of an oxytetracycline injectable solution to cattle and swine for the treatment of various bacterial diseases.

DATES: This rule is effective December 5, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed original ANADA 200–306 that provides for the use of Oxytetracycline Injection (200 milligrams per milliliter (mg/mL)) as a treatment for various bacterial diseases in cattle and swine. Norbrook's Oxytetracycline Injection (200 mg/mL) is approved as a generic copy of Pfizer's LIQUAMYCIN LA–200, approved under NADA 113–232. The application is approved as of June 18, 2002, and the regulations are amended in 21 CFR 522.1660 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 Dockets Management Branch (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.

The agency has determined under 21 CFR 25.33(a)(1) 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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (b) by removing ''*Sponsor*'' and by adding in its place ''*Sponsors*'', and by numerically adding ''055529''; in paragraph (d)(1)(iii) in the second and ninth sentences by numerically adding ''055529''; and in paragraph (d)(2)(iii) in the third sentence by removing ''when provided by 000010, 000069, 011722, 053389, 059130, and 061623''.

Dated: November 15, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–30782 Filed 12–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Tilmicosin

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 supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for subcutaneous injection of tilmicosin phosphate solution for the treatment of ovine respiratory disease (ORD). FDA is also amending the regulations to add tolerances for residues of tilmicosin in sheep muscle and liver and in cattle muscle.

DATES: This rule is effective December 5, 2002.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569, e-mail: ndas@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplemental application to NADA 140–929 that provides for the use of MICOTIL 300 (tilmicosin phosphate) Injection by subcutaneous injection for the treatment of ORD associated with *Mannheimia* (*Pasteurella) haemolytica*. The supplemental NADA is approved as of September 4, 2002, and the regulations are amended in 21 CFR 522.2471 and § 556.735 (21 CFR 556.735) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 556.735 is amended by adding a tolerance for residues of tilmicosin in sheep muscle and liver and in cattle muscle, and editorially, to reflect a current format.

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 Dockets Management Branch (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.

The agency 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 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 522.2471 is revised to read as follows:

§ 522.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Special considerations.* (1) Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes.

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

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 10 mg per kilogram (kg) body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia* (*Pasteurella) haemolytica.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*P.) haemolytica.*

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 28 days of last treatment.

(2) *Sheep*—(i) *Amount.* 10 mg/kg body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia* (*P.) haemolytica.*

(iii) *Limitations.* Do not slaughter within 28 days of last treatment.

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 556.735 is amended by revising paragraph (b) to read as follows:

§ 556.735 Tilmicosin.

* * * * *

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent tilmicosin (the marker residue) is 1.2 parts per million (ppm).

(ii) *Muscle.* The tolerance for parent tilmicosin (the marker residue) is 0.1 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for parent tilmicosin (the marker residue) is 7.5 ppm.

(ii) *Muscle.* The tolerance for parent tilmicosin (the marker residue) is 0.1 ppm.

(3) *Sheep*—(i) *Liver (the target tissue).* The tolerance for parent tilmicosin (the marker residue) is 1.2 ppm.

(ii) *Muscle.* The tolerance for parent tilmicosin (the marker residue) is 0.1 ppm.

Dated: November 21, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–30864 Filed 12–4–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

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 new animal drug application (NADA) filed by Purina Mills, Inc. The NADA provides for the use of a lasalocid Type A medicated article to make free-choice Type C medicated feed mineral blocks used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

DATES: This rule is effective December 5, 2002.

FOR FURTHER INFORMATION CONTACT: Amey L. Adams, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7560, e-mail: *aadams1@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166–6812, filed NADA 141–171 that provides for use of BOVATEC 68 (lasalocid) Type A medicated article to make Purina Sugar Mag Block 1440 BVT Medicated Mineral Block, a free-choice Type C medicated feed. The free-choice mineral block is used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The NADA is approved as of August 20, 2002, and the regulations are amended in § 558.311 (21 CFR 558.311) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.311 is being amended to collocate the entry for another free-choice mineral Type C medicated feed, approved under NADA 138–993, to the new entry created for NADA 141–171. This is being done to improve the readability and clarity of the regulations.

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 Dockets Management Branch (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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning August 20, 2002.

The agency has determined under 21 CFR 25.33(a)(6) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

2. Section 558.311 is amended by adding paragraph (b)(8); in paragraph (d)(7) by adding ''and (e)(1)(xviii)'' after ''(e)(1)(xii)''; by revising (e)(1)(xii); and by adding paragraph (e)(1)(xviii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(8) 15 percent activity to No. 017800 for use as in paragraph (e)(1)(xviii) of this section.

* * * * *

(e) * * *

(1) * * *