DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Enrofloxacin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Bayer HealthCare LLC. The supplemental NADA provides for use of enrofloxacin injectable solution in swine for the treatment and control of respiratory disease.

DATES: This rule is effective April 23, 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: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141–068 for BAYTRIL 100 (enrofloxacin) injectable solution. The supplemental NADA provides for use of enrofloxacin injectable solution in swine for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*. The supplemental NADA is approved as of March 14, 2008, and the regulations in 21 CFR 522.812 and 556.228 (§§ 522.812 and 556.228) are amended to reflect the approval.

In addition, FDA has noticed that § 556.228 is not in alphabetical sequence in 21 CFR part 556. At this time, that section is being redesignated to correct this error. A conforming change is also being made in § 522.812 to reflect the correction in part 556.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 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. The agency has determined under 21 CFR 25.33(d)(5) 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 522

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

■ 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 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.812, is amended by revising paragraph (c) and adding paragraph (e)(3) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(c) *Related tolerance*. See § 556.226 of this chapter

* * * * *

(e) * * *

(3) *Swine*. Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount*. Administer 7.5 mg/kg of body weight once, by subcutaneous injection behind the ear.

(ii) *Indications for use*. For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*.

(iii) *Limitations*. Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

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

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

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

§ 556.228 [Redesignated as § 556.226]

■ 4. Redesignate § 556.228 as § 556.226 and revise newly redesignated § 556.226 to read as follows:

§ 556.226 Enrofloxacin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of enrofloxacin is 3 micrograms per kilogram of body weight per day.

(b) *Tolerances*. The tolerances for enrofloxacin are:

(1) *Cattle*—(i) *Liver (target tissue)*. 0.1 part per million (ppm) desethylene ciprofloxacin (the marker residue).

(ii) [Reserved]

(2) *Swine*—(i) *Liver (target tissue)*. 0.5 ppm enrofloxacin (the marker residue).

(ii) [Reserved]

(c) *Related conditions of use*. See § 522.812 of this chapter.

Dated: April 11, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–8713 Filed 4–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 946

[VA–124–FOR; Docket ID OSM–2007–0013]

Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; Approval of amendment.

SUMMARY: We are approving an amendment to the Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The revisions concern Virginia's standards for revegetation success for certain postmining land uses, distribution of topsoil and subsoil materials, and allow approval of natural stream restoration channel design, as developed in consultation with the Army Corps of Engineers. The amendment is intended

to render the State's regulations no less effective than the Secretary's regulations in meeting the requirements of the Act.

DATES: *Effective Date:* April 23, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. Earl Bandy, Director, Knoxville Field Office; Telephone: (865) 545–4103 ext. 186. E-mail: *ebandy@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Virginia Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Virginia program on December 15, 1981. You can find background information on the Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Virginia program in the December 15, 1981, **Federal Register** (46 FR 61088). You can also find later actions concerning Virginia's program and program amendments at 30 CFR 946.12, 946.13, and 946.15.

II. Submission of the Amendment

By letter dated February 13, 2007 (Administrative Record Number VA–1059), the Virginia Department of Mines, Minerals and Energy (DMME) submitted an amendment to the Virginia program. In its submission, DMME proposed to revise the Virginia program regarding revegetation success standards for postmining land uses, distribution of topsoil and subsoil materials, and to allow approval of natural stream restoration channel design as developed in consultation with the Army Corp of Engineers. We announced receipt of the proposed amendment in the April 9, 2007, **Federal Register** (72 FR 17452). The public comment period closed on May 9, 2007.

The portion of the February 13, 2007, amendment dealing with revegetation success standards involved proposed changes to Virginia's regulations at 4 VAC 25–130–816 and 817.116(a)(2) and (b)(3)(v)(C). DMME proposed to revise subsection (a)(2) to consider the levels of ground cover, production, or stocking as being equal to the approved success standard when they were not less than 70% of that success standard. DMME also proposed to revise subsection (a)(2) by adding an exception to the success standard requirements as provided for in subsection (b). Subsection (b) provides success standards for certain approved postmining land uses. Finally, DMME proposed to amend subsection (a)(2) by deleting a provision requiring that the sampling techniques for measuring success use a 90% statistical confidence interval (i.e., one-sided test with a 0.10 alpha error). In subsection (b)(3)(v)(C), DMME proposed to amend standards for herbaceous vegetation success on postmining land uses where woody plants are used for wildlife management, recreation, shelter belts or forest uses other than commercial forest land by requiring that areas planted with a mixture of herbaceous and woody species sustain a herbaceous ground cover of 70%.

