Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing "000061, 000856, 054273, 057561, and 058711" and adding in its place, "000061, 000856, 000864, 054273, and 057561".

Dated: April 4, 1996. Robert C. Livingston, Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine. [FR Doc. 96–9870 Filed 4–22–96; 8:45 am] BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of the Secretary

25 CFR Part 1001

RIN 1076-AD26

Tribal Self-Governance Program Interim Rule Establishing Procedures for Awarding Negotiation/Planning Grants

AGENCY: Office of Self-Governance, Office of the Secretary, Interior.

ACTION: Interim rule.

SUMMARY: In this interim rule, the Office of Self-Governance (OSG) establishes procedures for awarding negotiation grants; advance planning grants; and negotiation/planning grants to negotiate for Department of the Interior (DOI) non-Bureau of Indian Affairs (BIA) programs, pursuant to the Tribal Self-Governance Act.

DATES: The effective date of this interim rule is April 19, 1996. OSG will consider Written comments on the interim rule when revising this rule. To be considered, comments must be received on or before May 31, 1996.

ADDRESSES: Written comments on the interim rule should be sent to the Director, Office of Self-Governance, U.S. Department of the Interior, Mail Stop 2548, 1849 C Street NW., Washington DC 20240

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth D. Reinfeld, U.S. Department of the Interior, Office of Self-Governance, 1849 C Street NW., Mail Stop 2548, Washington DC 20240, 202–219–0240.

SUPPLEMENTARY INFORMATION:

Justification for Interim Rule

This rule is not a rulemaking subject to the provisions of section 553 of the Administrative Procedure Act (5 U.S.C. 551, et seq.) (APA). Section 553(a)(2)

excepts from the scope of rulemaking rules "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts."

Even if this rule were considered rulemaking subject to the provisions of section 553 of the APA, good cause exists to publish this interim rule without prior opportunity for public comment.

Section 553 outlines the following rulemaking steps: (1) Publication of a notice of proposed rulemaking, (2) solicitation of public comment on the proposed rule, (3) review of comments received prior to developing the final rule, and (4) publication of the final rule 30 days prior to the effective date. Using this process at this time would not serve the goal of the Tribal Self-Governance Act of 1994, which is to expand tribal participation in the tribal selfgovernance program, because the process would diminish the ability of some selected tribes/consortia to effectively negotiate agreements for fiscal year 1997 or calendar year 1997. The process would also diminish the ability of other tribes/consortia in the near term to plan for and possibly delay their participation in tribal selfgovernance.

The Tribal Self-Governance Act of 1994 (Pub. L. 103–413) was enacted and became effective on October 25, 1994. While the interim rule may be changed by later rulemaking, the Act stipulates that the lack of promulgated regulations will not limit the Act's effect.

Under section 402(b) of the Act, the Director, Office of Self-Governance may select up to 20 additional participating tribes/consortia per year for the tribal self-governance program, and negotiate and enter into an annual written funding agreement with each participating tribe. In order to complete the negotiation process for 1997 funding agreements, it is necessary to make available negotiation grants to the new tribes by May 15, 1996. The Act mandates that the Secretary submit copies of the funding agreements at least 90 days before the proposed effective date to the appropriate committees of the Congress and to each tribe that is served by the BIA agency that is serving the tribe that is a party to the funding agreement. Initial negotiations with a tribe/consortium located in an area and/ or agency which has not previously been involved with self-governance negotiations, will take approximately two months from start to finish.

Publication of this interim rule without prior opportunity for public comment is necessary to complete the above procedures in a timely fashion. Therefore, applying the criteria at 5

U.S.C. 553(b)(3)(B) and 553(d), good cause exists to make the rule effective less than thirty days from today's date.

Background

The tribal self-governance program is designed to promote self determination by allowing tribes to assume more control through negotiated agreements of programs operated by the Department of the Interior. The new law allows for negotiations to be conducted for programs operated by BIA and for programs operated by other bureaus and offices within the Department that are available to Indians or when there is an historical, cultural, or geographic connection to an Indian tribe.

The Tribal Self-Governance Act of 1994 requires the Secretary, upon request of a majority of self-governance tribes, to initiate procedures under the Negotiated Rulemaking Act, 5 U.S.C. 561 et seq., to negotiate and promulgate regulations necessary to carry out the tribal self-governance program. The Act calls for a negotiated rulemaking committee to be established pursuant to 5 U.S.C. 565 comprised of Federal and tribal representatives, with a majority of the tribal representatives representing self-governance tribes. The Act also authorizes the Secretary to adapt negotiated rulemaking procedures to the unique context of self-governance and the government-to-government relationship between the United States and the Indian tribes. On November 1, 1994, a majority of self-governance tribes wrote the Secretary requesting the immediate initiation of negotiated rulemaking. On February 15, 1995, the self-governance negotiated rulemaking committee was established.

