combiner gear, in the bevel gear where the ring retains the pinion toe bearing. The alert telex specifies inspecting the bevel gear for cracks using a borescope, pending the result of the investigation into the cause of the fatigue crack initiation currently being conducted in France. The DGAC classified this alert telex as mandatory and issued AD 2002–424–081(A) R2, dated March 19, 2003, to ensure the continued airworthiness of these helicopters in France.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that this AD will affect 4 helicopters of U.S. registry, and the required actions will take approximately 4 work hours for the inspections and 16 work hours to replace the bevel gear, if necessary, at an average labor rate of $65 per work hour. Required parts will cost approximately $31,372. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $130,688, assuming that upon the first inspection a crack is detected and the bevel gear will need to be replaced.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2002–SW–45–AD Eurocopter France: Amendment 39–13471. Docket No. 2002–SW–45–AD.

Applicability: Model AS332C, L, and L1 helicopters, with main gearbox bevel gear (bevel gear), part numbers (P/N) 332A32–2027–00 or 332A32–2026–00, containing bevel gears, P/N 332A32–2181–00, –01, –02, –03, or –04, or 331A32–3110–07, –08, –09, or –19, installed, certificated in any category. This AD does not apply to:

- Main gearboxes that were overhauled after December 31, 2002;
- Parts inspected in accordance with AS332 letter to Repair Stations No. 183; or
- Parts repaired in accordance with Repair Sheet (F.R.) 332A32–2181–ZA or 331A32–3110–ZA.

Compliance: Required as indicated, unless accomplished previously.

To detect a bevel gear crack and prevent failure of the bevel gear, loss of torque to the main rotor system, and subsequent loss of control of the helicopter, accomplish the following:

(a) For bevel gears that have more than 6,600 hours time-in-service (TIS), within 50 hours TIS and thereafter at intervals not to exceed 150 hours TIS, or at intervals not to exceed 1,000 frequent torque variation cycles, whichever occurs first, inspect for a crack using a borescope in accordance with the Operational Procedure, paragraph 2.B.1. and 2.B.2. of Eurocopter Telex No. 05.00.58 R2, dated February 3, 2003. A frequent torque variation cycle is each landing or external load operation beginning at the point when there are 4 or more landings, or 4 or more external load operations, or any combination of 4 or more landings and external load operations in any 60 minute time period, and ending when any combination of landings and external load operations is less than 4 in any 60 minute time period.

(b) If a crack is found in the bevel gear, before further flight, replace the bevel gear with an airworthy bevel gear.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(d) The inspection and replacement, if necessary, shall be done in accordance with Eurocopter Telex No. 05.00.58 R2, dated February 3, 2003. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

(e) This amendment becomes effective on March 19, 2004.

Note: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 2002–424–081(A) R2, dated March 19, 2003.

Issued in Fort Worth, Texas, on January 30, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04–2782 Filed 2–12–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 610

[Docket No. 1980N–0208]

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule and final order that appeared in the **Federal Register** of January 5, 2004 (69 FR 255). The document amended the biologics regulations and categorized certain biological products licensed before July 1, 1972, based on their safety, effectiveness, and labeling. The document was published with some typographical errors in the reference section. This document corrects those errors.

DATES: Effective February 13, 2004.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–32255, appearing on page 255, in the

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.