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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Salinomycin**

**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 abbreviated new animal drug application (ANADA) filed by Intervet, Inc. The supplemental ANADA provides for use of a salinomycin Type A medicated article to make Type C medicated feeds used for the prevention of coccidiosis in roaster and replacement (breeder and layer) chickens and for the prevention of coccidiosis in quail.

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

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to ANADA 200-075 that provides for use of SACOX (salinomycin) Type A medicated article to make Type C medicated feeds used for the prevention of coccidiosis in roaster and replacement (breeder and layer) chickens and for the prevention of coccidiosis in quail. The supplemental ANADA is approved as of November 8, 2002, and

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**ANADA 200-075**

**NFR**

the regulations are amended in 21 CFR 558.550 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 Dockets Management Branch (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.

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.

§ 558.550 [Amended]

2. Section 558.550 *Salinomycin* is amended in paragraph (a)(2) by adding “(d)(2)(i),” numerically.

Dated: January 21, 2003  
January 21, 2003.

Steven D. Vaughn DVM  
Steven D. Vaughn,  
Director,  
Office of New Animal Drug Evaluation,  
Center of Veterinary Medicine.  
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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