On the same day, an interim rule was published in the Federal Register at 60 FR 8553 announcing the criteria for tribes to be included in an applicant pool and the establishment of the selection process for tribes to negotiate agreements pursuant to the Tribal Self-Governance Act of 1994. This interim rule allowed an additional 20 new tribes/consortia to negotiate compacts and annual funding agreements for fiscal year 1996 and calendar year 1996 as authorized by the Act. Using the same interim rule, a notice of deadline for submitting completed applications to begin participation in tribal selfgovernance in fiscal year 1997 or calendar year 1997 was published in the Federal Register on February 1, 1996. To date, a total of 54 compacts and annual funding agreements have been negotiated.

Since publication of the interim rule, the self-governance negotiated rulemaking committee has reached tentative agreement on draft provisions relating to the procedures for awarding negotiation grants; advance planning grants; and negotiation/planning grants to negotiate for DOI non-BIA programs. These provisions along with other sections of the negotiated rules are subject to notice and public comment procedures as part of the rulemaking process. Given the fact that more time is needed to reach agreement on other sections of the negotiated rules, it is not possible to provide notice and obtain public comment on the rule so as to award the grants in a timely fashion using fiscal year 1996 funds.

Purpose of Rule

This interim rule establishes procedures which are consistent with the self-governance negotiated rulemaking committee's negotiations for awarding negotiation and planning grants. The interim rule is intended to allow the grants to be awarded using fiscal year 1996 funds.

This interim rule will take immediate effect to allow the grant selection process for the upcoming year to begin under an interim rule that has been tentatively agreed upon by the self-governance negotiated rulemaking committee.

The Department is adopting this rule before the self-governance negotiated rulemaking process is completed. This interim rule will be subject to negotiation and amendment by the negotiated rulemaking process. The selfgovernance negotiated rulemaking committee will use any comments received following the publication of this interim rule in negotiating the final rule. Furthermore, the portion of the interim rule governing the awarding of the grants will be subject to additional comment once the proposed regulations recommended by the self-governance rulemaking committee are published in the Federal Register. The final published rule will supersede this interim rule.

A. E.O. 12612

The Department has determined that this interim rule does not have significant federalism effects.

B. E.O. 12630

In accordance with Executive Order 12630, the Department has determined that this interim rule does not have significant takings implications.

C. E.O. 2778

The Department has certified to the Office of Management and Budget that this interim rule meets the applicable standards provided in sections 2(a) and 2(b)(2) of Executive Order 12778.

D. E.O. 12886

This interim rule is not a significant regulatory action under Executive Order 12866, and therefore will not be reviewed by the Office of Management and Budget.

E. Regulatory Flexibility Act Statement

This interim rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

F. NEPA Statement

The Department has determined that this interim rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

G. Information Collection Statement

The information collection requirements contained in this interim rule are included in current collections 1076–0090, 0091, 0096, 1030 and OMB Circulars A–102, A–110, and SF–424.

H. Authorship Statement

The primary author of this document is Dr. Kenneth Reinfield, Office of Self-Governance.

List of Subjects in 25 CFR Part 1001

Indians, Native Americans.

For the reasons given in the preamble, title 25, part 1001 is amended as follows:

PART 1001—SELF-GOVERNANCE PROGRAM

1. The authority citation for part 1001 continues to read as follows:

Authority: 26 U.S.C. 450 note, 458aa–458gg.

2. Sections 1001.7 through 1001.10 are added to read as follows:

§ 1001.7 Availability, amount, and number of planning and negotiation grants.

- (a) What is the purpose of this section? This section describes how to apply for planning and negotiation grants authorized by section 402(d) of the Act to help meet tribal costs incurred:
- (1) In meeting the planning phase requirement of Pub. L. 103–413, including planning to negotiate non-BIA programs, services, functions and activities; and
 - (2) In conducting negotiations.

