

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 520**

[Docket No. FDA-2011-N-0003]

**New Animal Drugs; Change of Sponsor; Chlortetracycline Powder**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an abbreviated new animal drug application (ANADA) for chlortetracycline soluble powder from Teva Animal Health, Inc., to Quo Vademus, LLC.

**DATES:** This rule is effective February 6, 2012.

**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, (240) 276-8300, email: [steven.vaughn@fda.hhs.gov](mailto:steven.vaughn@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-236 for Chlortetracycline HCL Soluble Powder to Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349. Accordingly, the Agency is amending the regulations in 21 CFR 520.441 to reflect the transfer of ownership.

Quo Vademus, LLC, is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600 is being amended to add entries for this sponsor.

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 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 520*

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 parts 510 and 520 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add a new entry for "Quo Vademus, LLC"; and in the table in paragraph (c)(2), in numerical sequence add a new entry for "076475" to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

					Drug labeler code
Firm name and address					
*	*	*	*	*	
(c) * * *					
(1) * * *					
Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349					076475
*	*	*	*	*	
(2) * * *					
Drug labeler code	Firm name and address				
*	*	*	*	*	
076475	.....	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349			
*	*	*	*	*	

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 520.441 [Amended]**

■ 4. In paragraph (b)(4) of § 520.441, remove "059130" and in its place add "076475".

Dated: February 1, 2012.

**William T. Flynn,**  
*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 2012-2633 Filed 2-3-12; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9572]

**RIN 1545-BK53**

**Dividend Equivalents From Sources Within the United States**

*Correction*

In rule document 2012-01234 beginning on page 3108 of the issue of Monday, January 23, 2012 make the following correction:

On page 3108, in the second column, in the heading, immediately below "26 CFR Part 1", "[TD 9572]" should appear.

[FR Doc. C1-2012-1234 Filed 2-3-12; 8:45 am]

**BILLING CODE 1505-01-D**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R01-OAR-2011-0346, FRL-9627-8]

**Approval and Promulgation of Implementation Plans; New Hampshire: Prevention of Significant Deterioration; Greenhouse Gas Permitting Authority and Tailoring Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is approving revisions to the New Hampshire State Implementation Plan (SIP), submitted by the New Hampshire Department of Environmental Services (NH DES) to EPA on February 7, 2011. The SIP revision modifies New Hampshire's Prevention of Significant Deterioration (PSD) program to establish appropriate emission thresholds for determining which new stationary sources and modification projects become subject to New Hampshire's PSD permitting requirements for their greenhouse gas (GHG) emissions. EPA proposed approval of these regulatory revisions on June 14, 2011, and received no comments. This action affects major stationary sources in New Hampshire that have GHG emissions above the thresholds established in the PSD regulations.

**DATES: Effective Date:** This rule will be effective on March 7, 2012.

**ADDRESSES:** EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-

2011–0346. All documents in the docket are listed on the <http://www.regulations.gov> web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics, and Indoor Programs Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for further information. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

**FOR FURTHER INFORMATION CONTACT:** For information regarding the New Hampshire SIP, contact Donald Dahl, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics, and Indoor Programs Unit, 5 Post Office Square—Suite 100, (mail code OEP05–2), Boston, MA 02109–3912. Mr. Dahl's telephone number is (617) 918–1657; email address: [dahl.donald@epa.gov](mailto:dahl.donald@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

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- II. What comments did EPA receive?
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### I. What is the background for this action?

EPA has recently undertaken a series of actions pertaining to the regulation of GHGs that, although for the most part distinct from one another, establish the overall framework for today's final action on the New Hampshire SIP. Four of these actions include, as they are commonly called, the “Endangerment Finding” and “Cause or Contribute Finding,” which EPA issued in a single final action,<sup>1</sup> the “Johnson Memo

Reconsideration,”<sup>2</sup> the “Light-Duty Vehicle Rule,”<sup>3</sup> and the “Tailoring Rule.”<sup>4</sup> Taken together and in conjunction with the Clean Air Act (CAA), these actions established regulatory requirements for GHGs emitted from new motor vehicles and new motor vehicle engines; determined that such regulations, when they took effect on January 2, 2011, subjected GHGs emitted from stationary sources to PSD requirements; and limited the applicability of PSD requirements to GHG sources on a phased-in basis.

Recognizing that some states had approved SIP PSD programs that do apply PSD to GHGs, but that do so for sources that emit as little as 100 or 250 tons per year of GHG, and do not limit PSD applicability to GHGs to the higher thresholds in the Tailoring Rule, EPA published a final rule on December 30, 2010, narrowing its previous approval of PSD programs as applicable to GHG-emitting sources in SIPs for 24 states, including New Hampshire (PSD Narrowing Rule).<sup>5</sup> In the PSD Narrowing Rule, EPA withdrew its approval of New Hampshire's SIP, among other SIPs, to the extent that SIP applies PSD permitting requirements to GHG emissions from sources emitting at levels below those set in the Tailoring Rule. Subsequently, New Hampshire's approved SIP provided the state with authority to regulate GHGs, but only at and above the Tailoring Rule thresholds; and Federally required new and modified sources to receive a PSD permit based on GHG emissions only if they emitted at or above the Tailoring Rule thresholds.

