

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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11/1/05
11/2/05
J. Coyle

New Animal Drugs for Use in Animal Feeds; Melengestrol

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 a melengestrol acetate Type A medicated article with monensin and tylosin Type A medicated articles to make three-way combination 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: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9808, e-mail: *john.harshman@fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200-375 that provides for use of HEIFERMAX 500 Liquid Premix (melengestrol acetate), RUMENSIN (monensin sodium), and TYLAN (tylosin tartrate) Type A medicated articles to make dry and liquid three-way combination Type C medicated feeds used for increased rate of weight gain and improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E.*

zuernii, for suppression of estrus (heat), and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in heifers fed in confinement for slaughter. Ivy Laboratories' ANADA 200-375 is approved as a generic copy of Pharmacia & Upjohn's NADA 138-870. The ANADA is approved as of September 19, 2005, and the regulation in 21 CFR 558.342 is amended 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.

FDA 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

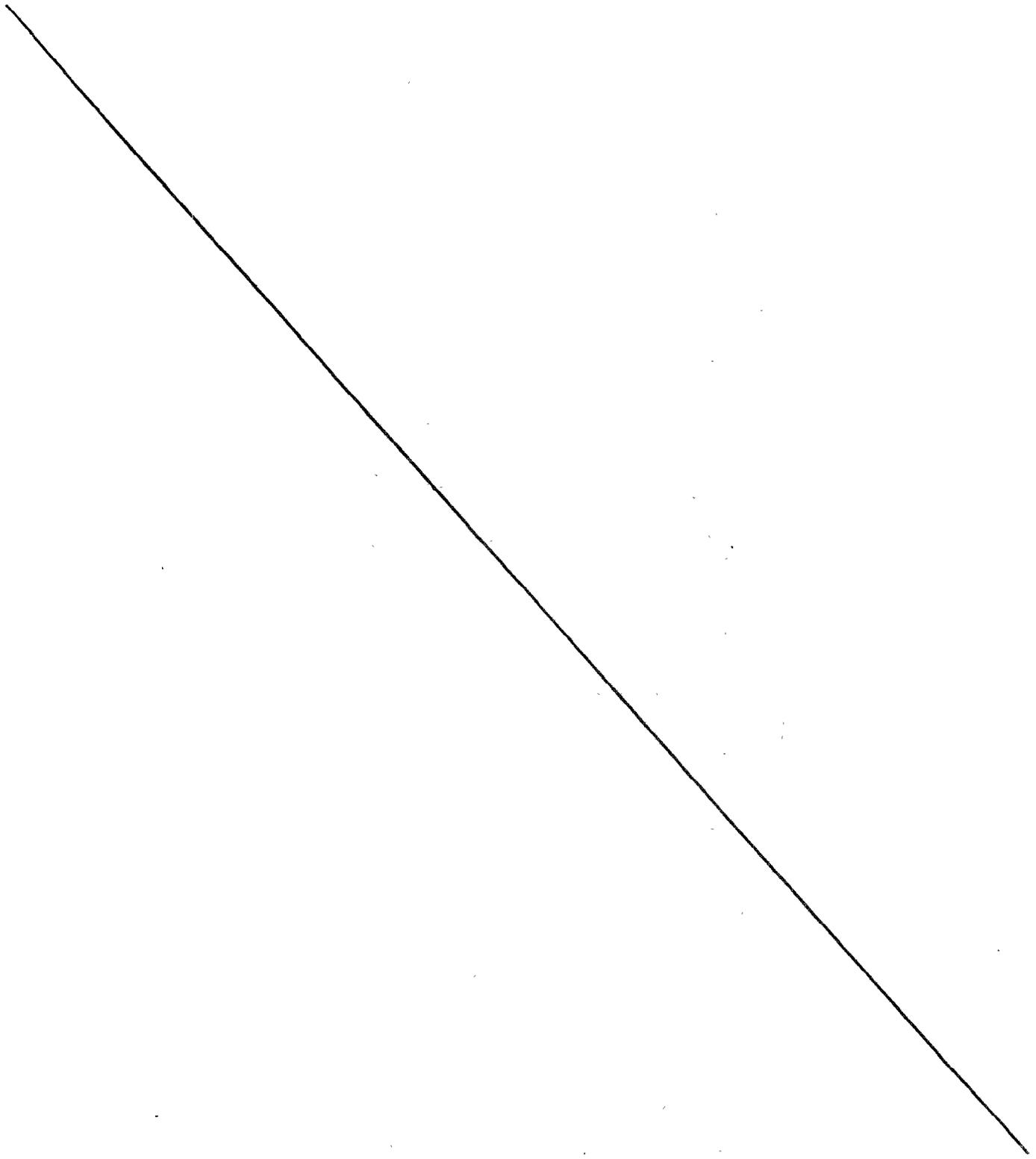
Animal drugs, Animal feeds.

■ 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. Section 558.342 is amended in paragraph (e)(1)(vii) in the table in the "Sponsor" column by adding in numerical sequence "021641".

Dated: SFS 10/13/05
October 13, 2005.

SR 10-07-05

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

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[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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