DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0039]

21 CFR Parts 520 and 558

New Animal Drugs; Tylosin

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 two supplemental new animal drug applications (NADAs) filed by Elanco Animal Health. The supplemental NADAs provide for use of tylosin tartrate soluble powder in drinking water of swine followed by tylosin phosphate in medicated swine feed for the treatment and control of swine dysentery and the control of porcine proliferative enteropathies.

DATES: This rule is effective December 18, 2008.

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: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 12 491 for use of TYLAN (tylosin phosphate) Type A medicated article. The supplement provides for use of tylosin tartrate in medicated drinking water for swine for 3 to 10 days followed by administration of tylosin phosphate in medicated swine feed for 2 to 6 weeks for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

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.

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.

Elanco Animal Health also filed a supplement to NADA 13 076 for use of TYLAN (tylosin tartrate) Soluble. The supplement provides for use of tylosin tartrate in medicated drinking water for swine for 3 to 10 days followed by administration of tylosin phosphate in medicated swine feed for 2 to 6 weeks for the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

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 period of marketing exclusivity applies only to the claim for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

The supplemental NADAs are approved as of November 13, 2008, and the regulations in 21 CFR 520.2640 and 558.625 are amended to reflect the approval.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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

21 CFR Part 520

Animal drugs.

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 parts 520 and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.2640, remove paragraph (c); redesignate paragraphs (d) and (e) as paragraphs (c) and (d); and revise paragraphs (a) and newly redesignated paragraphs (d)(1), (d)(2), and (d)(3) to read as follows:

§ 520.2640 Tylosin.

(a) *Specifications*. Each jar contains tylosin tartrate equivalent to 100 grams tylosin base.

* * * * *

(d) * * *

(1) *Chickens*—(i) *Amount*. 2 grams per gallon for 1 to 5 days as the sole source of drinking water. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(ii) *Indications for use*. As an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) associated with *M. gallisepticum* sensitive to tylosin at time of vaccination or other stress in chickens. For the control of chronic respiratory disease (CRD) associated with *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

(iii) *Limitations*. Prepare a fresh solution every 3 days. Do not use in layers producing eggs for human consumption. Do not administer within 24 hours of slaughter.

(2) *Turkeys*—(i) *Amount*. 2 grams per gallon for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

(ii) *Indications for use*. For maintaining weight gains and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations*. Prepare a fresh solution every 3 days. Do not use in layers producing eggs for human consumption. Do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount*. 250 mg per gallon as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

(ii) *Indications for use*. For the control and treatment of swine dysentery associated with *Brachyspira hyodysenteriae* and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

(iii) *Limitations*. Prepare a fresh solution daily. Do not administer within 48 hours of slaughter. Follow with tylosin phosphate medicated feed as in § 558.625(f)(1)(vi)(*c*) of this chapter.

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PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 4. In § 558.625, revise paragraphs (a), (f)(1)(vi)(*c*)(*1*), (f)(1)(vi)(*c*)(*2*), and (f)(1)(vi)(*e*)(*1*) to read as follows:

§ 558.625 Tylosin.

(a) *Specifications.* Type A medicated articles containing tylosin phosphate.

* * * * *

(f) * * *

(1) * * *

(vi) * * *

(*c*) * * *

(*1*) *Indications for use.* For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* Administer as tylosin phosphate in feed for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water as in § 520.2640(d)(3) of this chapter.

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(*e*) * * *

(*1*) *Indications for use.* For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

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Dated: December 10, 2008.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E8–29861 Filed 12–17–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2008–0537; FRL–8731–3]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the South Coast Air Quality Management District portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on July 24, 2008 and concern the District's analysis of whether its rules met reasonably available control technology (RACT) under the 8-hour ozone National Ambient Air Quality Standards (NAAQS). We are approving the analysis under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: *Effective Date:* This rule is effective on January 20, 2009.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2008–0537 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX, (415) 947–4122, *tong.stanley@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. Proposed Action

On July 24, 2007 (73 FR 43186), EPA proposed to approve the following document into the California SIP.

Local agency	Document	Adopted	Submitted
SCAQMD	Reasonably Available Control Technology Analysis	07/14/06	01/31/07

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the submitted RACT analysis and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, no comments were received.

III. EPA Action

No comments were submitted that change our assessment that the submitted RACT analysis complies with the relevant CAA requirements under the 8-hour ozone NAAQS. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving this document into the California SIP.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement