SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations that reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The previous amendment, which appeared in the Federal Register of April 13, 1994 (59 FR 17476), provided for making a semduramicin Type A medicated article used to make a Type C medicated broiler chicken feed for the prevention of coccidiosis. The agency has since realized it needs to more accurately reflect both the assay limits for semduramicin Type A articles and the limitation for its use. This action is being taken to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: November 24, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1656.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 13, 1994 (59 FR 17476), FDA published a final rule to announce the approval of Pfizer's new animal drug application (NADA) 140–940. The NADA provides for use of Aviax™ (semduramicin sodium) Type A medicated article to make a semduramicin Type C medicated broiler chicken feed used for the prevention of coccidiosis. That document inadvertently failed to reflect the correct assay limits for Type A medicated articles in 21 CFR 558.4 and the correct limitation for use in 21 CFR 558.555(b)(1)(iii). This document corrects those errors. Due to these amendments, FDA is also providing an amended freedom of information (FOI) summary for public display. The FOI summary has been amended to reflect the correct assay limits and efficacy evaluation. The amended copy of the FOI summary is available at the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d) in the ''Category I'' table in the entry for ''Semduramicin'' under the second column by removing ''94–102'' and adding in its place ''90–110''.

§ 558.555 [Amended]

3. Section 558.555 *Semduramicin* is amended in paragraph (b)(1)(iii) by removing the last sentence.

Dated: November 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–28598 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

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 Hoffmann-La Roche, Inc. The supplemental NADA provides for use of a 20-percent lasalocid Type A medicated article in making a Type C medicated feed for rabbits used as a coccidiostat.

EFFECTIVE DATE: November 24, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., 340 Kingsland Rd., Nutley, NJ 07110–1199, is the sponsor of NADA 96–298, which currently provides for the use of a Type A medicated article containing 20 percent (90.7 grams (g) per pound) of lasalocid sodium activity in making a 68- to 113-g per ton (g/t) Type C medicated feed for broiler or fryer chickens and growing turkeys, and a 113-g/t Type C medicated feed for chukar partridges, for prevention of coccidiosis. The firm has filed a supplemental NADA that expands the use of the Type A medicated article for use in making a 113-g/t Type C medicated feed for rabbits for the prevention of coccidiosis caused by *Eimeria stiedae*. Approval is based in part on data and information in Public Master File (PMF) 5042 established under the National Research Support Project (NRSP) 7 (formerly the Interregional Research Project No. 4 (IR–4)), Southern Region, University of Florida, Gainesville, FL 32610.

The supplemental NADA is approved as of October 20, 1995, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 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 does not qualify for marketing exclusivity because no new clinical or field investigations (other than bioequivalence or residue studies) and no new human food safety studies (other than bioequivalence or residue studies) essential to approval of the supplement were conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.311 is amended by revising paragraph (b)(7) and in the table in paragraph (e)(1) by adding new entry ''(xv)'' to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(7) 20 percent activity to No. 000004 for use as follows:

(i) Chukar partridges as in paragraph (e)(1)(xiii).

(ii) Turkeys as in paragraph (e)(1)(xiv).

(iii) Rabbits as in paragraph (e)(1)(xv).

* * * * *

(e) * * *

(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xv) 113 (0.0125 pct).		Rabbits; for prevention of coccidiosis caused by *Eimeria stiedae*.	Feed continuously as sole ration up to 6 1/2 weeks of age.	000004

* * * * *

Dated: November 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–28599 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1317

[NHTSA Docket No. 95–82; Notice 1]

RIN 2127–AG08

Highway Safety Innovative Project Grants Program

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule removes Part 1317 from title 23 of the Code of Federal Regulations (CFR). Part 1317 established criteria and administrative procedures for awards of innovative project grants to States and their political subdivisions, and to non-profit organizations including volunteer groups, in accordance with 23 U.S.C. 407. The regulation is being removed because it is unnecessary and obsolete. Funds for the section 407 program have not been authorized since 1981.

EFFECTIVE DATE: December 26, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Gary Butler, Office of State and Community Services, National Highway Traffic Safety Administration, 400 7th Street, S.W., Washington, D.C. 20590, telephone (202) 366–2121; or Ms. Sharon Y. Vaughn, Office of Chief Counsel, Room 5219, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, D.C. 20590, telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: On March 4, 1995, President Clinton directed all Federal Departments and agencies to take four steps to overhaul the nation's regulatory system. The first step was to conduct a page-by-page review of all agency regulations now in force and eliminate or revise those that are outdated or otherwise in need of reform. The review was to include careful consideration of a number of issues, including whether the regulation is obsolete, whether its intended goal can be achieved in more efficient less intrusive ways, or whether States or local governments can do the job (making Federal regulation unnecessary).

NHTSA conducted a thorough, page-by-page review of all agency regulations, including those that pertain to State and community highway safety programs.

As a result of these efforts, NHTSA has determined that Part 1317 should be removed from title 23 of the Code of Federal Regulations (CFR), because it is unnecessary and obsolete.

Part 1317 established criteria and administrative procedures for awards of innovative project grants to States and their political subdivisions, and to non-profit organizations including volunteer groups, in accordance with 23 U.S.C. 407. It was first published in the Federal Register, as 23 CFR Part 1217, on December 22, 1980 (45 FR 84037). It was redesignated as 23 CFR Part 1317 on March 22, 1984 (49 FR 10664).

Funds for the section 407 program have not been authorized since 1981. Because the regulation implements a program which is no longer active, and currently appears in the CFR among regulations that implement programs that continue to be active, its removal will avoid confusion for potential grant applicants.

Rulemaking Analyses and Notices

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

NHTSA has considered the impact of this rulemaking action under E.O. 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed under E.O. 12866, ''Regulatory Planning and Review.'' This action has been determined to be not ''significant'' under the Department of Transportation's regulatory policies and procedures.

(b) Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the agency has evaluated the effects of this rule on small entities. Based on the evaluation, the agency hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. Accordingly, the preparation of a Regulatory Flexibility Analysis is unnecessary.

(c) Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

(d) Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

(e) National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

(f) Executive Order 12778 (Civil Justice Reform)

This amendment to the regulation does not have any preemptive or retroactive effect. It imposes no requirements on the States, but rather simply removes from the regulation outdated and obsolete provisions that no longer apply. The enabling legislation does not establish a procedure for judicial review of final rules promulgated under its provisions. There is no requirement that individuals submit a petition for reconsideration or other administrative proceedings before they may file suit in court.

Notice and Comment

Because the amendments relate to a grant program and are therefore not covered by the Administrative Procedure Act, and since they merely contain technical changes that remove outdated and obsolete provisions from the regulation and do not impose any additional requirements, the amendments are being made without prior notice and opportunity to comment.

List of Subjects in 23 CFR Part 1317

Grant programs, Highway safety.

Under the authority of 49 CFR Part 1.50, the Administrator of the National Highway Traffic Safety Administration amends Title 23 of the Code of Federal Regulations by removing Part 1317.

Issued on: November 20, 1995.

Ricardo Martinez,

Administrator, National Highway Traffic Safety Administration.

[FR Doc. 95–28684 Filed 11–22–95; 8:45 am]

BILLING CODE 4910–59–P