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 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1192 [Amended]

2. Section 520.1192 *Ivermectin paste* is amended in paragraph (b)(2) by removing ''No.'' and by adding in its place ''Nos. 051311 and''.

Dated: November 18, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–30640 Filed 12–2–02; 8:45 am]

BILLING CODE 4160–01–S

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 provides for use of ractopamine and tylosin single-ingredient Type A medicated articles to make combination drug Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, increased carcass leanness; and for the prevention of swine dysentery in finishing swine.

DATES: This rule is effective December 3, 2002.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600, e-mail: candres@cvm.fda.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 PAYLEAN (9 or 45 grams per pound (g/lb) ractopamine hydrochloride) and TYLAN (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make combination drug Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for the prevention of swine dysentery in finishing swine. The supplemental NADA is approved as of June 19, 2002, and the regulations are amended in § 558.500 (21 CFR 558.500) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.500 is being revised to reflect a current format. The entire text of this section is being provided for the convenience of the reader.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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)(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 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. Section 558.500 is revised to read as follows:

§ 558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45 grams of ractopamine hydrochloride per pound.

(b) *Approvals.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Special considerations.*

(1) Labeling of Type B and Type C swine feeds shall bear the following:

(i) ''Caution: Pigs fed PAYLEAN are at an increased risk for exhibiting the downer pig syndrome (also referred to as ''slows,'' ''subs,'' or ''suspects''). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of PAYLEAN.''

(ii) ''Not for use in breeding swine.''

(2) Tylosin in combinations as tylosin phosphate.

(e) *Conditions of use.* (1) *Swine*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5		For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.	Feed continuously as sole ration.	000986

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 4.5	Tylosin 40	Finishing swine: As in paragraph (e)(1)(i) of this section; and for prevention of swine dysentery (vibrionic).	Feed continuously as sole ration until market weight following the use of tylosin at 100 grams per ton (g/t) for at least 3 weeks.	000986
(iii) 4.5	Tylosin 100	1. Finishing swine: As in paragraph (e)(1)(i) of this section; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis.* 2. Finishing swine: As in paragraph (e)(1)(i) of this section; and for prevention of swine dysentery (vibrionic).	Feed continuously as sole ration for 21 days. Feed continuously as sole ration for at least 3 weeks followed by tylosin at 40 g/t until market weight.	000986 000986
(iv) 4.5 to 18		For improved feed efficiency and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.	Feed continuously as sole ration.	000986
(v) 4.5 to 18	Tylosin 40	Finishing swine: As in paragraph (e)(1)(iv) of this section; and for prevention of swine dysentery (vibrionic).	Feed continuously as sole ration until market weight following the use of tylosin at 100 g/t for at least 3 weeks.	000986
(vi) 4.5 to 18	Tylosin 100	1. Finishing swine: As in paragraph (e)(1)(iv) of this section; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*. 2. Finishing swine: As in paragraph (e)(1)(iv) of this section; and for prevention of swine dysentery (vibrionic).	Feed continuously as sole ration for 21 days. Feed continuously as sole ration for at least 3 weeks followed by tylosin at 40 g/t until market weight.	000986 000986

(2) [Reserved]

Dated: November 8, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–30637 Filed 12–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Boehringer Ingelheim Vetmedica, Inc., to Pennfield Oil Co.

DATES: This rule is effective December 3, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 128–550 for ANCHOR Zinc Bacitracin Type A medicated article to Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137. Accordingly, the agency is amending the regulations in 21 CFR 558.78 to reflect the transfer of ownership.

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 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.

§ 558.78 [Amended]

2. Section 558.78 *Bacitracin zinc* is amended in paragraph (a)(2) by removing ''To 000010'' and by adding in its place ''No. 053389''.

Dated: November 8, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–30638 Filed 12–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9021]

RIN 1545–AX68

Loans From a Qualified Employer Plan to Plan Participants or Beneficiaries

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to loans made from a qualified employer plan to plan participants or beneficiaries. These final regulations affect administrators of, participants in, and beneficiaries of qualified employer plans that permit