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

reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This final rule is effective February 2, 2009. The classification was effective March 16, 2007.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0725.

SUPPLEMENTARY INFORMATION:

I. What is the Background of This Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on March 9, 2007, classifying the Xpert EV™ Assay as class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. Cepheid submitted a petition dated March 9, 2007, requesting classification of the Xpert EV™ Assay under section 513(f)(2) of the act. FDA filed the petition on March 12, 2007. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Xpert EV™ Assay can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''enterovirus nucleic acid assay.'' It is identified as a device that consists of primers, probes, enzymes, and controls for the amplification and detection of enterovirus RNA in cerebrospinal fluid (CSF) from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.

Failure of nucleic acid assays for detection of enterovirus RNA to perform as expected, or failure to interpret results correctly, may lead to incorrect patient management decisions. A false negative report could lead to delays in providing (or even failure to provide) a definitive diagnosis, and the unnecessary treatment of the patient with antibiotics. A false positive report could lead to a delayed treatment of bacterial meningitis or other forms of meningitis. This delayed treatment due to a false positive result could cause progression of potentially life-threatening bacterial meningitis with subsequent severe morbidity to the patient and potentially even patient death. Device failure leading to no result (for example, due to failure of reagents, instrumentation, data management, or software) or an invalid or equivocal result could delay diagnosis, and could require an additional collection of CSF fluid, a procedure that is associated with the risk of infection. Furthermore, the appearance of new serotypes of enterovirus may affect the performance of an enterovirus nucleic acid amplification assay for the detection of enterovirus RNA in CSF specimens. Primers and probes for detection of enteroviruses are selected for their homology with highly conserved regions within viral RNA segments that are present in most enterovirus serotypes. Primers and probes might not detect new serotypes that appear over time. In addition, test performance can be affected, as the epidemiology and pathology of disease caused by the new enterovirus serotypes could change.

FDA believes the class II special controls guidance document will aid in mitigating potential risks by providing recommendations on labeling and validation of performance characteristics. The guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that following the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph. Therefore, on March 16, 2007, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 866.3225.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an enterovirus nucleic acid assay will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket review of the system's key performance characteristics, test methodology, labeling, and other requirements as outlined in § 807.87, will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type

of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the gene expression profiling test system for breast cancer prognosis they intend to market.

II. What is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) 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.

III. What is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device type into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe *** a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute. Federal law includes an express preemption provision that preempts certain state requirements ''different from, or in addition to'' certain federal requirements applicable to devices. See 21 U.S.C. 360k; *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S.Ct. 999 (2008).

In this rulemaking, FDA has determined that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish special controls to provide such assurance. FDA has therefore imposed a special control to address the amplification and detection of enterovirus RNA in CSF from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.

As with any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would be preempted. See *Geier* v. *American Honda Co.*, 529 U.S. 861, (2000); *English* v. *General Electric Co.*, 496 U.S. 72, 79 (1990), *Florida Lime & Avocado Growers, Inc.*, 373 U.S. 132, 142–143 (1963); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance entitled ''Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA'' references previously approved collections of information found in FDA regulations.

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Cepheid, dated March 9, 2007.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3225 is added to subpart D to read as follows:

§ 866.3225 Enterovirus nucleic acid assay.

(a) *Identification.* An enterovirus nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of enterovirus ribonucleic acid (RNA) in cerebrospinal fluid (CSF) from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA.'' See § 866.1(e) for the availability of this guidance document.

Dated: December 16, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–31213 Filed 12–31–08; 8:45 am]

BILLING CODE 4160–01–S