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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for ''Endo Pharmaceuticals Inc.'' and ''United Vaccines, A Harlan Sprague Dawley, Inc., Co.''; and in the table in paragraph (c)(2), remove the entries for ''058639'' and ''060951''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1081 [Amended]

■ 4. In § 522.1081, remove and reserve paragraph (b)(2).

§ 522.1462 [Removed]

■ 5. Remove § 522.1462.

§ 522.1642 [Removed]

■ 6. Remove § 522.1642.

§ 522.1680 [Amended]

■ 7. In § 522.1680, in paragraph (b), remove ''058639,''.

Dated: September 5, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–22196 Filed 9–7–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 556

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Enrofloxacin; Tylvalosin

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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective September 10, 2012.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect original and supplemental approval actions during July 2012, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY 2012

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–336	ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131.	AIVLOSIN (tylvalosin tartrate) Water Soluble Granules.	Original approval for control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.	520.2645 556.748	yes	CE [1]
141–068	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	BAYTRIL 100 (enrofloxacin) Injectable Solution.	Supplement adding control of bovine respiratory disease (BRD) in beef and non-lactating dairy cattle at high risk of developing BRD associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis;* and revising a food safety warning statement.	522.812	yes	CE [1]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY 2012—Continued

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
200–482	Cross VetPharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	AMPROMED for Calves (amprolium) 9.6% Oral Solution.	Original approval as a generic copy of NADA 13–149.	520.100	yes	CE [1]

[1] The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

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 Parts 520 and 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 520, 522, 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.

■ 2. In § 520.100, revise paragraph (b)(4) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(4) No. 061623 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(2); and for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

■ 3. Add § 520.2645 to read as follows:

§ 520.2645 Tylvalosin.

(a) *Specifications.* Granules containing 62.5 percent tylvalosin (w/w) as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 50 parts per million tylvalosin in drinking water for 5 consecutive days.

(2) *Indications for use.* For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 5. In 522.812, revise paragraphs (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(e) * * *

(2) * * *

(i) *Amount*—(A) *Single-dose therapy:* For treatment of bovine respiratory disease (BRD), administer 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds (/100 lb)) once by subcutaneous injection. For control of BRD, administer 7.5 mg/kg of body weight (3.4 mL/100 lb) once by subcutaneous injection.

(B) *Multiple-day therapy:* For treatment of BRD, administer 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL/100 lb) by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use*—(A) *Single-dose therapy:* For the treatment of BRD associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica, P. multocida, H. somni* and *M. bovis.*

* * * * *

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

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

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

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

■ 7. Add § 556.748 to read as follows:

§ 556.748 Tylvalosin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of tylvalosin is 47.7 micrograms per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for tylvalosin in edible tissues of swine is not required.

(c) *Related conditions of use.* See § 520.2645 of this chapter.

Dated: September 5, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–22194 Filed 9–7–12; 8:45 am]

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