

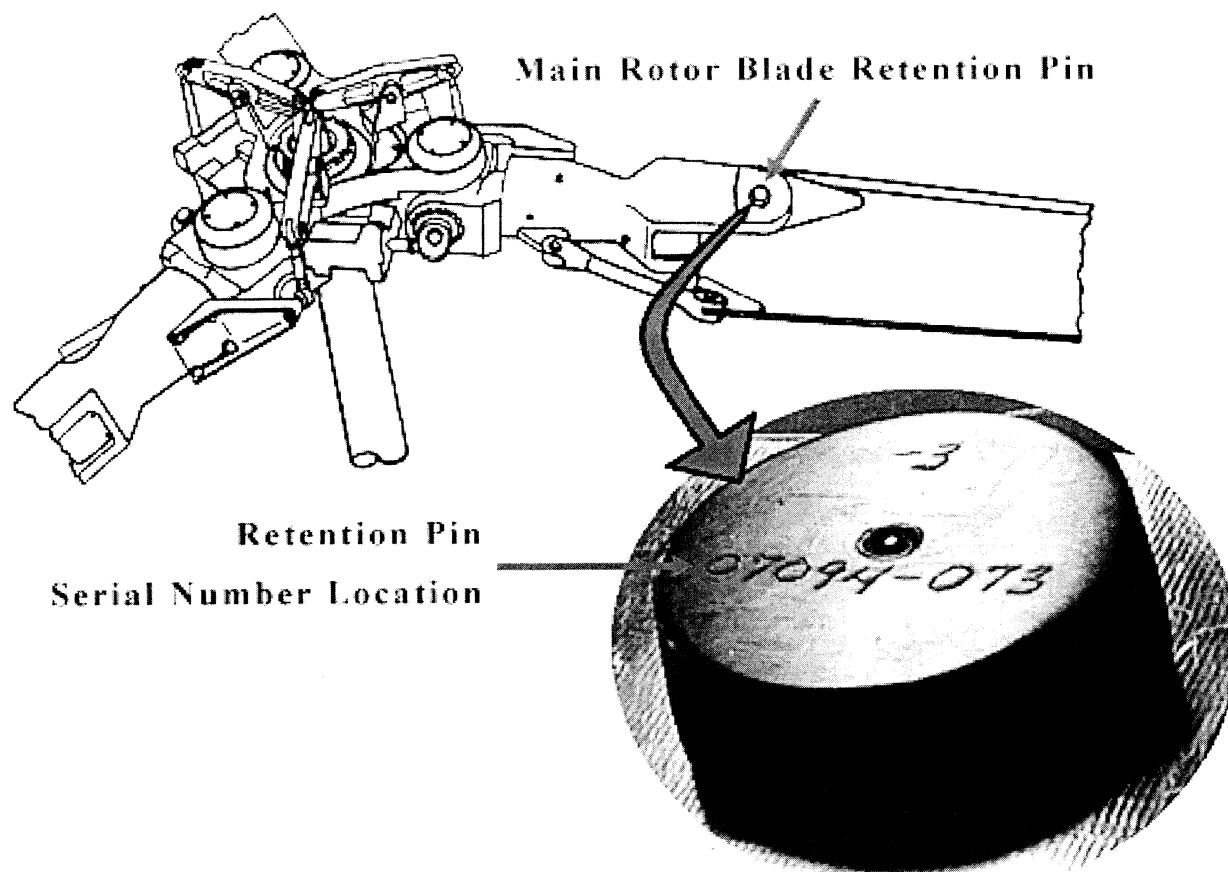


Figure 1

(b) The visual check required by paragraph (a) of this AD may be performed by an owner/operator (pilot) holding at least a private pilot certificate, and must be entered into the aircraft records showing compliance with paragraph (a) of this AD in accordance with 14 CFR sections 43.11 and 91.417(a)(2)(v).

(c) Determine the number of hours TIS for any affected retention pin and replace the retention pin with an airworthy retention pin as follows:

(1) For a retention pin with 545 or more hours TIS, remove the retention pin and replace it with an airworthy retention pin with a S/N that is not listed in the Applicability section of this AD within the next 5 hours TIS or within 30 days, whichever occurs first.

