the business hours defined in § 40.1 of this chapter) that the Commission is in receipt of the application. Unless the Commission notifies the applicant during the 90-day period that the expedited review has been terminated pursuant to § 38.3(b), the Commission will designate the applicant as a contract market during the 90-day period. If deemed appropriate by the Commission, the designation may be subject to such conditions as the Commission may stipulate.

(i) The applicant must demonstrate compliance with the criteria for designation of section 5(b) of the Act, the core principles for operation of section 5(d) of the Act and the provisions of this part 38;

(ii) The application must include the items described in § 38.3(a)(1)(ii) and (iii); and

(iii) The applicant must not amend or supplement the application, except as requested by the Commission or for correction of typographical errors, renumbering or other nonsubstantive revisions, during the 90-day review period.

(b) *Termination of 90-day review.* (1) During the 90-day period for review pursuant to paragraph (a)(2) of this section, the Commission shall notify the applicant seeking designation that the Commission is terminating review under this section, and will review the application under the 180-day time period and procedures of section 6(a) of the Act, if it appears to the Commission that the application:

(i) Is materially incomplete;

(ii) Fails in form or substance to meet the requirements of this part;

(iii) Raises novel or complex issues that require additional time for review; or

(iv) Is amended or supplemented in a manner that is inconsistent with § 38.3(a)(2)(iii).

(2) The Commission shall also terminate review under this section if requested in writing to do so by the applicant.

(3) The termination notification shall identify the deficiencies in the application that render it incomplete, the manner in which the application fails to meet the requirements of this part, the novel or complex issues that require additional time for review, or the amendment or supplement that is inconsistent with § 38.3(a)(2)(iii).

(c) *Reinstatement of dormant designation.* Before listing or relisting products for trading, a dormant designated contract market as defined in § 40.1 of this chapter must reinstate its designation under the procedures of paragraph (a)(1) or (a)(2) of this section; provided, however, that an application for reinstatement may rely upon previously submitted materials that still pertain to, and accurately describe, current conditions.

(d) *Delegation of authority.* (1) The Commission hereby delegates, until it orders otherwise, to the Director of the Division of Market Oversight or such other employee or employees as the Director may designate from time to time, with the concurrence of the General Counsel or the General Counsel's delegate, authority to notify the applicant seeking designation under section 6(a) of the Act that the application is materially incomplete and the running of the 180-day period is stayed or that the 90-day review under paragraph (a)(2) of this section is terminated.

(2) The Director may submit to the Commission for its consideration any matter that has been delegated in this paragraph.

(3) Nothing in this paragraph prohibits the Commission, at its election, from exercising the authority delegated in paragraph (d)(1) of this section.

(e) *Request for withdrawal of application for designation.* An applicant for designation may withdraw its application submitted pursuant to paragraph (a)(1) or (a)(2) of this section by filing such a request with the Commission at its Washington, DC, headquarters. Withdrawal of an application for designation shall not affect any action taken or to be taken by the Commission based upon actions, activities or events occurring during the time that the application for designation was pending with the Commission.

(f) *Request for vacation of designation.* A designated contract market may vacate its designation under section 7 of the Act by filing such a request with the Commission at its Washington, DC, headquarters. Vacation of designation shall not affect any action taken or to be taken by the Commission based upon actions, activities or events occurring during the time that the facility was designated by the Commission.

(g) *Guidance for applicants.* Appendix A to this part provides guidance on how the criteria for designation under section 5(b) of the Act can be satisfied. Appendix B to this part provides guidance on how the core principles of section 5(d) of the Act can be satisfied.

Issued in Washington, DC, on November 12, 2004, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 04–25614 Filed 11–19–04; 8:45 am]

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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 Acetate and Estradiol Benzoate

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 Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for the addition of statements to labeling of subcutaneous implants containing trenbolone acetate and estradiol benzoate warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 22, 2004.

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: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141–043 for SYNOVEX PLUS (trenbolone acetate and estradiol benzoate) and SYNOVEX CHOICE (trenbolone acetate and estradiol benzoate), two subcutaneous implants products used in steers and heifers fed in confinement for slaughter for increased rate of weight gain and/or improved feed efficiency. The supplemental NADA provides for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental application is approved as of October 28, 2004, and the regulations are amended in 21 CFR 522.2478 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.

■ 2. Section 522.2478 is amended by revising paragraphs (d)(1)(i)(C), (d)(1)(ii)(C), and (d)(2)(iii) to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) * * *

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Not for subsequent breeding dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 10, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–25878 Filed 11–19–04; 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; 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 new animal drug application (NADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADA provides for the addition of statements to labeling of subcutaneous implants containing estradiol warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 22, 2004.

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 a supplement to NADA 118–123 for ENCORE (estradiol) and COMPUDOSE (estradiol). The supplemental NADA provides for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental application is approved as of October 28, 2004, and the regulations are amended in 21 CFR 522.840 to reflect the approval and a current format. 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 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 522.840 is revised to read as follows:

§ 522.840 Estradiol.

(a) *Specifications.* Each silicone rubber implant contains 25.7 or 43.9 milligrams (mg) estradiol and is coated with not less than 0.5 mg oxytetracycline powder.

(b) *Sponsor.* See No. 021641 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.240 of this chapter.

(d) *Conditions of use.* For implantation in steers and heifers as follows:

(1) *Amount.* Insert one 25.7-mg implant every 200 days; insert one 43.9-mg implant every 400 days.

(2) *Indications for use.* For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-mg implant or 400 days for the 43.9-mg implant.