approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing for this petition FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 23, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. New § 173.325 is added to subpart D to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758–19–2) with any generally recognized as safe (GRAS) acid.

(b) The additive is used as an antimicrobial agent in poultry processing water as a component of a carcass spray or dip solution prior to immersion of the carcass in a prechiller or chiller tank, or in a prechiller or chiller solution in accordance with current industry practice for use of poultry processing water.

(1) When used in a carcass spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9. The concentration of sodium chlorite is determined by a method entitled ''Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) When used in a prechiller or chiller tank, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2. The concentration of sodium chlorite is determined by a method entitled ''Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this method is listed in paragraph (b)(1) of this section.

Dated: April 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–9783 Filed 4–22–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 529

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for an approved abbreviated new animal drug application (ANADA) from Macleod Pharmaceuticals, Inc., to Anthony Products Co.

EFFECTIVE DATE: April 23, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525, has informed FDA that it has transferred the ownership of, and all rights and interests in, approved ANADA 200–115 (Gentamicin Sulfate) to Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006. Accordingly, FDA is amending the regulations in 21 CFR 529.1044a to reflect the change of sponsor.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 529 continues to read as follows:

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 self-governance 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 self-governance.

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 self-governance 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