information on any already approved alternative methods of compliance, contact Ingrid Knox, Aerospace Engineer, FAA, Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150; telephone: (817) 222–5139; facsimile: (817) 222–5960.

(f) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Fairchild Service Letter 226–SL–023 or Fairchild Service Letter 227–SL–039, both dated September 6, 2000; or Fairchild Service Letter CC7–SL–031, pages 1 and 3 dated September 6, 2000, and page 2 dated September 25, 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You may get copies from Fairchild Aircraft, Inc., P.O. Box 790490, San Antonio, Texas 78279–0490.

You may view copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) *When does this amendment become effective?* This amendment becomes effective on November 7, 2003.

Issued in Kansas City, Missouri, on September 15, 2003.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–23931 Filed 9–22–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for over-the-counter marketing status for pyrantel pamoate suspension, when labeled for oral administration to horses and ponies for the removal and control of certain internal parasites.

DATES: This rule is effective September 23, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 301–827–8549; e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed a supplement to ANADA 200–246 that currently provides for the veterinary prescription use of ANTHELBAN V (pyrantel pamoate) Equine Anthelmintic Suspension, administered orally or by nasogastric tube (stomach tube) to horses and ponies for the removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles. The supplemental ANADA provides for the over-the-counter use of Pyrantel Pamoate Equine Anthelmintic Suspension, an identical formulation labeled for the same conditions of use, except administration by stomach tube, a veterinary procedure. Phoenix Scientific, Inc.'s Pyrantel Pamoate Equine Anthelmintic Suspension is approved as a generic copy of Pfizer, Inc.'s PAMOBAN Horse Wormer Suspension, approved with over-the-counter marketing status under NADA 91–739. The supplemental ANADA is approved as of August 19, 2003, and the regulations are amended in 21 CFR 520.2043 to reflect the approval and the current indications for use. 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.

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 520

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 520 is 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 520.2043 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For the removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

* * * * *

Dated: September 15, 2003.

Steven D. Vaughn.

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

[FR Doc. 03–24162 Filed 9–22–03; 8:45 am]

BILLING CODE 4160–01–S

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; Technical Amendment

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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot steers for increased rate of weight gain and improved feed efficiency. This section of the regulations is also being amended to remove a redundant description of another strength implant. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective September 23, 2003.

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: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200–221 for COMPONENT TE–IS (trenbolone acetate/estradiol), a subcutaneous ear implant containing 80 milligrams (mg) trenbolone acetate and 16 mg estradiol, in four pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol. The implants are used in steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Ivy Laboratories' COMPONENT TE–IS is approved as a generic copy of Intervet, Inc.'s REVALOR–IS, approved under NADA 140–897. The supplemental application is approved as of September 3, 2003, and 21 CFR 522.2477 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.2477 is being amended to remove a redundant description of another strength implant. This action is being taken to improve the accuracy 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 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.

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.

■ 2. Section 522.2477 is amended in paragraph (b)(1) by removing ''(d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(ii)'' and by adding in its place ''(d)(1)''; and by revising paragraph (d)(1)(i)(D) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

* * * * *

Dated: September 15, 2003.

Steven D. Vaugh,

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

[FR Doc. 03–24161 Filed 9–22–03; 8:45 am]

BILLING CODE 4160–01–S

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 an additional dose of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain.

DATES: This rule is effective September 23, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200–346. The supplemental ANADA provides for the use of COMPONENT TE–IH (trenbolone acetate and estradiol), a subcutaneous implant containing 80 milligrams (mg) trenbolone acetate and 8 mg estradiol in heifers fed in confinement for slaughter for increased rate of weight gain. Ivy Laboratories' COMPONENT TE–IH is approved as a generic copy of Intervet, Inc.'s REVALOR–IH, approved under NADA 140–992. The application is approved as of August 19, 2003, 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.

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.