

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Display Date 2.28.07  
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Certifier

New Animal Drugs For Use in Animal Feeds; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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**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 Intervet Inc. The supplemental NADA provides for the removal of a caution statement against the formulation of pelleted feeds from labeling of zilpaterol hydrochloride Type A medicated article and Type B and Type C medicated feeds.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301 827-1600, e-mail: *charles.andres@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Intervet Inc., P.O. Box 318, 29160 Intervet Ln., Millsboro, DE 19966, filed a supplement to NADA 141-258 for use of ZILMAX (zilpaterol hydrochloride 4.8%) Type A medicated article to formulate Type B and Type C medicated cattle feeds. The supplemental NADA provides for the removal of a caution statement against the formulation of pelleted feeds from labeling. The supplemental NADA is approved as of January 29, 2007, and the regulations are amended in 21 CFR 558.665 to reflect the approval.

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2007. 141.258

NFR2

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

FDA 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.

#### **§ 558.665 [Amended]**

■ 2. Remove paragraph (d)(3) of § 558.665.

Dated: February 12, 2007  
February 12, 2007.

Steven D. Vaughn

SR 2-26-07

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

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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