- (b) What types of grants are available? Three categories of grants may be available:
- (1) Negotiation grants for tribes/ consortia selected from the applicant pool as described in § 1001.5 of these regulations;
- (2) Planning grants for tribes/consortia requiring advance funding to meet the planning phase requirement of Pub. L. 103–413; and
- (3) Financial assistance for tribes/ consortia to plan for negotiating for non-BIA programs, services, functions and activities, as described in § 1001.10.
- (c) Will grants always be made available to meet the planning phase requirement as described in section 402(d) of Pub. L. 103–413? No. Grants to cover some or all of the planning costs that a tribe/consortium may incur may be made available depending upon the availability of funds appropriated by Congress. We will publish notice of availability of grants in the Federal Register as described in this section.
- (d) May a tribe use its own resources to meet its planning and negotiation expenses in preparation for entering into self-governance? Yes. A tribe/consortium may use its own resources to meet these costs. Receiving a grant is not necessary to meet the planning phase requirement of the Act or to negotiate a compact and annual funding agreement.
- (e) What happens if there are insufficient funds to meet the anticipated tribal requests for planning and negotiation grants in any given year? If appropriated funds are available but insufficient to meet the total requests from tribes/consortia, we will give first priority to those that have been selected from the applicant pool to negotiate an annual funding agreement. We will give second priority to tribes/ consortia that require advance funds to meet the planning requirement for entry into the self-governance program. We will give third priority to tribes/ consortia that require negotiation/ planning funds to negotiate for DOI non-BIA programs.
- (f) How many grants will the Department make each year and what funding will be available? The number and size of grants awarded each year will depend on Congressional appropriations and tribal interest. Each year, we will publish a notice in the Federal Register which provides relevant details about the application process, including: The funds available, timeframes, and requirements for negotiation and advance planning specified in this part.

§ 1001.8 Selection criteria for tribes/ consortia to receive a negotiation grant.

- (a) Who may be selected to receive a negotiation grant? Any tribe/consortium that has been accepted into the applicant pool in accordance with § 1001.5 and has been selected to negotiate a self-governance annual funding agreement is eligible to apply for a negotiation grant. Each year, we will publish a notice in the Federal Register with all relevant details as to how tribes/consortia which have been selected can apply for negotiation grants.
- (b) What must a tribe/consortium do to receive a negotiation grant?
- (1) To receive a negotiation grant, a tribe/consortium must:
- (i) Be selected from the applicant pool to negotiate an annual funding agreement;
- (ii) Be identified as eligible to receive a negotiation grant; and
- (iii) Not have received a negotiation grant within the 3 years preceding the date of the latest Federal Register announcement described in § 1001.7.
- (2) The tribe/consortium must submit a letter affirming its readiness to negotiate and formally request a negotiation grant to prepare for and negotiate a self-governance agreement. These grants are not competitive.
- (c) May a selected tribe negotiate without applying for a negotiation grant? Yes. In this case, the tribe should notify us in writing so that funds can be reallocated for other grants.

§ 1001.9 Selection criteria for tribes/ consortia seeking advance planning grant funding.

- (a) Who is eligible to apply for a planning grant that will be awarded before a tribe/consortium is admitted into the applicant pool? Any tribe/consortium that is not a self-governance tribe and needs advance funding in order to complete the planning phase requirement may apply. Tribes/consortia that have received a planning grant within 3 years preceding the date of the latest Federal Register announcement described in § 1001.7 are not eligible.
- (b) What must a tribe/consortium seeking a planning grant submit in order to meet the planning phase requirements? A tribe/consortium must submit the following material:
- (1) a tribal resolution or other final action of the tribal governing body indicating a desire to plan for tribal selfgovernance;
- (2) audits from the last 3 years which document that the tribe meets the requirement of being free from any material audit exception;