On February 7, 2011, in response to the Tailoring Rule and earlier GHG-related EPA rules, NH DES submitted a revision to EPA for approval into the New Hampshire SIP to establish appropriate emission thresholds for determining which new or modified stationary sources become subject to PSD permitting requirements for GHG emissions. Subsequently, on June 14, 2011 (76 FR 34630), EPA published a proposed approval of this SIP submittal. Specifically, New Hampshire's February 7, 2011 SIP revision establishes

<sup>2</sup> “Interpretation of Regulations that Determine Pollutants Covered by Clean Air Act Permitting Programs.” 75 FR 17004 (April 2, 2010).

<sup>3</sup> “Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards; Final Rule.” 75 FR 25324 (May 7, 2010).

<sup>4</sup> “Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule; Final Rule.” 75 FR 31514 (June 3, 2010).

<sup>5</sup> “Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans.” 75 FR 82536 (December 30, 2010).

appropriate emissions thresholds for determining PSD applicability to new and modified GHG-emitting sources in accordance with EPA's Tailoring Rule. Detailed background information and EPA's rationale for the proposed approval are provided in EPA's June 14, 2011, **Federal Register** action.

EPA also stated in the proposal that if the Agency did approve New Hampshire's changes to its air quality regulations to incorporate the appropriate thresholds for GHG permitting applicability into New Hampshire's SIP, then Section 52.1522(c) of 40 CFR part 52, as included in EPA's SIP Narrowing Rule—which codifies EPA's limiting its approval of New Hampshire's PSD SIP to not cover the applicability of PSD to GHG-emitting sources below the Tailoring Rule thresholds—is no longer necessary. Therefore, EPA is amending section 52.1522 of 40 CFR part 52 by removing the unnecessary regulatory language in subsection (c).

### II. What comments did EPA receive?

The public comment period on the proposed approval of New Hampshire's SIP revision ended on July 14, 2011. EPA did not receive any comments on the proposed approval of this SIP revision.

### III. What is the effect of this action?

Final approval of New Hampshire's February 2, 2011, SIP revision incorporates changes to the state's rules to establish the GHG emission thresholds for PSD applicability set forth in EPA's Tailoring Rule, confirming that smaller GHG sources emitting less than these thresholds will not be subject to PSD permitting requirements under the approved New Hampshire SIP. EPA has determined the SIP revision approved by today's action is consistent with EPA's regulations, including the Tailoring Rule. Furthermore, EPA has determined this SIP revision is consistent with section 110 of the CAA. Pursuant to section 110 of the CAA, EPA approves this revision into New Hampshire's SIP.

As a result of today's action approving New Hampshire's incorporation of the appropriate GHG permitting thresholds into its SIP, paragraph 40 CFR 52.1522(c), as included in EPA's PSD Narrowing Rule, is no longer necessary.<sup>6</sup> Thus, today's action also amends 40 CFR 52.1522 to remove this unnecessary regulatory language.

<sup>6</sup> 40 CFR 52.1522(c) codifies EPA's limiting its approval of New Hampshire's PSD SIP to not cover the applicability of PSD to GHG-emitting sources below the Tailoring Rule thresholds.

<sup>1</sup> “Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act.” 74 FR 66496 (December 15, 2009).

#### IV. What action is EPA taking?

Pursuant to section 110 of the CAA, EPA is approving New Hampshire's February 7, 2011 SIP revision relating to PSD requirements for GHG-emitting sources, except for the revised Env-A 619.03(a), which the state withdrew on May 16, 2011. Our approval includes: A new Env-A 101.35, definition of "Carbon dioxide equivalent emissions"; a new Env-A 101.96, definition of "Greenhouse gases"; an amendment to the definition of "Major source" in Env-A 101.115; and certain amendments to Env-A 619.03, "PSD Permit Requirements."

Specifically, EPA is approving into the SIP Env-A 619.03(b)–(e) as revised. However, in place of the state's revisions to Env-A 619.03(a), the SIP retains the previously-approved provision, which was then numbered as Env-A 623.03(a).<sup>7</sup> New Hampshire's previously-approved PSD regulations became effective under state law on July 23, 2001 and were approved by EPA on October 28, 2002 (67 FR 65710). EPA and New Hampshire agree that relying on previously-approved Env-A 623.03(a) does not affect the manner in which Env-A 619.03(b)–(e) functions. New Hampshire and EPA may take action on the revision to Env-A 619.03(a) in the future.

