Securities Exchange Act of 1934 [15 U.S.C. 78p] and the rules and regulations thereunder.

* * * * *

(13)(i) Notwithstanding the provisions of paragraph (a)(12) of this section, an investment adviser that is primarily engaged in a business or businesses other than advising registered investment companies or other advisory clients, must maintain a record of every transaction in a security in which the investment adviser or any advisory representative (as defined in paragraph (a)(13)(iii)(A) of this section) of the investment adviser has, or by reason of the transaction acquires, any direct or indirect beneficial ownership, except:

(A) Transactions effected in any account over which neither the investment adviser nor any advisory representative of the investment adviser has any direct or indirect influence or control; and

(B) Transactions in securities that are: direct obligations of the Government of the United States; bankers' acceptances, bank certificates of deposit, commercial paper, and high quality short-term debt instruments, including repurchase agreements; or shares issued by registered open-end investment companies.

(ii) The record required by paragraph (a)(13)(i) of this section must state the title and amount of the security involved; the date and nature of the transaction (*i.e.*, purchase, sale or other acquisition or disposition); the price at which it was effected; and the name of the broker, dealer or bank with or through whom the transaction was effected. Any record required by paragraph (a)(13)(i) of this section also may contain a statement declaring that the record of the transaction will not be construed as an admission that the investment adviser or advisory representative has any direct or indirect beneficial ownership in the security. A transaction must be recorded no later than 10 days after the end of the calendar quarter in which the transaction was effected. An investment adviser will be considered to have made a record required by paragraph (a)(13)(i) of this section if:

(A) The investment adviser receives a broker trade confirmation or account statement in the time period required by this paragraph (a)(13)(ii);

(B) The broker trade confirmation, account statement or other records of the investment adviser contains all the information required by this paragraph (a)(13)(ii);

(C) The investment adviser keeps the broker trade confirmation, account statement, and other records containing the information required by this paragraph (a)(13)(ii); and

(D) All broker trade confirmations and account statements that are printed on paper and kept under paragraph (a)(13)(ii)(C) of this section are organized in a manner that allows easy access to and retrieval of any particular confirmation or statement.

(iii) * * *

(B) *Beneficial ownership* will be interpreted in the same manner as it would be under § 240.16a–1(a)(2) of this chapter in determining whether a person has beneficial ownership of a security for purposes of section 16 of the Securities Exchange Act of 1934 [15 U.S.C. 78p] and the rules and regulations thereunder.

* * * * *

By the Commission.

Dated: August 20, 1999.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–22310 Filed 8–26–99; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Zeranol

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 supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for use of a zeranol implant in steers fed in confinement for slaughter for improved feed efficiency.

EFFECTIVE DATE: August 27, 1999.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083–1982, filed supplemental NADA 38–233 that provides for use of Ralgro® Magnum (zeranol) implant in steers being fed in confinement for slaughter at a dose of 72 milligrams per steer for improved feed efficiency. The supplemental NADA is approved as of June 25, 1999, and the regulations are amended in 21 CFR 522.2680(d)(3)(ii) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning June 25, 1999, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to use of the drug for improved feed efficiency in steers fed in confinement for slaughter.

FDA has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 21 CFR Part 522

Animal drugs.

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.2680 [Amended]

2. Section 522.2680 *Zeranol* is amended in paragraph (d)(3)(ii) by removing ''For increased rate of weight gain'' and adding in its place ''For increased rate of weight gain and improved feed efficiency''.

Dated: August 2, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaulation, Center for Veterinary Medicine.

[FR Doc. 99–22312 Filed 8–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 98F–0195]

Food Additives Permitted in the Feed and Drinking Water of Animals; Menadione Nicotinamide Bisulfite

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of menadione nicotinamide bisulfite (MNB) in diets of growing and finishing swine as a nutritional supplement for the prevention of vitamin K deficiency and as a source of supplemental niacin. This action is in response to a food additive petition (animal use) filed by Vanetta S.p.A.

DATES: The regulation is effective August 27, 1999; submit written objections and requests for a hearing by September 27, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michaela G. Alewynse, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6657.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 12, 1998 (63 FR 26194), FDA announced that a food additive petition (animal use) (FAP 2239) had been filed by Vanetta S.p.A., Via Alzia Trento 10, Milano, Corsico, Italy. The petition proposed to amend the food additives regulations in part 573 (21 CFR part 573) to provide for use of menadione nicotinamide bisulfite in swine diets as a source of vitamin K activity and niacin. The notice of filing provided that written comments be sent to the Dockets Management Branch. No comments were received.

The agency has evaluated the information submitted by the sponsor in support of the petition and other relevant material and concluded that it establishes the safety and utility of up to 10 grams MNB per ton of complete feed in the diets of growing and finishing swine as a nutritional supplement for the prevention of vitamin K deficiency and as a source of supplemental niacin. Therefore, § 573.625 is amended to provide for this use. Furthermore, the section is revised to conform to current format.

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in § 571.1(h), FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has determined under 21 CFR 25.32(r) 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.

Any person who will be adversely affected by this regulation may at any time on or before September 27, 1999, file with the Dockets Management Branch (see above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 573.625 is revised to read as follows:

§ 573.625 Menadione nicotinamide bisulfite.

The food additive may be safely used as follows:

(a) The additive is 1,2,3,4-tetrahydro-2-methyl-1,4-dioxo-2-naphthalene sulfonic acid with 3-pyridine carboxylic acid amine (CAS No. 73581–79–0).

(b) The additive is used or intended for use as a nutritional supplement for both the prevention of vitamin K deficiency and as a source of supplemental niacin as follows:

(1) In chicken and turkey feeds at a level not to exceed 2 grams per ton of complete feed.

(2) In growing and finishing swine feeds at a level not to exceed 10 grams per ton of complete feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

Dated: August 2, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–22313 Filed 8–26–99; 8:45 am]

BILLING CODE 4160–01–F