have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the United States, except into areas of Texas quarantined because of said disease or tick infestation as specified in § 72.5 of this chapter, either at one of the land border ports in Texas listed in § 93.403(c) or at the port of Santa Teresa, NM, provided that the following conditions are strictly observed and complied with:

* * * * *

Done in Washington, DC, this 22nd day of December 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–31212 Filed 12–31–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2008–N–0039]

New Animal Drugs for Use in Animal Feeds; Tiamulin

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 supplemental new animal drug applications (NADAs) filed by Novartis Animal Health US, Inc. The supplemental NADAs provide for removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling of tiamulin medicated feeds used for the treatment or control of certain bacterial enteric diseases in swine.

DATES: This rule is effective January 2, 2009.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 139–472 for DENAGARD (tiamulin) Medicated Premixes used for the treatment or control of certain bacterial enteric diseases in swine. Novartis Animal Health US, Inc., also filed a supplement to NADA 141–011 for the use of DENAGARD (tiamulin) Medicated Premixes and Chlortetracycline Type A medicated articles to manufacture 2-way combination drug medicated swine feeds used for the treatment or control of certain bacterial enteric diseases. The supplemental NADAs provide for removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling. The supplemental NADAs are approved as of December 9, 2008, and 21 CFR 558.600 is amended to reflect the approval.

Approval of these supplemental NADAs did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33 that these actions are of a type that do 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. In § 558.600, revise paragraphs (d)(2) and (e)(1)(i) to read as follows:

§ 558.600 Tiamulin.

* * * * *

(d) * * *

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

* * * * *

(e) * * *

(1) * * *

Tiamulin grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10	.....	For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds.	058198
*	*	*	*	*	*	*

* * * * *

Dated: December 22, 2008.

Steven D. Vaughn,

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

[FR Doc. E8–31128 Filed 12–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2008–N–0517]

Medical Devices; Immunology and Microbiology Devices; Classification of Enterovirus Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying enterovirus nucleic acid assay into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA'' (ribonucleic acid). The agency is classifying the device into class II (special controls) in order to provide a