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.

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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