After the February 13, 2007, proposed rule was published in the **Federal Register**, DMME revised the portion of its proposed amendment dealing with revegetation success standards. By electronic mail dated April 18, 2007, (Administrative Record No. VA–1074), DMME stated that it wished to withdraw the changes it previously made to 4 VAC 25–130–816 and 817.116(a)(2) regarding the sampling techniques and retain the original language. Additionally, DMME indicated that it wished to revise the herbaceous ground cover success standard of 4 VAC 25–130–816 and 817.117(b)(3)(v)(C) to require that postmining land uses of wildlife management, recreation, shelter belts, or forest uses other than commercial forest land that are planted with a mixture of herbaceous and woody species must sustain a herbaceous ground cover of 80%. We announced these proposed revisions in a July 5, 2007, **Federal Register** notice (72 FR 36632) in which we reopened the public comment period. The reopened public comment period closed July 20, 2007.

After our review of the second resubmission of the amendments and based on our discussions regarding the amendment with DMME, DMME chose to resubmit 4 VAC 25–130–816 and 817.116(b)(3) and 816 and 817.116(b)(3)(v)(C) with added language that would facilitate the growth of woody plants in areas to be developed for fish and wildlife habitat, recreation, shelter belts, or forestry. By electronic mail dated August 30, 2007 (Administrative Record No. VA–1082), DMME stated that it would revise parts of 4 VAC 25–130–816.116 and 817.116 based, in part, on discussions with us regarding the benefits of using the Forestry Reclamation Approach (FRA). The FRA is a method for reclaiming coal-mined land to forests and is based on knowledge gained from both scientific research and experience. It is designed to restore forest land capability and accelerate the natural process of forest development. The FRA advocates selection of a suitable rooting medium for tree growth, loosely grading the growth medium to reduce compaction, using ground covers compatible with growing trees, planting early succession and commercially valuable tree species, and using proper tree planting techniques. We announced these proposed revisions in the December 17, 2007 (Administrative Record No. VA–1084) **Federal Register** notice (72 FR 71295) in which we reopened the public comment period. The public comment period closed January 2, 2008. No public hearing was held because one was not requested.

III. OSM's Findings

Following are the findings that we made concerning the amendment under SMCRA and 30 CFR 732.15 and 732.17. We are approving the amendment.

1. *4 VAC 25–130–816.22 and 817.22 Topsoil and subsoil.*

Subpart (d)(1) is amended by inserting the words ''and substitutes'' between the word ''materials'' and the word ''removed.'' Also, the phrase ''and (b)'' is added immediately after the phrase ''under Paragraph (a).'' The word ''Paragraph'' is pluralized. Subpart (d)(1)(i) is amended by adding the word ''when'' between the word ''thickness'' and the word ''consistent.'' Also, the following sentence is added at the end of subpart (d)(1)(i): ''Soil thickness may also be varied to the extent such variations help meet the specific revegetation goals identified in the permit.'' Currently subsection (d) provides as follows:

(d) Redistribution.

(1) Topsoil materials removed under Paragraph (a) of this section shall be redistributed in a manner that—

(i) Achieves an approximately uniform, stable thickness consistent with the approved postmining land use, contours, and surface-water drainage systems;

(ii) Prevents excess compaction of the materials; and

(iii) Protects the materials from wind and water erosion before and after seeding and planting.

As amended, 4 VAC 25–130–816.22(d) and 817.22(d) provide as follows:

(d) Redistribution.

(1) Topsoil materials and substitutes removed under Paragraphs (a) and (b) of this section shall be redistributed in a manner that—

(i) Achieves an approximately uniform, stable thickness when consistent with the approved postmining land use, contours, and surface-water drainage systems. Soil thickness may also be varied to the extent such variations help meet the specific revegetation goals identified in the permit;

(ii) Prevents excess compaction of the materials; and

(iii) Protects the materials from wind and water erosion before and after seeding and planting.

We find that as amended, 4 VAC 25–130–816.22 and 817.22 are substantively identical to and no less effective than the Federal regulations concerning topsoil and subsoil at 30 CFR 816.22 and 817.22 and are therefore approved.

2. *4 VAC 25–130–816.43 and 817.43 Diversions.*

Subpart (a)(4) is amended by deleting the second sentence and by revising the first sentence. In the first sentence, all the words following the phrase ''continuously or frequently shall be'' are deleted and are replaced by the words ''designed by a qualified registered professional engineer and constructed to ensure stability and compliance with the standards of this Part and any other criteria set by the Division.'' Subpart (a)(5) is deleted in its entirety.

