Federal Register of January 5, 2004, the following corrections are made:

1. On page 265, in the third column, the second reference is corrected to read ''Lois M. Joellenbeck, Lee L. Zwanziger, Jane S. Durch, and Brian L. Strom, Editors, Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, Medical Follow-Up Agency, The National Academies Press, Washington, DC, April 2002, *http://www.nap.edu/catalog/10310.html* (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).''

2. On page 266, in the first column, the third reference is corrected to read ''Fellows, P. F., M. K. Linscott, B. E. Ivins, M. L. M. Pitt, C. A. Rossi, P. H. Gibbs and A. M. Friedlander, 'Efficacy of a Human Anthrax Vaccine in Guinea Pigs, Rabbits, and Rhesus Macaques Against Challenge by Bacillus Anthracis Isolates of Diverse Geographical Origin,' *Vaccine*, 19(23/24):3241–3247, 2001.''

3. On page 266, in the first column, the fourth reference is corrected to read ''Ivins, B. E., P. F. Fellows, M. L. M. Pitt, J. E. Estep, S. L. Welkos, P. L. Worsham and A. M. Friedlander, 'Efficacy of a Standard Human Anthrax Vaccine Against Bacillus Anthracis Aerosol Spore Challenge in Rhesus Monkeys,' *Salisbury Medical Bulletin* 87(Suppl.):125–126, 1996.''

4. On page 266, in the first column, the fifth reference is corrected to read ''Ivins, B. E.; M. L. M. Pitt; P. F. Fellows; J. W. Farchaus; G. E. Benner; D. M. Waag; S. F. Little; G. W. Anderson, Jr.; P. H. Gibbs; and A. M. Friedlander, 'Comparative Efficacy of Experimental Anthrax Vaccine Candidates Against Inhalation Anthrax in Rhesus Macaques,' *Vaccine*, 16(11/12):1141–1148, 1998.''

5. On page 266, in the first column, the seventh reference is corrected to read ''Wright, G. G.; Green, T. W.; and Kanode, Jr., R. G., 'Studies on Immunity in Anthrax: V. Immunizing Activity of Alum-Precipitated Protective Antigen,' *Journal of Immunology*, 73:387–391, 1954.''

6. On page 266, in the first column, the tenth reference is corrected to read '''Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS–1)', September 1998, *http://www.fda.gov/cber/gdlns/vaers–1.pdf*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).''

7. On page 266, in the first column, the eleventh reference is corrected to read '''Estimated Vaccination Coverage With 3+DTP Among Children 19–35 Months of Age by Race/Ethnicity,' and by State and Immunization Action Plan Area—U.S., National Immunization Survey, Q3/2000 - Q2/2001, *http://www.cdc.gov/nip/coverage/NIS/00–01/tab19–3dpt__race__iap.htm*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).''

8. On page 266, in the second column, the twelfth reference is corrected to read ''Protecting Our Kids: What Is Causing the Current Shortage in Childhood Vaccines?—Testimony Before the Committee on Governmental Affairs, United States Senate, June 12, 2002, *http://www.cdc.gov/nip/news/testimonies/vac-shortages-walt–6–12–2002.htm*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).''

Dated: February 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3135 Filed 2–12–04; 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; 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 feedlot steers.

DATES: This rule is effective February 13, 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 ANADA 200–346 for COMPONENT TE–200 (trenbolone acetate and estradiol) with TYLAN, a subcutaneous implant used for increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter. The supplemental ANADA provides for the addition of a pellet containing 29 milligrams tylosin tartrate to the approved implant. The supplemental application is approved as of January 9, 2004, 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.

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 522.2477 is amended by adding paragraph (d)(1)(i)(E) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(E) 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: January 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–3134 Filed 2–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 140, 200, 630, 633, 635 and 640

RIN 2125–AF01

Contract Administration; Removal of Miscellaneous Obsolete or Redundant Regulations

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: Through this final rule the FHWA will remove several regulations that have been superseded by legislation. We are removing sections related to construction engineering costs, administration of Direct Federal Construction Contracts, Interstate maintenance guidance, and the Certification Acceptance program. The changes reflect applicable provisions of title 23, United States Code, as amended by legislation, and avoid any possible redundancy or conflict with other regulations.

