DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

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, 21 CFR Part 520, 7520 Standish Pl., Rockville, MD 20855, (240) 276–8300, email: 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. 801(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:


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.

<table>
<thead>
<tr>
<th>Drug labeler code</th>
<th>Firm name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td>* * * * * *</td>
<td>Quo Vademus, LLC, 277</td>
</tr>
<tr>
<td></td>
<td>Faison McGowan Rd.,</td>
</tr>
<tr>
<td></td>
<td>Kenansville, NC 28349</td>
</tr>
<tr>
<td></td>
<td>076475</td>
</tr>
</tbody>
</table>

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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


§ 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 4150–01–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:


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

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

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–
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 the stated 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. Thus, today’s action also amends 40 CFR 52.1522 to remove this unnecessary regulatory language.

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.
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 “Greenhouse gases”; an amendment to Env-A 101.96, definition of “Carbon dioxide equivalent emissions”; and a new Env-A 101.115, 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).7 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.


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.
I. Background

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). As of November 30, 2010, North Carolina submitted an SIP that contains provisions that ensure the 1997 8-hour ozone NAAQS is implemented, enforced, and maintained in North Carolina. The SIP provides for the following: emissions inventories, monitoring, and modeling to assure attainment and maintenance for that new NAAQS.

II. This Action

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. As of November 30, 2010, North Carolina submitted an SIP that contains provisions that ensure the 1997 8-hour ozone NAAQS is implemented, enforced, and maintained in North Carolina.

III. Final Action

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.

SUPPLEMENTARY INFORMATION:

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.