the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include ''AD Docket No. 2003–NE–51–AD'' in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive:

2004–24–05 Rolls-Royce Deutschland Ltd. & Co KG (formerly Rolls-Royce plc): Amendment 39–13881. Docket No. 2003–NE–51–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective December 29, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce Deutschland Ltd. & Co KG (RRD) (formerly Rolls-Royce plc), models Spey 555–15, 555–15H, 555–15N, and 555–15P turbojet engines, with magnesium split low pressure (LP) compressor case, part number (P/N) EU.73418A installed. These engines are installed on, but not limited to, Fokker F.28 Mark 1000, Mark 2000, Mark 3000, and Mark 4000 series airplanes.

Unsafe Condition

(d) This AD is prompted by several reports of bird ingestion and LP compressor stage 1 rotor blade failures that have resulted in penetration of the magnesium split LP compressor case and damage to the airplane. We are issuing this AD to prevent possible uncontained LP compressor stage 1 rotor blade failures that could result in damage to the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within 60 months after the effective date of this AD, unless the actions have already been done.

Replacement of Magnesium Split LP Compressor Case With a Serviceable Compressor Case

(f) Remove the magnesium split LP compressor case, P/N EU.73418A, from the engine and install a serviceable LP compressor case. Information on removing and replacing this P/N case can be found in RRD Service Bulletin No. Sp72–893, Revision 3, dated August 25, 2003.

Alternative Methods of Compliance

(g) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(h) None.

Related Information

(i) LBA airworthiness directive 2003–261, dated August 25, 2003, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on November 15, 2004.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–25790 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Estradiol Benzoate and Testosterone Propionate

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 supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth, and Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADAs provide for the addition of statements to labeling of subcutaneous implants containing estradiol benzoate and testosterone propionate warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 24, 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 011–427 for SYNOVEX H (estradiol benzoate and testosterone propionate). Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 135–906 for COMPONENT E–H (estradiol benzoate and testosterone propionate) and COMPONENT E–H with TYLAN (estradiol benzoate and testosterone propionate with tylosin tartrate). The supplemental NADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 18, 2004, and the regulations are amended in 21 CFR 522.842 to reflect the approvals and a current format. The basis of approval is discussed in the freedom of information summaries.

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.

The agency has determined under 21 CFR 25.33(a)(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 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 522.842 is revised to read as follows:

§ 522.842 Estradiol benzoate and testosterone propionate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 000856 for use as in paragraph (c)(1)(i), (c)(2), and (c)(3) of this section.

(2) No. 021641 for use as in paragraph (c) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

(c) *Conditions of use.* For implantation in heifers as follows:

(1) *Amount.* (i) 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.

(ii) 20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(3) *Limitations.* For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in 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 5, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–25977 Filed 11–23–04; 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 Acetate 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 two supplemental new animal drug applications (NADAs) filed by Intervet Inc.; three supplemental abbreviated new animal drug applications (ANADAs) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc.; and a supplemental ANADA filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADAs and ANADAs provide for the addition of statements to labeling of subcutaneous implants containing trenbolone acetate and estradiol warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 24, 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: Intervet Inc., 29160 Intervet Lane, P.O. Box 318, Millsboro, DE 19966, filed supplements to NADA 140–897 and NADA 140–992 for REVALOR (trenbolone acetate and estradiol) implants. Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplements to ANADA 200–221 and ANADA 200–346 for COMPONENT (trenbolone acetate and estradiol) and COMPONENT plus TYLAN (trenbolone acetate and estradiol with tylosin tartrate) implants. Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to ANADA 200–367 for SYNOVEX (trenbolone acetate and estradiol) implants. The supplemental NADAs and ANADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 28, 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), 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.

The agency has determined under 21 CFR 25.33(a)(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 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 by revising paragraphs (d)(1)(iii), (d)(2)(iii), and (d)(3)(iii) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. 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. Do not use in animals intended for subsequent breeding or in dairy animals. 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.

(3) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. 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. 04–25978 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S