 608a, 610, 610a, 622, 624, 640d–10, 1466, 1495, and other authorizing acts.

- 2. Revise § 151.1 to read as follows:

#### § 151.1 Purpose and Scope.

These regulations set forth the authorities, policy, and procedures governing the acquisition of land by the United States in trust status for individual Indians and tribes. Acquisition of land by individual Indians and tribes in fee simple status is not covered by these regulations even though such land may, by operation of law, be held in restricted status following acquisition. Acquisition of land in trust status by inheritance or escheat is not covered by these regulations.

Dated: April 21, 2014.

**Kevin K. Washburn,**

*Assistant Secretary—Indian Affairs.*

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