DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol, Ractopamine, Monensin, and Tylosin

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, ractopamine, monensin, and tylosin to make four-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter.

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

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.*

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–424 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, OPTAFLEXX (ractopamine hydrochloride), RUMENSIN (monensin sodium), and TYLAN (tylosin phosphate) single-ingredient Type A medicated article to make dry and liquid, four-way combination drug Type C medicated feeds for heifers fed in

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confinement for slaughter. Ivy Laboratories' ANADA 200–424 is approved as a generic copy of Elanco Animal Health's NADA 141–233 for combination feed use of MGA (melengestrol acetate), OPTAFLEXX, RUMENSIN, and TYLAN. The application is approved as of April 27, 2006, and the regulations are amended in 21 CFR 558.500 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 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.

§ 558.500 [Amended]

■ 2. In the table in paragraph (e)(2)(x) of § 558.500, in the "Limitations" column remove "No. 000009" and add in its place "Nos. 000009 and 021641", and in the "Sponsor" column add in numerical sequence "021641".

Dated: 5/23/06
May 23, 2006.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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