

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Parts 520 and 556

#### New Animal Drugs; Moxidectin

**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 new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The NADA provides for oral use of moxidectin solution in sheep for the treatment and control of a variety of internal parasites.

**DATES:** This rule is effective December 23, 2005.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141-247 for CYDECTIN (moxidectin) Oral Drench for Sheep, used for the treatment and control of various internal parasites in sheep. The NADA is approved as of November 30, 2005, and the regulations are amended in part 520 (21 CFR part 520) by adding § 520.1454 and in part 556 (21 CFR part 556) by revising § 556.426 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.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2), this approval qualifies for 7 years of exclusive marketing rights beginning November 30, 2005, because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

FDA has determined under 21 CFR 25.33(d)(4) 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

##### 21 CFR Part 520

Animal drugs.

##### 21 CFR Part 556

Animal drugs, Foods.

■ 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 520 and 556 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.

##### § 520.1451 [Amended]

■ 2. Section 520.1451 is amended by revising the section heading to read "Moxidectin tablets."

■ 3. Add § 520.1454 to read as follows:

##### § 520.1454 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 1 milligram (mg) moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this section.

(e) *Conditions of use in sheep*—(1) *Amount.* Administer 1 mL per 11 pounds body weight (1 mL per 5 kilograms) by mouth.

(2) *Indications for use.* For the treatment and control of the adult and L4 larval stages of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*.

(3) *Limitations.* Sheep must not be slaughtered for human consumption within 7 days of treatment. Because a withholding time in milk has not been established for this product, do not use

in female sheep providing milk for human consumption.

#### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 4. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

■ 5. Section 556.426 is amended by adding paragraph (b)(2) and revising paragraph (c) to read as follows:

##### § 556.426 Moxidectin.

\* \* \* \* \*

(b) \* \* \*

(2) *Sheep*—(i) *Fat (the target tissue).* The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver.* The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) *Muscle.* The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(c) *Related conditions of use.* See §§ 520.1454 and 522.1450 of this chapter.

Dated: December 12, 2005.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-24386 Filed 12-22-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF JUSTICE

### Office of the Attorney General

#### 28 CFR Part 0

[Docket No. OAG 114; AG Order No. 2791-2005]

#### Professional Responsibility Advisory Office

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This rule will amend part 0 of title 28 of the Code of Federal Regulations to reflect the establishment of the Professional Responsibility Advisory Office at the Department of Justice. The Professional Responsibility Advisory Office (PRAO) was created by the Attorney General to provide advice and guidance to Justice Department attorneys on matters involving professional responsibility. The PRAO offers training, provides informational memoranda, and issues opinions in response to individual attorney inquiries. This rule, which sets forth the PRAO's organization, mission and functions, amends the Code of Federal

Regulations in order to reflect accurately the Department's internal management structure.

**EFFECTIVE DATE:** December 23, 2005.

**FOR FURTHER INFORMATION CONTACT:** Barbara Kammerman, Acting Director, Professional Responsibility Advisory Office, U.S. Department of Justice, Washington, DC Telephone (202) 514-0458.

**SUPPLEMENTARY INFORMATION:**

**Background**

In 1994, the Attorney General established a Professional Responsibility Office (PRO) Program and the Professional Responsibility Advisory Board to assist Department attorneys in resolving professional responsibility issues. Over time, experience and a number of developments have emphasized the importance of creating a centralized resource for Department attorneys and PROs. Thus, on March 30, 1999, the Attorney General created the Professional Responsibility Advisory Office (PRAO) to coordinate the Department's position regarding various professional responsibility issues and to ensure that the advice and guidance provided to Department attorneys and the PROs are correct and consistent throughout the United States.

The PRAO serves several functions. It provides definitive advice to Department attorneys on issues relating to professional responsibility. It is responsible for assembling and maintaining reference materials, including the codes of ethics and relevant interpretative decisions and bar opinions of the District of Columbia and every state and territory, and for serving as a central repository for briefs and pleadings as cases arise. The PRAO provides coordination with the litigating components of the Department to defend attorneys in any disciplinary or other hearing in which it is alleged that they failed to meet their obligations under applicable rules of professional conduct. It coordinates with other Department components to conduct training for Department attorneys and client agencies to provide them with the tools to make informed judgments about matters which implicate professional responsibility issues. The PRAO serves as liaison with the state and federal bar associations in matters related to the implementation of Section 530B of title 28 of the United States Code pertaining to ethical standards for attorneys for the government, and amendments and revisions to the various rules of professional conduct. The PRAO also serves as advisory counsel on

professional responsibility to the Attorney General, the Deputy Attorney General, the Associate Attorney General, the Solicitor General, and their designees, and to the Attorney General's Advisory Committee. Nothing in the final rule shall be construed as affecting the functions or overriding the authority of the Office of Legal Counsel as established by 28 CFR 0.25.

**Administrative Procedure Act 5 U.S.C. 553**

This rule is a rule of agency organization and is therefore exempt from the notice requirement of 5 U.S.C. 553(b), and is made effective upon issuance.

**Regulatory Flexibility Act**

The Attorney General in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. A Regulatory Flexibility Analysis was not required to be prepared for this final rule since the Department was not required to publish a general notice of proposed rulemaking for this matter.

