(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 2, 2004.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–18897 Filed 8–17–04; 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; Bacitracin Methylene Disalicylate and Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides for the use of single-ingredient Type A medicated articles containing bacitracin methylene disalicylate and chlortetracycline to make two-way combination drug Type B and Type C medicated feeds for swine.

DATES: This rule is effective August 18, 2004.

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: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed ANADA 200–358 for use of PENNCHLOR (chlortetracycline) and BMD (bacitracin methylene disalicylate) Type A medicated articles to make two-way combination drug Type B and Type C medicated feeds for swine. Pennfield Oil Co.'s ANADA 200–358 is approved as a generic copy of Alpharma, Inc.'s new animal drug application 141–059. The ANADA is approved as of July 2, 2004, and the regulations are amended in § 558.76 (21 CFR 558.76) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA is amending § 558.76 by removing specifications for a bacitracin methylene disalicylate and chlortetracycline combination drug Type B medicated feed that was added to the regulations in 1998 (63 FR 44385, August 19, 1998). The specification contains an error, but also was codified unnecessarily. This amendment is being done to improve the accuracy and consistency of the animal drug regulations.

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.

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 558.76 is amended in the table by revising paragraph (d)(1)(iv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(1) * * *

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
(iv) 10 to 30		Swine: for increased rate of weight gain and improved feed efficiency.	For growing and finishing swine	046573 053389
	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.	Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline provided by Nos. 046573 and 053389 in § 510.600(c) of this chapter.	046573 053389
		Swine; for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline and BMD as provided by 046573 in § 510.600(c) of this chapter.	046573

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*	*	*

* * * * *

Dated: August 2, 2004.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–18845 Filed 8–17–04; 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; Carbadox and Oxytetracycline

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 new animal drug application (NADA) filed by Phibro Animal Health. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing carbadox and oxytetracycline to formulate two-way combination drug Type C medicated feeds for swine.

DATES: This rule is effective August 18, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rt. 46 East, suite 401, Fairfield, NJ 07004, filed NADA 141–211 that provides for the use of MECADOX (carbadox), approved under NADA 41–061, and TERRAMYCIN (oxytetracycline) Type A medicated articles, approved under NADA 95–143, to formulate two-way combination drug Type C medicated feeds for swine. The Type C medicated feeds are used for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency. The application is approved as of July 21, 2004, and the regulations are amended in 21 CFR 558.115 and 558.450 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.

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 558.115 is amended by adding paragraph (d)(4) to read as follows:

§ 558.115 Carbadox.

* * * * *

(d) * * *

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

■ 3. Section 558.450 is amended by redesignating paragraph (d)(3)(i) as paragraph (d)(3)(iv); and by adding new paragraph (d)(3)(i) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(d) * * *

(3) * * *

(i) Carbadox as in § 558.115 of this chapter.

* * * * *

Dated: August 2, 2004.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–18844 Filed 8–17–04; 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; Ractopamine

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 new animal drug applications (NADAs) filed by Elanco Animal Health. One NADA provides for use of ractopamine, melengestrol, and monensin Type A medicated articles to make three-way combination Type C medicated feeds for heifers fed in confinement for slaughter. The other NADA provides for use of ractopamine, melengestrol, monensin, and tylosin Type A medicated articles to make four-way combination Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective August 18, 2004.