

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this original approval of NADA 141-262 qualifies for 5 years of marketing exclusivity beginning January 29, 2007.

Under section 512(c)(2)(F)(ii) of the act, this original approval of NADA 141-263 qualifies for 3 years of marketing exclusivity beginning January 29, 2007.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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 Parts 520 and 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 parts 520 and 522 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. Section 520.1315 is added to read as follows:

##### § 520.1315 Maropitant.

(a) *Specifications.* Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Indications for use and amount.* For the prevention of acute vomiting, administer a minimum of 2.0 mg per

kilogram (/kg) body weight once daily for up to 5 consecutive days. For the prevention of vomiting due to motion sickness, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

(2) *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

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

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

■ 4. Section 522.1315 is added to read as follows:

##### § 522.1315 Maropitant.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 1.0 mg per kilogram body weight by subcutaneous injection once daily for up to 5 consecutive days.

(2) *Indications for use.* For the prevention and treatment of acute vomiting.

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

Dated: February 16, 2007.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

**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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for the addition of tylosin tartrate to an approved subcutaneous implant containing

trenbolone and estradiol used for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter.

**DATES:** This rule is effective March 1, 2007.

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: [eric.dubbin@fda.hhs.gov](mailto:eric.dubbin@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-346 for COMPONENT TE-200 with TYLAN (trenbolone acetate and estradiol with tylosin tartrate), a subcutaneous implant used for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter. The supplemental ANADA provides for the addition of a pellet containing 29 milligrams (mg) tylosin tartrate to the approved COMPONENT TE-200 implant for steers and heifers fed in confinement for slaughter. The supplemental application is approved as of January 26, 2007, and the regulations are amended in 21 CFR 522.2477 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 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 (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning January 26, 2007.

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 the 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 § 522.2477, add paragraph (d)(2)(i)(F) to read as follows:

**§ 522.2477 Trenbolone acetate and estradiol.**

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(i) \* \* \*

(F) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

\* \* \* \* \*

Dated: February 12, 2007.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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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; Monensin**

**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 Elanco Animal Health. The supplemental NADA provides for minor revisions to labeling of monensin Type A medicated articles for chickens. FDA is also amending the regulations to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing

monensin for poultry and game birds. This action is being taken to improve the clarity of the regulations.

**DATES:** This rule is effective March 1, 2007.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 38-878 that provides for use of COBAN 60 and COBAN 90 (monensin, USP) Type A medicated articles in feed of chickens. The supplement provides for minor revisions to labeling. The supplemental NADA is approved as of February 7, 2007, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

In addition, FDA is taking this opportunity to amend the regulations to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin for poultry and game birds. Similar restructuring was done recently for monensin formulations used in ruminants (71 FR 66231, November 14, 2006). This action is being taken to improve the clarity of the regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA 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 558**

Animal drugs, Animal feeds.

■ 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 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. In § 558.355, revise paragraphs (a), (b)(1), (b)(4), (b)(6), (d)(4), (d)(5), and (d)(8); and add paragraphs (d)(9)(iv) through (d)(9)(vi), and (d)(10)(iv) through (d)(10)(vi) to read as follows:

**§ 558.355 Monensin.**

(a) *Specifications.* Type A medicated articles containing monensin, USP.

(b) \* \* \*

(1) To No. 000986: 36.3 (for export only), 44, 45, 60, or 90.7 grams per pound for use as in paragraphs (f)(1)(i) and (f)(4) of this section.

\* \* \* \* \*

(4) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(2) of this section.

\* \* \* \* \*

(6) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(5) of this section.

\* \* \* \* \*

(d) \* \* \*

(4) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(5) All Type A medicated articles containing monensin shall bear the following warning statement: When mixing and handling monensin Type A medicated articles, use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

\* \* \* \* \*

(8) Type A medicated articles containing monensin intended for use in chickens, turkeys, and quail shall bear the following statements:

(i) Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

(ii) Must be thoroughly mixed in feeds before use.

(iii) Do not feed undiluted.

(iv) Do not feed to laying chickens.

(v) Do not feed to chickens over 16 weeks of age.

(vi) For replacement chickens intended for use as cage layers only.

(vii) Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.