Currently, subparts (a)(4) and (a)(5) provide as follow:

(a) General requirements.

* * * * *

(4) Diversions which convey water continuously or frequently shall be lined with rock rip rap to at least the normal flow depth, including an allowance for freeboard. Diversions constructed in competent bedrock and portions of channels above normal flow depth shall comply with the velocity limitations of Paragraph (5) below.

(5) The maximum permissible velocity for the following methods of stabilization are:

Vegetated channel constructed in soil: 3.5 feet per second

Vegetated channel with jute netting: 5.0 feet per second

Rock rip rap lined channel: 16.0 feet per second

Channel constructed in competent bedrock: No limit

* * * * *

As amended, 4 VAC 25–130–816.43(a)(4) and 817.43(a)(4) provide as follows:

(4) Diversions which convey water continuously or frequently shall be designed by a qualified registered professional engineer and constructed to ensure stability and compliance with the standards of this Part and any other criteria set by the Division.

In its submittal letter, the DMME stated that these changes to the Virginia rules will allow the approval of natural stream restoration channel design approved by the U.S. Army Corps of Engineers. While these amendments have no direct federal counterparts, they are consistent with the federal regulations at 30 CFR 816.43(a)(4) and 817.43(a)(4), both of which allow the regulatory authority to specify additional design criteria for diversions to meet the requirements of 30 CFR 816.43 and 817.43. Therefore, the amendments are approved.

3. *4 VAC 25–130–816.116(b)(3) and 817.116(b)(3). Revegetation; standards for success.*

Subsection (b) of each of these sections, concerning standards for success, is amended by revising subpart (b)(3). Currently, subpart (b)(3) provides as follows:

(b) Standards for success shall be applied in accordance with the approved postmining land use and, at a minimum, the following conditions:

* * * * *

(3) For areas to be developed for fish and wildlife habitat, recreation, shelter belts, or forest products, success of vegetation shall be determined on the basis of tree and shrub stocking and vegetative ground cover. Such parameters are described as follows:

The DMME is amending these sections to indicate that for areas to be developed for fish and wildlife habitat, recreation, shelter belts, or forest products, woody plants must be stocked at least equal to the rates specified in the approved reclamation plan. Additionally, the DMME is adding a requirement that in order to minimize competition with woody plants, herbaceous ground cover should be limited to that necessary to control erosion and support the postmining land use. Seed mixtures and seeding rates will be specified in the approved reclamation plan.

As amended, 4 VAC 25–130–816 and 817.116(b)(3) provide as follows:

4 VAC 25–130–816.116(b)(3) and 817.116(b)(3). Revegetation; standards for success.

(3) For areas to be developed for fish and wildlife habitat, recreation, shelter belts, or forestry, the stocking of woody plants must be at least equal to the rates specified in the approved reclamation plan. To minimize competition with woody plants, herbaceous ground cover should be limited to that necessary to control erosion and support the postmining land use. Seed mixtures and seeding rates will be specified in the approved reclamation plan. Such parameters are described as follows:

* * * * *

While these amendments have no direct federal counterparts, they are consistent with the federal regulations at 30 CFR 816.116(b)(3) and 817.116(b)(3), both of which govern revegetation success for areas to be developed for fish and wildlife habitat, recreation, undeveloped land or forest products. Therefore, we are approving the amendments.

It should be noted that these amendments mirror the changes recently promulgated by OSM to the counterpart revegetation success standards in the Tennessee federal program, at 30 CFR 942.816(b)(3) and 942.817(b)(3). (72 FR 9637, March 2, 2007)

4. *4 VAC 25–130–816.116(b)(3)(v)(C) and 817.116(b)(3)(v)(C). Revegetation; standards for success.*

Subsection (b), concerning standards for success, is amended by revising subparts (b)(3)(v)(C). Currently, subsection (b)(3)(v)(C) provides as follows:

(v) Where woody plants are used for wildlife management, recreation, shelter belts, or forest uses other than commercial forest land:

* * * * *

(C) Areas planted with a mixture of herbaceous and woody species shall sustain an herbaceous vegetative ground cover of 90% and an average of 400 woody plants per acre. At least 40 of the woody plants for each acre shall be wildlife food-producing shrubs located suitably for wildlife enhancement, which may be distributed or clustered on the area.

* * * * *

The DMME is amending this section by deleting the 90% herbaceous ground cover requirement, and by adding a phrase requiring herbaceous ground cover to comply with guidelines provided by the division and with the approved forestry reclamation plan.

