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Issued in Burlington, Massachusetts, on April 14, 2006.

**Robert G. Mann,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

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**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

#### New Animal Drugs for Use in Animal Feeds; Melengestrol and Monensin

**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 an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing melengestrol and monensin to make two-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter.

**DATES:** This rule is effective April 21, 2006.

**FOR FURTHER INFORMATION CONTACT:** Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: [daniel.benz@fda.hhs.gov](mailto:daniel.benz@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200-422 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix and RUMENSIN (monensin sodium) single-ingredient Type A medicated articles to make, two-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter. Ivy Laboratories' ANADA 200-422 is approved as a generic copy of Pharmacia and Upjohn's NADA 125-

476 for combination use of MGA 500 (melengestrol acetate) Liquid Premix and RUMENSIN in cattle feed. The application is approved as of March 22, 2006, and the regulations are amended in 21 CFR 558.342 to reflect the approval. The basis of approval is discussed in 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 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 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.

#### § 558.342 [Amended]

■ 2. In § 558.342, amend the table in paragraphs (e)(1)(v) and (e)(1)(vi) in the "Sponsor" column by adding in numerical sequence "021641".

Dated: April 7, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 06-3820 Filed 4-20-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 610

[Docket No. 2005N-0355]

**RIN 0910-AF20**

#### Revocation of Status of Specific Products; Group A Streptococcus; Confirmation of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of June 2, 2006, for the direct final rule that appeared in the **Federal Register** of December 2, 2005 (70 FR 72197). The direct final rule removes the regulation applicable to the status of specific products; Group A streptococcus. FDA is removing the regulation because the existing requirement for Group A streptococcus organisms and derivatives is both obsolete and a perceived impediment to the development of Group A streptococcus vaccines. This document confirms the effective date of the direct final rule.

**DATES:** Effective date confirmed: June 2, 2006.

#### FOR FURTHER INFORMATION CONTACT:

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 2, 2005 (70 FR 72197), FDA solicited comments concerning the direct final rule for a 75-day period ending February 15, 2006. FDA stated that the effective date of the direct final rule would be on June 2, 2006, 6 months after the date of publication in the **Federal Register**, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments. Therefore, FDA is removing from the regulation 21 CFR 610.19 because this provision is obsolete and a perceived impediment to the development of Group A streptococcus vaccines.

**Authority:** Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, the amendment issued thereby becomes effective on June 2, 2006.