DATES: This rule is effective February 13, 2004.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Balis, Office of Program Administration, HIPA–30, (202) 493–7302, or Mr. Michael Harkins, Office of the Chief Counsel, (202) 366–4928, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded by using a computer, modem, and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's Home page at: *http://www.archives.gov* and the Government Printing Office's Web site at: *http://www.gpo.gov.*

Background

Over time various legislative or policy changes have made sections of title 23 of the Code of Federal Regulations (CFR) obsolete. This rulemaking will remove several regulations that have become obsolete or redundant as a result of various surface transportation statutes and other pertinent laws. Specifically, we believe that the following regulations must be removed or amended as described in the following section-by-section analysis.

Section-by-Section Discussion

Part 140 Subpart B, Construction Engineering Costs

Section 1305 of the Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178, 112 Stat. 107, June 9, 1998, as amended) repealed former 23 U.S.C. 106(c), which contained the 15 percent limitation previously established for Federal-aid reimbursement of construction engineering costs. The limitation for Federal-aid reimbursement of construction engineering costs was established by section 1018(a) of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) (Pub. L. 102–240, 105 Stat. 1914, December 18, 1991).

On July 22, 1993, the FHWA amended 23 CFR part 140 to conform with section 1018 of the ISTEA. However, section 1305 of the TEA–21 amended 23 U.S.C. 106 by deleting 23 U.S.C. 106(c), ''Limitation on Estimates for Construction Engineering,'' and substituting a new 23 U.S.C. 106(c), ''Assumption by States of Responsibilities of the Secretary.'' Therefore, 23 CFR 140, Subpart B, is revised to remove the limitation on construction engineering costs.

However, this subpart is not necessary in order for a State to recover these costs. We have determined that 23 CFR 1.11 allows for the reimbursement of ''directly attributable and properly allocable'' engineering costs incurred by a State or local transportation department for specific highway construction projects. For State or local transportation departments that have chosen to include construction engineering costs with other overhead costs, section 1212(a) of the TEA–21 amended 23 U.S.C. 302(b) to allow reimbursement of indirect costs through a cost allocation plan approved by the FHWA. Therefore we believe that 23 CFR part 140, Subpart B, is no longer necessary, and may be removed without adversely impacting the ability of the FHWA or the State or local transportation departments to carry out the Federal-aid Highway Program (FAHP).

Part 200, Title VI Program and Related Statutes—Implementation and Review Procedures

This subpart is revised to conform with the removal of Part 640, Certification Acceptance. Section 200.13 is removed.

Part 630, Subpart B, Plans, Specifications and Estimates

This subpart is revised to conform with the removal of Part 640, Certification Acceptance. Section 630.203 is revised.

Part 633, Subpart A, Federal-Aid Construction Contracts (Other Than Appalachian Contracts)

This subpart is revised to conform with the removal of Part 640, Certification Acceptance. Section 633.102(c) is removed and reserved.

Part 633, Subpart C, Direct Federal Construction Contracts

Prior to 1984, Federal procurement was done using one of two procedures. The military followed the Defense Acquisition Regulations (DAR) while civilian agencies followed the Federal Procurement Regulations (FPR).

In the Office of Federal Procurement Policy Act of 1974 (Pub. L. 93–400, 88 Stat. 796, August 30, 1974), the Congress ordered that a unified procurement system be developed for the Federal government. The Federal Acquisition Regulations System (FARS) was implemented in 1984. The FHWA is required to comply with FARS when the agency directly procures highway-related design or construction services.

The FHWA issued 23 CFR 633, Subpart C, on June 24, 1974, at 39 FR 22418. This subpart deals primarily with supplementary language for the Standard Form 19A (Labor Standards Provisions) which is an obsolete FPR form. Labor Standards provisions are now covered by FARS clauses in 48 CFR 52.222. Additionally, the remaining requirements contained in Subpart C are covered by current FARS clauses.