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Kathy Kutch,

Manager, System Support Group, Eastern Service Center.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin

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. The supplemental NADA revises the concentration of monensin in Type C medicated feeds used for improved feed efficiency, and for the prevention and control of coccidiosis in cattle fed in confinement for slaughter.

DATES: This rule is effective January 8, 2007.

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: eric.dubbin@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 95-735 that provides for use of RUMENSIN 80 (monensin) Type A medicated articles. The supplement revises the concentration of monensin in Type C medicated feeds used for improved feed efficiency, and for the prevention and control of coccidiosis in cattle fed in confinement for slaughter. The supplemental NADA is approved as of December 1, 2006, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

FDA has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 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. Section 558.355 is amended as follows:

- a. Revise paragraph (d)(2);
- b. Revise the introductory text of paragraphs (f)(3)(i) and (f)(3)(vii);
- c. Revise paragraph (f)(3)(vii)(b);
- d. Amend paragraph (f)(3)(i)(b)(1) by revising the second sentence and adding a new third sentence.

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(2) Type C cattle feeds containing 40 grams or less monensin per ton shall bear an expiration date of 30 days after its date of manufacture.

(f) * * *

(3) * * *

(i) [Amount per ton]. Monensin, 5 to 40 grams.

(b) * * *

(1) *Limitations.* * * * Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels

greater than 30 grams per ton (360 milligrams per head per day). * * *

* * * * *

(vii) *Amount per ton.* Monensin, 10 to 40 grams.

* * * * *

(b) *Limitations.* For cattle fed in confinement for slaughter, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.

* * * * *

Dated: December 19, 2006.

Steven D. Vaughn,

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

[FR Doc. E7-4 Filed 1-5-07; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2006-0648; FRL-8266-1]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Identification of the Northern Virginia PM2.5 Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Virginia State Implementation Plan (SIP). The revision consists of the addition of counties in Northern Virginia which were designated as nonattainment for the fine particulate (PM2.5) national ambient air quality standard (NAAQS). EPA is approving this revision in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on March 9, 2007 without further notice, unless EPA receives adverse written comment by February 7, 2007. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2006-0648 by one of the following methods:

A. www.regulations.gov. Follow the on-line instructions for submitting comments.

B. E-mail: miller.linda@epa.gov.

C. Mail: EPA-R03-OAR-2006-0648, Linda Miller, Acting Chief, Air Quality Planning and Analysis Branch,

Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No EPA-R03-OAR-2006-0648. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, *i.e.*, CBI 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 in www.regulations.gov or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are

available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Linda Miller, (215) 814-2068, or by e-mail at miller.linda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 8, 2006, the Commonwealth of Virginia submitted a formal revision to its State Implementation Plan (SIP). The SIP revision consists of the addition of counties in the Northern Virginia PM_{2.5} nonattainment area to the air quality regulations in the Virginia Code (9 VAC 5-20-204). This section of the Virginia regulations identifies areas included in nonattainment areas for the National Ambient Air Quality Standards (NAAQS).

On July 18, 1997, EPA revised the NAAQS for particulate matter to add a new standard for fine particulates (PM_{2.5}), airborne particles with a nominal aerodynamic diameter of 2.5 micrometers or less. The health-based standards for air quality are the PM_{2.5} annual NAAQS, 15 micrograms per cubic meter, based on a 3-year average of annual mean PM_{2.5} concentrations; and the 24-hour NAAQS, 65 micrograms per cubic meter based on a 3-year average of the 98th percentile of 24-hour concentrations. Nonattainment areas for the fine particle standard (PM_{2.5}) were promulgated by EPA on January 5, 2005 as required by section 197(d) of the Clean Air Act (CAA). Additional information on the designation process and requirements for nonattainment areas is found in the **Federal Register** document for the designations (70 FR 944 and 71 FR 19844). The designation of these counties and local jurisdictions in a PM_{2.5} nonattainment area is not the subject of this rulemaking.

II. Summary of SIP Revision

The Commonwealth of Virginia is amending 9 VAC 5-20-204.A.3 to include the previously designated counties and local jurisdictions into the Northern Virginia portion of the Washington, DC PM_{2.5} nonattainment area. The counties and local areas included in the nonattainment area are Arlington County, Fairfax County, Loudon County, Prince William, Alexandria City, Fairfax City, Falls Church City, Manassas City, and Manassas Park City. This SIP revision approves the addition of these counties and local jurisdictions to the planning areas listed in the Virginia Code (9 VAC 5-20-204.A.3).

III. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1-1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) That are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1-1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts * * *." The opinion concludes that "[r]egarding § 10.1-1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval."

Virginia's Immunity law, Va. Code Sec. 10.1-1199, provides that "[t]o the extent consistent with requirements

imposed by Federal law,” any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General’s January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since “no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.”

Therefore, EPA has determined that Virginia’s Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, state audit privilege or immunity law.

IV. Final Action

EPA is approving the revision (VA D05) which identifies areas designated as part of the Northern Virginia portion of the Washington, DC PM_{2.5} nonattainment area. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. The designation process included opportunity for public comment. In addition, there were no public comments in the State public participation process. However, in the “Proposed Rules” section of today’s **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on March 9, 2007 without further notice unless EPA receives adverse comment by February 7, 2007. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA

will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

V. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by State law, it 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). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal requirement, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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 rule 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**. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

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 by March 9, 2007.

Filing a petition for reconsideration by the Administrator of this final rule to update the Virginia regulations to include counties and local jurisdictions in the Northern Virginia PM_{2.5} nonattainment area does not affect the finality of this rule 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, Particulate matter,

Reporting and recordkeeping requirements.

Dated: December 22, 2006.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (c) is amended by revising the entry for

Chapter 20, Part II, Section 5–20–204 to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
*	*	*	*	*
Chapter 20 General Provisions				
*	*	*	*	*
Part II Air Quality Programs				
*	*	*	*	*
5–20–204	Nonattainment Areas	5/4/05	1/8/07 [Insert page number where the document begins]	Paragraph 5–20–204A.3 is added.
*	*	*	*	*

* * * * *

[FR Doc. E6–22552 Filed 1–5–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2006–0843; FRL–8261–3]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District and Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the South Coast Air Quality Management District (SCAQMD) and the Ventura County Air Pollution Control District (VCAPCD) portions of the California State Implementation Plan (SIP). This action revises various definitions of terms used by the SCAQMD and rescinds duplicative requirements for landfills from the VCAPCD. We are approving and rescinding these local rules under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule is effective on March 9, 2007 without further notice, unless EPA receives adverse comments by February 7, 2007. If we receive such comments, we will publish a timely withdrawal in

the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2006–0843, by one of the following methods:

1. Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions.
2. E-mail: steckel.andrew@epa.gov.
3. Mail or deliver: Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through www.regulations.gov or e-mail. www.regulations.gov is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: The index to the docket for this action 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: Cynthia G. Allen, EPA Region IX, (415) 947–4120, allen.cynthia@epa.gov.

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

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I. The State’s Submittal

A. What rules did the State submit?

Table 1 lists the rules we are approving and rescinding with the date that they were adopted by the local air