**Executive Order 12866**

This action has been drafted and reviewed in accordance with Executive Order 12866 Regulatory Planning and Review, § 1(b), Principles of Regulation. This rule is limited to agency organization, management and personnel as described by Executive Order 12866 § 3(d)(3) and, therefore, is not a "regulation" or "rule" as defined by its Executive Order. Accordingly, this action has not been reviewed by the Office of Management and Budget.

**Executive Order 13132**

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant a certification.

**Executive Order 12988—Civil Justice Reform**

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

**Unfunded Mandates Reform Act of 1995**

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

**Congressional Review Act**

This action pertains to agency management, personnel and organizations and does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a "rule" as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

**List of Subjects in 28 CFR Part 0**

Government employees, Lawyers, Ethical conduct.

■ Accordingly, by virtue of the authority vested in me as Attorney General, including 5 U.S.C. 301 and 28 U.S.C. 509, 510, part 0 of title 28 of the Code of Federal Regulations is amended as follows:

**PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE**

■ 1. The authority citation for part 0 continues to read as follows:

**Authority:** 5 U.S.C. 301; 28 U.S.C. 509, 510, 515-519.

■ 2. Part 0 is amended by adding a new subpart, V-2, to read as follows:

**Subpart V-2—Professional Responsibility Advisory Office**

**§ 0.129 Professional Responsibility Advisory Office.**

(a) The Professional Responsibility Advisory Office is headed by a Director appointed by the Deputy Attorney General. The Director shall be responsible to, and report directly to, the Deputy Attorney General and shall be a member of the Senior Executive Service.

(b) The Professional Responsibility Advisory Office shall:

(1) Advise Department of Justice attorneys on specific questions involving professional responsibility, including compliance with 28 U.S.C. 530b ("Section 530B"), which requires certain federal attorneys to comply with state rules of ethics.

(2) Assist or support training and informational programs for Department attorneys and client agencies concerning Section 530B and other professional responsibility requirements, including disseminating relevant and timely information.

(3) Assemble, centralize and maintain ethics reference materials, including the codes of ethics of the District of Columbia and every state and territory, and any relevant interpretations thereof.

(4) Coordinate with the relevant litigating components of the Department to defend attorneys in any disciplinary or other proceeding where it is alleged that they failed to meet their ethical obligations, provided that the attorney made a good-faith effort to ascertain the ethics requirements and made a good-faith effort to comply with those requirements.

(5) Serve as a liaison with the state and federal bar associations in matters relating to the implementation and interpretation of Section 530B, and amendments and revisions to the various state ethics codes.

(6) Perform such other duties and assignments as deemed necessary from time to time by the Attorney General or the Deputy Attorney General.

(c) Nothing in this subpart shall be construed as affecting the functions or overriding the authority of the Office of Legal Counsel as established by 28 CFR 0.25.

Dated: December 15, 2005.

**Alberto R. Gonzales,**

*Attorney General.*

[FR Doc. 05-24329 Filed 12-22-05; 8:45 am]

BILLING CODE 4410-19-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 52 and 81

[EPA-R03-OAR-2005-VA-0007; FRL-8012-2]

#### Approval and Promulgation of Air Quality Implementation Plans; Virginia; Redesignation of the City of Fredericksburg, Spotsylvania County, and Stafford County Ozone Nonattainment Area to Attainment and Approval of the Area's Maintenance Plan

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

**ACTION:** Final rule.

**SUMMARY:** EPA is approving a redesignation request and a State Implementation Plan (SIP) revision submitted by the Commonwealth of

Virginia. The Virginia Department of Environmental Quality (VADEQ) is requesting that the City of Fredericksburg, Spotsylvania County, and Stafford County (the Fredericksburg area) be redesignated as attainment for the 8-hour ozone national ambient air quality standard (NAAQS). In conjunction with its redesignation request, the Commonwealth submitted a SIP revision consisting of a maintenance plan for the Fredericksburg area that provides for continued attainment of the 8-hour ozone NAAQS for the next 10 years. EPA is also approving the adequacy determination for the motor vehicle emission budgets (MVEBs) that are identified in the 8-hour maintenance plan for the Fredericksburg area for purposes of transportation conformity, and is approving those MVEBs. EPA is approving the redesignation request and the maintenance plan revision to the Virginia SIP in accordance with the requirements of the CAA.

**DATES:** *Effective Date:* This final rule is effective on January 23, 2006.

**ADDRESSES:** EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2005-VA-0007. All documents in the docket are listed in the <http://www.regulations.gov> Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (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 through <http://www.regulations.gov> or in hard copy for public inspection 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:** Amy Caprio, (215) 814-2156, or by e-mail at [caprio.amy@epa.gov](mailto:caprio.amy@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On September 12, 2005 (70 FR 53746), EPA proposed approval of a redesignation request and maintenance plan submitted by the Commonwealth of Virginia for the Fredericksburg area. On September 30, 2005 (70 FR 57238), EPA withdrew the September 12, 2005 proposed rule.

On November 2, 2005 (70 FR 66316), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. The NPR proposed approval of both Virginia's redesignation request and a SIP revision that establishes a maintenance plan for the Fredericksburg area that sets forth how the Fredericksburg area will maintain attainment of the 8-hour ozone NAAQS for the next 10 years. The formal SIP revision was submitted by the VADEQ on May 2, 2005 and May 4, 2005. Other specific requirements of Virginia's redesignation request SIP revision for the maintenance plan, and the rationale for EPA's proposed action are explained in the NPR and will not be restated here. No public comments were received on the NPR.

## II. 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,"