

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 3A4749 (68 FR 59794). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections (see **DATES**). 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 are to be submitted and are to 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Reference

The following reference has 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.

1. Memorandum from D. Doell, FDA, Division of Petition Review, Chemistry Review Group, and David Carlson, FDA, Division of Petition Review, Toxicology Review Group I, to A. Zajac, FDA Division of Petition Review, Regulatory Review Group I, February 17, 2005.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.735 is amended by revising the section heading and the introductory text to read as follows:

§ 172.735 Glycerol ester of wood or gum rosin.

Glycerol ester of wood or gum rosin may be safely used in food in accordance with the following prescribed conditions:

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Dated: March 18, 2005.

Leslye M. Fraser,

*Director, Officer of Regulations and Policy,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 05-6089 Filed 3-28-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Zeranol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being removed from the animal drug regulations.

DATES: This rule is effective March 29, 2005.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 38-233 for RALGRO (zeranol), a subcutaneous implant used in cattle and in sheep for improved feed efficiency and/or increased rate of weight gain. The supplemental NADA provides for the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being removed from part 556 (21 CFR part 556). The supplemental application is approved as of March 4, 2005, and the regulations are amended in § 556.760 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

■ 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 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. Section 556.760 is amended by revising paragraph (b) and by adding paragraph (c) to read as follows:

§ 556.760 Zeranol.

* * * * *

(b) *Tolerances.* The tolerances for residues of zeranol in edible tissues are:

- (1) *Cattle.* A tolerance is not needed.
- (2) *Sheep.* 20 parts per billion.

(c) *Related conditions of use.* See § 522.2680 of this chapter.

Dated: March 21, 2005.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 05-6156 Filed 3-28-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

RIN 1076-AE52

Law and Order on Indian Reservations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule and request for comments.

SUMMARY: This document adds the Winnemucca Indian Tribe (Western Region, Nevada) to the listing of Courts of Indian Offenses. This amendment will establish a Court of Indian Offenses for a period not to exceed 2 years. It is necessary to establish a Court of Indian Offenses with jurisdiction over the Winnemucca Indian Tribe of the Winnemucca Reservation and Colony in order to protect lives and property.

DATES: This rule is effective on March 29, 2005. Comments must be received on or before May 31, 2005. Section 11.100(a)(15) expires March 29, 2007.

ADDRESSES: You may submit comments, identified by the number 1076-AE52, by any of the following methods:

- Federal rulemaking portal: <http://www.regulations.gov> Follow the instructions for submitting comments.
- Fax: (202) 208-5113.
- Mail: Ralph Gonzales, Office of Tribal Services, Bureau of Indian Affairs, 1951 Constitution Avenue, NW., MS 320-SIB, Washington, DC 20240.
- Hand delivery: Office of Tribal Services, Bureau of Indian Affairs, 1951 Constitution Avenue, NW., MS 320-SIB, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sharlot Johnson, Tribal Operations Officer, Western Regional Office, Bureau

of Indian Affairs, 400 N. Fifth Street, Phoenix, Arizona 85004, (602) 379-6786; or Ralph Gonzales, Office of Tribal Services, Bureau of Indian Affairs, 1951 Constitution Avenue, NW., MS 320-SIB, Washington, DC 20240, (202) 513-7629.

SUPPLEMENTARY INFORMATION: The authority to issue this rule is vested in the Secretary of the Interior by 5 U.S.C. 301 and 25 U.S.C. 2 and 9; and 25 U.S.C. 13, which authorizes appropriations for "Indian judges." See *Tillett v. Hodel*, 730 F. Supp., 381 (W.D. Okla. 1990), *aff'd* 931 F.2d 636 (10th Cir. 1991), *United States v. Clapox*, 13 Sawy. 349, 35 F. 575 (D. Ore. 1888). This rule is published in the exercise of the rulemaking authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs in the Departmental Manual at 209 DM 8.1. The territorial jurisdiction is extended to the land described in this document. The tract of land located in Nevada, within which the Winnemucca Indian Tribe is located, and more particularly described as:

(1) That 160 acres set aside by Executive Order of June 18, 1917, described as the NE $\frac{1}{4}$ of Section 32, Township 36 N., Range 38 E., M.D.M.;

(2) That 160 acres withdrawn by Executive Order of February 8, 1918, described as the SE $\frac{1}{4}$ of Section 32, Township 36 N., Range 38 E., M.D.M.; and

(3) That 20 acres acquired by the Acts of May 21, 1928 (45 Stat. 618) and May 29, 1928 (45 Stat 899) and described as N $\frac{1}{2}$, NE $\frac{1}{4}$, Section 29, Township 36 N., Range 38 E., M.D.M.

In addition, the territorial jurisdiction is extended to any lands hereafter acquired by or for the Colony. A provisional Court of Indian Offenses must be established for the Winnemucca Indian Tribe to protect the lives, persons, and property of people residing at and attending or visiting the Winnemucca Reservation and Colony, until they establish a tribal court in accordance with 25 CFR 11.100(c). This court shall function for a period not to exceed 2 years.

Judges of the Court of Indian Offenses shall be authorized to exercise all authority provided under 25 CFR part 11, including: Subpart D—Criminal Offenses; Subpart H—Appellate Proceedings; Subpart J—Juvenile Offender Procedure; issuance of arrest and search warrants pursuant to 25 CFR 11.302 and 11.305 and the Indian Law Enforcement Reform Act, 25 U.S.C. 2803(2) (1998). Officials of the Bureau of Indian Affairs have already set up a provisional Court of Indian Offenses

pursuant to 25 CFR 11.100(a) for the Western Region to address this law enforcement need. This rule merely affirms the legitimacy of the establishment of this court.

This final rule will not authorize judges to exercise the following authority under 25 CFR part 11: Subpart E—Civil Actions; Subpart F—Domestic Relations; Subpart G—Probate Proceedings; Subpart I—Children's Court; and Subpart K—Minor-in-Need-of-Care Procedure.

Determination To Publish a Direct Final Rule Effective Immediately

The Bureau of Indian Affairs has determined that the public notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b), do not apply because of the good cause exception under 5 U.S.C. 553(b)(3)(B), which allows the agency to suspend the notice and public procedure when the agency finds for good cause that those requirements are impractical, unnecessary and contrary to the public interest. This amendment will establish a provisional Court of Indian Offenses for the Winnemucca Indian Tribe of Winnemucca, Nevada, on land that was placed in trust for the benefit of the Winnemucca Indian Tribe. If this provisional court is not established, there is a high potential risk to public safety and a further risk of significant financial liability to the Federal Government from a lawsuit for failure to execute diligently its trust responsibility and provide adequate law enforcement on trust land. Delaying this rule to solicit public comment through the proposed rulemaking process would thus be contrary to the public interest. The Bureau of Indian Affairs Law Enforcement Services provides Law Enforcement Services to the Winnemucca Indian Tribe and an increase in visitors to the Winnemucca Reservation and Colony is imminent. For these reasons, an immediate effective date is in the public interest and in the interest of the Winnemucca Tribe. Accordingly, this amendment is issued as a final rule effective immediately.

We invite comments on any aspect of this rule and we will revise the rule if comments warrant. Send comments on this rule to the address in the **ADDRESSES** section.

Regulatory Planning and Review (Executive Order 12866)

In accordance with the criteria in Executive Order 12866, this rule is not a significant regulatory action. OMB makes the final determination under Executive Order 12866.