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 Pharmacia & Upjohn Co. The supplemental NADA provides for the use of neomycin sulfate Type A medicated articles to make Type B and Type C medicated feeds for cattle, swine, sheep, and goats in a broader range of concentrations.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, has filed a supplemental application to NADA 140–976 that provides for use of Neomix® (neomycin sulfate) Type A medicated articles to make Type B and Type C medicated feeds for cattle, swine, sheep, and goats used for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin. The supplemental NADA requested that the approved range of concentrations for neomycin Type C medicated feeds of 400 to 1,600 grams per ton (g/ton) be broadened to 250 to 2,250 g/ton. The approved daily dose of 10 milligrams per pound of body weight remains unchanged. The supplemental NADA is approved as of June 28, 2000, and the regulations are amended in 21 CFR 558.364 to reflect the approval.

Approval of this supplemental NADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary is not required.

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 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.

§ 558.364 [Amended]

2. Section 558.364 *Neomycin sulfate* is amended in the table in paragraph (d) in entry ''(1)'' under ''Neomycin sulfate'' by removing ''400 to 1,600'' and by adding in its place ''250 to 2,250''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18826 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

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 Alpharma, Inc. The supplemental NADA provides for use of approved chlortetracycline (CTC) Type A medicated articles to make Type C medicated feeds used for control of porcine proliferative enteropathies (ileitis) in swine.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7574.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., PO Box 1399, Fort Lee, NJ 07024, filed a supplement to approved NADA 046–699 that provides for use of CHLORMAX™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline as chlortetracycline hydrochloride) Type A medicated articles to make Type C medicated feeds for use in growing and finishing swine. The Type C medicated feeds contain approximately 400 g per ton CTC (to provide 10 milligrams/lb body weight) and are used for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. The supplemental NADA is approved as of July 7, 2000, and the regulations are amended in 21 CFR 558.128 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 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on July 7, 2000, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new claim for which the supplemental application was approved.

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 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 558.128 is amended in the table in paragraph (d)(1)(xii) by adding an entry ''4.'' to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(d) * * *

(1) * * *

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xii) 10 mg/lb of body weight		* * *		
		4. Swine; for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 d.	046573
*	*	*	*	*

* * * * *

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18823 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 140

RIN 2125–AE76

Temporary Matching Fund Waiver

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule; rescission of regulation.

SUMMARY: This document rescinds the regulation that prescribes procedures for administering section 1054 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) providing for a temporary waiver of State matching fund requirements. Since the period of this special provision has expired, and all money has been repaid, the regulation is obsolete.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Max Inman, Federal-aid Financial Management Division, (202) 366–2583 or Mr. Steve Rochlis, Office of the Chief Counsel, (202) 366–1395, Federal Highway Administration, 400 Seventh Street, SW., Room 4310, Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at *http://www.nara.gov/fedreg* and the Government Printing Office's database at *http://www.access.gpo.gov/nara.*

Background

Under the provisions of section 1054 of the ISTEA, Public Law 102–240, 105 Stat. 1914, at 2001 (23 U.S. Code. 120 note), a State could request an increased Federal share up to 100 percent for any qualifying title 23, U.S. Code, project beginning October 1, 1991, and ending September 30, 1993. The total amount of any such increase had to be repaid to the United States on or before March 30, 1994. If a State did not make the required repayment by March 30, 1994, the Secretary of Transportation could make deductions from funds apportioned to the States for fiscal years 1995 and 1996. Since the period of this special provision has expired, and all money has been repaid, it is no longer necessary to have this particular regulation.

Rulemaking Analyses and Notices

This final rule makes only minor technical corrections to our existing regulation. The rule replaces outdated statutory language due to the expiration of a special provision under ISTEA granting States temporary matching fund waiver and requiring repayment by March 30, 1994. Because the Congress did not enact a similar matching fund waiver in the Transportation Equity Act for the 21st Century (TEA–21), (Pub. L. 105–178, 112 Stat. 107 (1998) or any other statute, there is no need for the provision in the current regulations. Therefore, the FHWA finds good cause to rescind the rule without prior notice or opportunity for public comment [5 U.S.C. 553(b)]. The DOT's regulatory policies and procedures also authorize rescission of the rule without prior notice because it is anticipated that such action would not result in the receipt of useful information. The FHWA is making the rule effective upon publication in the **Federal Register** because it imposes no new burdens and merely rescinds an existing regulation that has become obsolete.

Executive Order 12866 (regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has considered the impact of this action and has determined that it is not a significant regulatory action within the meaning of Executive Order 12866 or a significant within the meaning of the Department of Transportation regulatory policies and procedures. Since this rulemaking action merely removes an obsolete regulation, it is anticipated that its economic impact is minimal; therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this action on small entities. Based on the evaluation, and since this rulemaking action merely removes an outdated regulation, the FHWA hereby certifies that this action will not have a significant economic impact on a