(2) For a retention pin with less than 545 hours TIS, remove the retention pin and replace it with an airworthy retention pin with a S/N that is not listed in the Applicability section of this AD on or before reaching 550 hours TIS or within 30 days, whichever occurs first.

Note: Enstrom Service Directive Bulletin No. T-029 and Enstrom Service Directive Bulletin 0102, both dated March 20, 2007, pertain to the subject of this AD.

(d) Removing any affected retention pin and replacing it with an airworthy retention pin that is not included in the Applicability section of this AD is considered a terminating action for the requirements of this AD for that retention pin.

(e) 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 Manager, Chicago Aircraft Certification Office, FAA, ATTN: Gregory J. Michalik, Senior Aerospace Engineer, 2300 E. Devon Ave., Room 107, Des Plaines, Illinois, 60018, telephone (847) 298-7135, fax (847) 294-7834, for information about previously approved alternative methods of compliance.

(f) This amendment becomes effective on August 15, 2007.

Issued in Fort Worth, Texas, on July 24, 2007.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 07-3711 Filed 7-30-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Ractopamine and Tylosin

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 Elanco Animal Health. The supplemental NADA revises the indications for use of two-way combination Type B and Type C medicated swine feeds formulated with ractopamine hydrochloride and tylosin phosphate.

DATES: This rule is effective July 31, 2007.

FOR FURTHER INFORMATION CONTACT:

Harlan J. Howard, Center for Veterinary Medicine (HFV-120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0231, e-mail: harlan.howard@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141-172 that provides for use of two-way combination Type B and Type C medicated swine feeds formulated with PAYLEAN (ractopamine hydrochloride) and TYLAN (tylosin phosphate) single-

ingredient Type A medicated articles. The supplement provides for revised indications for use of Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for control of swine dysentery associated with *Brachyspira hyodysenteriae* and porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis* in finishing swine, weighing not less than 150 pounds (lbs), fed a complete ration containing at least 16 percent crude protein for the last 45 to 90 lbs of gain prior to slaughter. The supplemental NADA is approved as of June 20, 2007, and the regulations in 21 CFR 558.500 are amended to reflect the approval.

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)(2) 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.500, revise the table in paragraphs (e)(1)(ii) and (e)(1)(iii) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(1) * * *

Ractopamine grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 4.5 to 9	Tylosin 40	Finishing swine: As in paragraph (e)(1)(i) of this section; and for control of swine dysentery associated with <i>Brachyspira hyodysenteriae</i> and porcine proliferative enteropathies (ileitis) associated with <i>Lawsonia intracellularis</i> .	Feed continuously as sole ration until market weight following the use of tylosin at 100 grams per ton (g/ton) for at least 3 weeks.	000986
(iii) 4.5 to 9	Tylosin 100	1. Finishing swine: As in paragraph (e)(1)(i) of this section; and for control of porcine proliferative enteropathies (ileitis) associated with <i>Lawsonia intracellularis</i> . 2. Finishing swine: As in paragraph (e)(1)(i) of this section; and for control of swine dysentery associated with <i>Brachyspira hyodysenteriae</i> .	Feed continuously as sole ration for 21 days. Feed continuously as sole ration for at least 3 weeks followed by tylosin at 40 g/ton until market weight.	000986
*	*	*	*	*

* * * * *

Dated: July 12, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-14699 Filed 7-30-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 584

Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals; Ethyl Alcohol Containing Ethyl Acetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations for food substances affirmed as generally recognized as safe (GRAS) in feed and drinking water of animals to correct a cross-reference. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective July 31, 2007.

FOR FURTHER INFORMATION CONTACT:

Michaela G. Alewynse, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6866, e-mail: mika.alewynse@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has found that the regulation affirming as

GRAS the use of ethyl alcohol containing ethyl acetate as a source of added energy in ruminant feed does not reflect the correct cross-reference to the regulations of the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF). This error was introduced when sections containing formulas for denatured alcohol and rum were removed and added by ATF in 1983 (48 FR 24672, June 2, 1983). At this time, the regulation is being amended in 21 CFR 584.200 to add the correct cross-reference. This action is being taken to improve the accuracy of the regulations.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting a nonsubstantive error.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because