- (3) a proposal that describes the tribe's/consortium's plans to conduct:
 - (i) legal and budgetary research, and
- (ii) internal tribal government and organization planning;
- (4) a timeline indicating when planning will start and end; and
- (5) evidence that the tribe/consortium can perform the tasks associated with its proposal (i.e., submit resumes and position descriptions of key staff or consultants to be used).
- (c) How will tribes/consortia know when and how to apply for planning grants? Each year, we will publish in the Federal Register a notice of the availability of planning grants for additional tribes as described in § 1001.7. This notice will identify the specific details for applying.
- (d) What criteria will be used to award planning grants to those tribes/consortia requiring advance funding to meet the planning phase requirement of Public Law 103–413? Advance planning grants are discretionary and based on need. The following criteria will be used to determine whether to award a planning grant to a tribe/consortium before the tribe is being selected into the applicant pool:
- (1) A complete application as described in §§ 1001.9(b) and 1001.9(c);
- (2) A demonstration of financial need. We will rank applications according to the percentage of tribal resources to total resources as indicated in the latest A–128 audit. We will give priority to applications that demonstrate financial need by having a lower level of tribal resources as a percent of total resources; and
- (3) Other factors that demonstrate the readiness of the tribe/consortium to enter into a self-governance agreement, including previous efforts of the tribe/consortium to participate in self-governance.
- (e) Can tribes/consortia that receive advance planning grants also apply for a negotiation grant? Yes. Tribes/consortia that receive advance planning grants may submit a completed application to be included in the applicant pool. Once approved for inclusion in the applicant pool, the tribe/consortium may apply for a negotiation grant according to the process identified in § 1001.7 above.
- (f) When and how will a tribe/consortium know whether it has been selected to receive an advance planning grant? Within 30 days of the deadline for submitting applications we will notify the tribe/consortium by letter whether it has been selected to receive an advance planning grant.

§ 1001.10 Selection criteria for other planning and negotiating financial assistance.

- (a) What is the purpose of this section? This section describes how to apply for other financial assistance for planning and negotiating of a DOI non-BIA program, service, function or activity that may be available, as well as the selection process.
- (b) Are there other funds that may be available to self-governance tribes/consortia for planning and negotiating with DOI non-BIA bureaus? Yes. Tribes/consortia may contact the Director, Office of Self-Governance to determine if funds are available for the purpose of planning and negotiating with DOI non-BIA bureaus under this section. A tribe/consortium may also request information from a DOI non-BIA bureau on any funds which may be available from that bureau.
- (c) Who is eligible to apply for financial assistance to plan and negotiate for a DOI non-BIA program? Any existing self-governance tribe/consortium is eligible.
- (d) Under what circumstances may planning and negotiation financial assistance be made available to tribes/consortia? At the discretion of the Director, grants may be awarded when requested by the tribe and coordinated with the DOI non-BIA agency involved.
- (e) How does the tribe/consortium apply for a grant to plan and negotiate for a DOI non-BIA program? When such funds are available, we will publish a notice of their availability and a deadline for submitting applications for such grants in the Federal Register as indicated in § 1001.7.
- (f) What must be included in the application? The application must include the following:
- (1) the tribal resolution or other final action of the tribal governing body indicating that the tribe/consortium intends to negotiate for a DOI non-BIA program;
- (2) a copy of the proposal or summary that was submitted to the DOI non-BIA bureau;
- (3) a time line indicating when planning will begin and end;
- (4) the planning resources from all other sources that are approved and/or anticipated for the planning activity; and
- (5) the amount requested and a justification of why it is needed by the tribe/consortium.
- (g) What criteria will we use to award grants to those tribes/consortia requesting financial assistance to plan and negotiate for a DOI non-BIA program? The award of such grants is discretionary. After consulting with the

requesting tribe/consortium and the appropriate DOI non-BIA bureau, the Director will determine whether to award a grant to plan and negotiate for a DOI non-BIA program. The determination will be based upon the complexity of the project, the availability of resources from all other sources, and the relative need of the tribe/consortium to receive such funds for the successful completion of the planning and negotiating activity, as determined by the percentage of tribal resources to total resources as indicated in the latest A-128 audit. All decisions to award or not to award grants as described in paragraphs (e) and (f) of this section are final for the Department.

Dated: April 4, 1996. Ada E. Deer, Assistant Secretary—Indian Affairs. [FR Doc. 96–9740 Filed 4–22–96; 8:45 am] BILLING CODE 4310–02–M

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 756

[HO-OO3-FOR]

Hopi Tribe Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior. **ACTION:** Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving, with certain exceptions and additional requirements, a proposed amendment to the Hopi Tribe Abandoned Mine Land Reclamation (AMLR) plan (hereinafter, the "Hopi Tribe plan'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The Hopi Tribe proposed revisions of and additions to plan provisions pertaining to the purpose of the plan; eligible lands and water subsequent to certification; coordination with other programs; land acquisition, management, and disposal; reclamation on private land and rights of entry; public participation; organization of the Hopi Tribe; personnel staffing policies; purchasing policies, procurement procedures, and accounting systems; economic conditions on the Hopi Reservation; a description of flora and fauna at abandoned mine sites; the Hopi Tribe's authority to administer its plan, as amended, in the absence of a specific statute; changing the name of the designated agency; and affirmation that the manual for purchasing policies and

procedures is in accordance with the Office of Management and Budget's (OMB) Common Rule. Additionally, the Hopi Tribe is proposing numerous editorial and recodification changes. The amendment revised the Hopi Tribe plan to meet the requirements of and incorporate the additional flexibility afforded by the revised Federal regulations and SMCRA, as amended, and improve operational efficiency. EFFECTIVE DATE: April 23, 1996.
FOR FURTHER INFORMATION CONTACT: Guy Padgett, Telephone: (505) 248–

