

florfenicol and flunixin meglumine in cattle.

DATES: This rule is effective January 11, 2010.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed NADA 141-299 that provides for use RESFLOR GOLD (florfenicol and flunixin meglumine), a combination injectable solution, for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle. The NADA is approved as of November 23, 2009, and the regulations in 21 CFR part 522 are amended by adding § 522.956 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 522.956 to read as follows:

§ 522.956 Florfenicol and flunixin.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) florfenicol and 16.5 mg flunixin (27.37 mg flunixin meglumine).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Tolerances.* See §§ 556.283 and 556.286 of this chapter.

(d) *Conditions for use in cattle*—(1) *Amount.* 40 mg florfenicol/kg body weight (BW) and 2.2 mg flunixin/kg BW (equivalent to 2 mL/15 kg BW or 6 mL/100 lbs) once, by subcutaneous injection.

(2) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Animals intended for human consumption must not be slaughtered within 38 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

Dated: December 31, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010-209 Filed 1-8-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2009-N-0665]

New Animal Drugs; Ractopamine

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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for administering ractopamine hydrochloride Type C medicated feeds as a top dress to cattle fed in confinement for slaughter.

DATES: This rule is effective January 11, 2010.

FOR FURTHER INFORMATION CONTACT:

Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, e-mail: suzanne.sechen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141-221 that provides for use of OPTAFLEXX 45 (ractopamine hydrochloride) Type A medicated articles to formulate Type B and Type C medicated feeds administered to cattle fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed. The supplement provides for feeding ractopamine hydrochloride Type C medicated feed as a top dress. The supplemental NADA is approved as of December 11, 2009, and the regulations in 21 CFR 558.500 are amended 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 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 2. In § 558.500, in paragraph (e)(2), in the heading of the first table column,

remove “Ractopame” and in its place add “Ractopamine”; and add paragraph (e)(2)(xi) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) *Cattle*—

| Ractopamine in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|---|--------------------------|---|---|---------|
| * | * | * | * | * |
| (xi) Not to exceed 800; to provide 70 to 400 mg/head/day. | | Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section. | Top dress in a minimum of 1.0 lb of medicated feed. | 000986 |
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Dated: December 31, 2009.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

[FR Doc. 2010-208 Filed 1-8-10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

[Docket ID MMS-2007-OMM-0066]

RIN 1010-AD45

Requirements for Subsurface Safety Valve Equipment

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: The MMS is incorporating by reference the Eleventh Edition of the American Petroleum Institute’s Specification for Subsurface Safety Valve Equipment (API Spec 14A) into its regulations. The MMS is incorporating the Eleventh Edition of API Spec 14A because it updated the design validation and functional testing requirements, incorporated new design changes, and corrected ambiguous areas open to misinterpretation. These changes will ensure that lessees and operators use the best available and safest technologies while operating in the Outer Continental Shelf. The rule will also require that lessees and operators provide supporting design verification information for subsurface safety valves intended for use in high pressure high temperature environments.

DATES: *Effective Date:* This final rule is effective on February 10, 2010. The

incorporation by reference of the publication listed in the regulation is approved by the Director of the Federal Register as of February 10, 2010.

FOR FURTHER INFORMATION CONTACT: Wilbon Rhome, Office of Offshore Regulatory Programs, Regulations and Standards Branch at (703) 787-1587.

SUPPLEMENTARY INFORMATION: The MMS uses standards, specifications, and recommended practices developed by standard-setting organizations and the oil and gas industry as a means of establishing requirements for activities on the OCS. This practice, known as incorporation by reference, allows us to incorporate the provisions of technical standards into the regulations. The legal effect of incorporation by reference is that the material is treated as if the entire document were published in the **Federal Register**. This material, like any other properly issued regulation, then has the force and effect of law. We hold operators/lessees accountable for complying with the documents incorporated by reference in our regulations. We currently incorporate by reference 97 private sector consensus standards into the offshore operating regulations. The regulations at 1 CFR part 51 govern how we and other Federal agencies incorporate various documents by reference. Agencies may only incorporate a document by reference by publishing the document title and affirmation/reaffirmation date in the **Federal Register**. Agencies must also gain approval from the Director of the **Federal Register** for each publication incorporated by reference. Incorporation by reference of a document or publication is limited to the specific edition, supplement, or addendum cited in the regulations.

This rule adds the following API document to those currently

incorporated by reference in MMS regulations:

ANSI/API Specification 14A, Specification for Subsurface Safety Valve Equipment, Eleventh Edition, October 2005, Effective Date: May 1, 2006; also available as ISO 10432: 2004, Product No. GX14A11.

The MMS has reviewed this document and determined that incorporating it into regulations ensures that industry uses the best available and safest technologies for downhole safety valves.

This final rule updates the requirements for subsurface safety valves operating in high pressure, high temperature (HPHT) environments in 30 CFR part 250 Subpart A—General and Subpart H—Oil and Gas Production Safety Systems. Subpart A is amended to incorporate by reference *ANSI/API Specification 14A, Specification for Subsurface Safety Valve (SSSV) Equipment*. The MMS is also adding a new section (30 CFR 250.807) to Subpart H that identifies additional safety valve information requirements for HPHT environments.

The Eleventh Edition of API Spec. 14A contains significant technological and design changes that will increase the safety of downhole operations in the Outer Continental Shelf (OCS). The updated API Spec. 14A is an improvement over the current API Spec. 14A, Tenth Edition, incorporated in the regulations because it does the following:

- Strengthens the guidelines for preparation of a functional specification by the user/purchaser to submit to the manufacturer/supplier when ordering equipment addressed by this standard. Functional characteristics in the specification must include, but are not limited to, well parameters, operational parameters, environmental