These revisions establish appropriate emissions thresholds for determining PSD applicability with respect to new or modified GHG-emitting stationary sources in accordance with EPA's June 3, 2010, Tailoring Rule. With this approval, EPA also amends 40 CFR 52.1522 by removing subsection (c).

EPA has made the determination this SIP revision is approvable because it is in accordance with the CAA and EPA regulations regarding PSD permitting for GHGs. The detailed rationale for this action is set forth in the proposed rulemaking referenced above, and in this final rule.

#### V. 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 Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides

that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit April 6, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: January 11, 2012.

#### H. Curtis Spalding,

*Regional Administrator, EPA New England.*

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart EE—New Hampshire

■ 2. In § 52.1520, the table in paragraph (c) is amended by revising the entries for Env-A 100 and Env-A 600 to read as follows:

#### § 52.1520 Identification of plan.

\* \* \* \* \*

(c) EPA approved regulations.

<sup>7</sup> Env-A 623 was renumbered to Env-A 619 for reasons unrelated to the Tailoring Rule or this proposed revision.

EPA APPROVED NEW HAMPSHIRE REGULATIONS

State citation	Title/subject	State effective date	EPA approval date <sup>1</sup>	Explanations
Env-A 100 .....	Organizational Rules: Definitions.	12/21/2010	2/6/2012 [Insert <b>Federal Register</b> page number where the document begins].	Added sections 101.35, Env-A 101.96, and Env-A 101.115.
* * *	* * *	* * *	* * *	* * *
Env-A 600 .....	Statewide Permit System .....	12/21/2010	2/6/2012 [Insert <b>Federal Register</b> page number where the document begins].	Added section Env-A 619.03(b)–(e).
* * *	* * *	* * *	* * *	* * *

<sup>1</sup> In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

\* \* \* \* \*

**§ 52.1522 [Amended]**

■ 3. Section 52.1522 is amended by removing paragraph (c).

[FR Doc. 2012–2598 Filed 2–3–12; 8:45 am]

BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA–R04–OAR–2011–0352–201204; FRL–9627–6]

**Approval and Promulgation of Implementation Plans; North Carolina; 110(a)(1) and (2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is taking final action to approve in part and conditionally approve in part, the State Implementation Plan (SIP) submission, submitted by the State of North Carolina, through the Department of Environment and Natural Resources (NC DENR), Division of Air Quality (DAQ), as demonstrating that the State meets the state implementation plan (SIP) requirements of sections 110(a)(1) and (2) of the Clean Air Act (CAA or the Act) for the 1997 8-hour ozone national ambient air quality standards (NAAQS). Section 110(a) of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by the EPA, which is commonly referred to as an “infrastructure” SIP. North Carolina certified that the North Carolina SIP

contains provisions that ensure the 1997 8-hour ozone NAAQS is implemented, enforced, and maintained in North Carolina (hereafter referred to as “infrastructure submission”). With the exception of sub-element 110(a)(2)(E)(ii), North Carolina’s infrastructure submission, provided to EPA on December 12, 2007, and clarified in a subsequent submission submitted on June 20, 2008, addresses all the required infrastructure elements for the 1997 8-hour ozone NAAQS.

**DATES:** *Effective Date:* This rule will be effective March 7, 2012.

**ADDRESSES:** EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2011–0352. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office’s official hours of business are Monday through Friday, 8:30 to 4:30 excluding federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Nacosta C. Ward, Regulatory Development Section, Air Planning

Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can be reached via electronic mail at [ward.nacosta@epa.gov](mailto:ward.nacosta@epa.gov).

**SUPPLEMENTARY INFORMATION:**

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- II. This Action
- III. Final Action
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**I. Background**

Upon promulgation of a new or revised NAAQS, sections 110(a)(1) and (2) of the CAA require states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance for that new NAAQS. On July 18, 1997, EPA promulgated a new NAAQS for ozone based on 8-hour average concentrations, thus states were required to provide submissions to address sections 110(a)(1) and (2) of the CAA for this new NAAQS. North Carolina provided its infrastructure submission for the 1997 8-hour ozone NAAQS on December 12, 2007, and clarified it in a subsequent submission submitted on June 20, 2008. On March 27, 2008, North Carolina was among other states that received a finding of failure to submit because its infrastructure submission was deemed incomplete for elements 110(a)(2)(C) and (J) for the 1997 8-hour ozone NAAQS by March 1, 2008. See 73 FR 16205. Infrastructure elements 110(a)(2)(C) and (J) relate to a SIP addressing changes to its part C prevention of significant deterioration (PSD) permit program as required by the 1997 8-Hour Ozone NAAQS Implementation Rule New Source