SUPPLEMENTARY INFORMATION:

I. Background on the Hopi Tribe Plan

On June 28, 1988, the Secretary of the Interior approved the Hopi Tribe plan. General background information on the Hopi Tribe plan, including the Secretary's findings and the disposition of comments, can be found in the June 28, 1988, Federal Register (53 FR 24262). Subsequent actions concerning the Hopi Tribe plan and plan amendments can be found at 30 CFR 756.16, 756.17, and 756.18.

II. Proposed Amendment

By letter dated November 2, 1995, the Hopi Tribe submitted a proposed amendment to its plan (administrative record No. HO–148) pursuant to SMCRA (30 U.S.C. 1201 et seq.). The Hopi Tribe submitted the proposed amendment in response to a September 26, 1994, letter (administrative record No. HO–145.1) that OSM sent to the Hopi Tribe in accordance with 30 CFR 884.15(b), and at its own initiative.

The provisions of the Hopi Tribe plan that the Hopi Tribe proposed to revise or add were: the table of contents, including a list of appendices; a preface to the amended reclamation plan; a list of addenda and errata, including a list of figures; the Chairman's letter of designation and Hopi Tribe resolution; the General Counsel's opinion on the authority of the Hopi Tribe to conduct an AMLR program; Part I, purpose of the Hopi Tribe plan; Part II, eligible lands and water subsequent to certification; Part III, coordination of the Hopi AMLR Program with other programs; Part IV, land acquisition, management, and disposal; Part V, reclamation on private land; Part VI, rights of entry; Part VII, Hopi Department of Natural Resources (DNR) policy on public participation; Part VIII, organization of the Hopi Tribe; Part IX, personnel staffing policies; Part X, purchasing policies and procurement procedures; Part XI, accounting systems and management accounting; Part XII, economic conditions on the Hopi

Reservation; and Part XIII, a description of flora and fauna at abandoned mine sites. The Hopi Tribe also proposed numerous minor editorial and grammatical revisions and recodification changes. Finally, the Hopi Tribe proposed changes to the appendices included in its plan as follows: (a) provided as "Appendix 1," the "Constitution and By-Laws of the Hopi Tribe," which was approved December 19, 1936, and amended on August 1, 1969, February 14, 1980, and December 7, 1993, (b) provided cover pages for Appendices 2 through 12, and (c) changed the title of Appendix 7 from "Hopi Tribe Resolution H–93–80" to "Hopi Tribe Resolution H–93–80 and Subsequent Correspondence to the Bureau of Census.'

In addition, the Hopi Tribe proposed the deletion of the following sections in their entirety: (a) Section 884.13(e)(1), which is replaced by specific criteria for eligible lands and waters subsequent to certification at Part II of the Hopi Tribe plan; (b) Sections 884.13(e)(2) and 884.13(e)(3), which are replaced by a description of current problems and needs and current proposals at Part II, section H of the Hopi Tribe plan; and (c) Section 884.13(f)(2), Description of Aesthetic, Cultural and Recreational Conditions of the Hopi Reservation.

The Hopi Tribe also proposed adding the following items to its plan: (1) A memorandum dated May 18, 1995, from the Hopi Tribe's Assistant General Counsel affirming the authority of the Tribe's AMLR Program to administer the Hopi Tribe plan as amended in the absence of any AMLR statute; (2) Hopi Tribal Resolution H-134-89 that provides documentation of the Tribe's action changing the name of the Office of Natural Resources to the Department of Natural Resources; and (3) a memorandum dated August 31, 1995, from the Tribe's Office of Financial Management that affirms that the Hopi Tribe "Purchasing Policies and Procedures Manual" is in accordance with OMB's Common Rule.

OSM announced receipt of the proposed amendment in the December 7, 1995, Federal Register (60 FR 62786), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. HO–150). Because no one requested a public hearing or meeting, none was held. The public comment period ended on January 8, 1996.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 884.14 and 884.15, finds, with certain