SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for use of an ivermectin injectable solution for treatment and control of various internal and external parasites in cattle, swine, reindeer, and American bison.

DATES: This rule is effective September 19, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, *e-mail: john.harshman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–447 for the use of BIMECTIN (ivermectin) Injection for Cattle and Swine for treatment and control of various internal and external parasites in cattle, swine, reindeer, and American bison. Cross Vetpharm Group Ltd.'s BIMECTIN Injection for Cattle and Swine is approved as a generic copy of Merial Ltd.'s IVOMEC (ivermectin) Injection for Cattle and Swine, approved under NADA 128–409. The ANADA is approved as of July 5, 2011, and the regulations in 21 CFR 522.1192 are amended to reflect the approval.

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 determined under 21 CFR 25.33 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 in 21 CFR Part 522

Animal drugs.

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 522 is 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. In § 522.1192, revise paragraph (b)(2) to read as follows:

§ 522.1192 Ivermectin.

* * * * *

(b) * * *

(2) Nos. 055529, 058005, 059130, and 061623 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

* * * * *

Dated: September 13, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–23865 Filed 9–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

[Docket No. FDA–2011–N–0003]

New Animal Drugs; Gamithromycin

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 an original new animal drug application (NADA) filed by Merial, Ltd. The NADA provides for the veterinary prescription use of gamithromycin injectable solution for the management of bovine respiratory disease (BRD). FDA is also amending the regulations to add the established tolerances for residues of gamithromycin in edible tissues of cattle.

DATES: This rule is effective September 19, 2011.

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: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640 filed NADA 141–328 that provides for the veterinary prescription use of ZACTRAN (gamithromycin), an injectable solution, in beef and non-lactating dairy cattle for the treatment of BRD associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni;* and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida.* The application is approved as of June 16, 2011, and the regulations are amended in 21 CFR parts 522 and 556 to reflect the approval.

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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 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, 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 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 522.1014 is added to read as follows:

§ 522.1014 Gamithromycin.

(a) *Specifications.* Each milliliter (mL) of solution contains 150 milligrams (mg) gamithromycin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.292 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 6 mg/kilogram of body weight (2 mL per 110 pounds) one time by subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida.*

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 35 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

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.

■ 4. Section 556.292 is added to read as follows:

§ 556.292 Gamithromycin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of gamithromycin is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for gamithromycin (the marker residue) are:

(1) *Cattle*—(i) *Liver (the target tissue):* 500 parts per billion (ppb).

(ii) *Muscle.* 150 ppb.

(2) *[Reserved]*

(c) *Related conditions of use.* See § 522.1014 of this chapter.

Dated: September 13, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–23874 Filed 9–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

[Docket No. FDA–2011–N–0003]

Tolerances for Residues of New Animal Drugs in Food; Progesterone

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 update the allowable incremental increase for residues of progesterone in edible tissues of cattle and sheep based on the 1994 revised daily consumption values. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective September 19, 2011.

FOR FURTHER INFORMATION CONTACT: Kevin Gaido, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8212, e-mail: *kevin.gaido@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) (21 CFR 514.105(a)) directs FDA to establish tolerances by regulation, as necessary, when a new animal drug is approved for use in food-producing animals. Progesterone is approved for use in subcutaneous implants used for increased rate of weight gain in suckling beef calves and steers (21 CFR 522.1940) and in vaginal inserts used for management of the estrous cycle in female cattle and ewes (21 CFR 529.1940).

FDA has noticed the animal drug tolerance regulations do not reflect levels for progesterone using the daily consumption values in the current guidance document, ''Guideline for Establishing a Safe Concentration'' (59 FR 37499, July 22, 1994). At this time, FDA is amending 21 CFR 556.540 to reflect the revised daily consumption values as applied to edible tissues of cattle. Sheep are considered a minor species for human food safety assessment, and the updated allowable incremental increase limits for cattle tissues based on the revised daily consumption values are applicable to sheep. This action is being taken to improve the accuracy of the regulations.

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 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 part 556 is amended as follows:

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

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

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

■ 2. Revise § 556.540 to read as follows:

§ 556.540 Progesterone.

(a) [Reserved]

(b) *Tolerances.* Residues of progesterone are not permitted in excess of the following increments above the concentrations of progesterone naturally present in untreated animals:

(1) *Cattle and sheep*—(i) *Muscle:* 5 parts per billion (ppb).

(ii) *Liver:* 15 ppb.

(iii) *Kidney:* 30 ppb.

(iv) *Fat:* 30 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.1940 and 529.1940 of this chapter.

Dated: September 13, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–23867 Filed 9–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 240

RIN 1510–AB25

Indorsement and Payment of Checks Drawn on the United States Treasury

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: This final rule authorizes the Department of the Treasury (Treasury), Financial Management Service (FMS), to direct Federal Reserve Banks to debit a financial institution's Master Account for all check reclamations against the financial institution that the financial institution has not protested. Financial