DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Zilpaterol

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 new animal drug application (NADA) filed by Intervet Inc. The NADA provides for use of approved, single-ingredient Type A medicated articles containing zilpaterol hydrochloride, monensin USP, and melengestrol acetate in three-way combination Type B and Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective April 10, 2008.

FOR FURTHER INFORMATION CONTACT: Gerald L. Rushin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8103, e-mail: *gerald.rushin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–282 that provides for use of ZILMAX (zilpaterol hydrochloride), RUMENSIN (monensin USP), and MGA (melengestrol acetate) Type A medicated articles to make dry and liquid three-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 20 to 40 days on feed. The NADA is approved as of February 22, 2008, and the regulations in 21 CFR 558.665 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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.

The agency has determined under 21 CFR 25.33(a)(2) 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 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 § 558.665, redesignate paragraphs (e)(4) and (e)(5) as paragraphs (e)(5) and (e)(6), and add new paragraph (e)(4) to read as follows:

§ 558.665 Zilpaterol.

(e) * * *

Zilpaterol grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
(4) 6.8 to provide 60 to 90 mg/head/day	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(1) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat).	As in paragraph (e)(1) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 000986; melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	057926
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Dated: March 12, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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