As amended, 4 VAC 25–130–816 and 817.116(b)(3)(v)(C) provide as follows:

4 VAC 25–130–816.116(b)(3)(v)(C) and 817.116(b)(3)(v)(C). Revegetation; standards for success.

(v) Where woody plants are used for wildlife management, recreation, shelter belts, or forest uses other than commercial forest land:

* * * * *

(C) Areas planted with a mixture of herbaceous and woody species shall sustain an herbaceous vegetative ground cover in accordance with guidance provided by the division and the approved forestry reclamation plan and establish an average of 400 woody plants per acre. At least 40 of the woody plants for each acre shall be wildlife

food-producing shrubs located suitably for wildlife enhancement, which may be distributed or clustered on the area.

* * * * *

While these amendments have no direct federal counterparts, they are consistent with the Federal regulations at 30 CFR 816.116(b)(3) and 817.116(b)(3), which govern revegetation success on areas to be developed for fish and wildlife habitat, recreation, undeveloped land or forest products. Therefore, we are approving the amendments.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment (Administrative Record No. VA–1084) and received comments from one person.

The commenter was opposed to the addition ''and substitutes'' in subpart (d)(1) without any clarification. The commenter's concern was that the word ''substitute'' could be construed to mean whatever the operator wanted it to mean. However, the Virginia regulation cited below clearly limits the use of substitutes, thereby preventing the unfettered operator discretion feared by the commenter. This limitation is substantively identical to its federal counterparts at 30 CFR 816.22(b) and 817.22(b).

The Virginia regulations at 4 VAC 25–130–816.22/817.22(b) state as follows:

> *Substitutes and supplements.*
> Selected overburden materials may be substituted for, or used as a supplement to topsoil if the operator demonstrates to the division, in accordance with 4 VAC 25–130–780.18 [or 784.13] that the resulting soil medium is equal to, or more suitable for sustaining vegetation than, the existing topsoil, and the resulting soil medium is the best available in the permit area to support revegetation.

The commenter also urged suspension of consideration of these amendments until Virginia submits an adequate definition of the term ''substitutes''. In response, we disagree that a definition is needed. The language of limitation above is sufficient to prevent the unrestricted use of substitutes. Also, we note that the Federal regulations likewise contain no definition of this term.

Federal Agency Comments

Under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, on February 22, 2007, we requested comments on the amendments from various Federal agencies with an actual or potential interest in the Virginia program (Administrative Record No. VA–1060). The United States Department of Labor, Mine Safety and Health Administration responded and stated that such amendments are deemed appropriate and there appears to be no conflict with MSHA regulations (Administrative Record No. VA–1061). The United States Department of the Interior, Bureau of Land Management responded and stated that they found no inconsistencies between the proposed changes and the Federal Laws, which govern mining (Administrative Record No. VA–1062). The United States Department of the Interior, Fish and Wildlife Service, Ecological Services responded and stated that it appears that no impacts to federally listed or proposed species or federally designated critical habitat will occur (Administrative Record No. VA–1066).

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Virginia proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment.

V. OSM's Decision

Based on the above findings, we are approving the amendment sent to us by Virginia on February 13, 2007. To implement this decision, we are amending the Federal regulations at 30 CFR part 946, which codify decisions concerning the Virginia program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

The provisions in the rule based on counterpart Federal regulations do not have takings implications. This determination is based on the analysis performed for the Federal Regulations.

Executive Order 12866—Regulatory Planning and Review

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally recognized Indian tribes and have determined that the rule does not have substantial direct effects 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.

The basis for this determination is that our decision is on a State regulatory program and does not involve Federal regulations involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that the provisions in 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 they are based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State provisions are based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 946

Intergovernmental relations, Surface mining, Underground mining.

Dated: April 1, 2008.

Thomas D. Shope,

Regional Director, Appalachian Region.

■ For the reasons set out in the preamble, 30 CFR part 946 is amended as set forth below:

PART 946—VIRGINIA

■ 1. The authority citation for part 946 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 946.15 is amended in the table by adding a new entry in chronological order by ''Date of final publication'' to read as follows:

§ 946.15 Approval of Virginia regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* *	* * *	* *
February 13, 2007	April 23, 2008	4 VAC 25–130–816.22(d)(1) and 817.22(d)(1). 4 VAC 25–130–816.43(a) and 817.43(a). 4 VAC 25–130–816.116(b) and 817.116(b).

[FR Doc. E8–8838 Filed 4–22–08; 8:45 am]

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