

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; 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 the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being removed from the animal drug regulations.

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

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 38-233 for RALGRO (zeranol), a subcutaneous implant used in cattle and in sheep for improved feed efficiency and/or increased rate of weight gain. The supplemental NADA provides for the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being

removed from part 556 (21 CFR part 556). The supplemental application is approved as of March 4, 2005, and the regulations are amended in § 556.760 to reflect the approval.

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)(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 556

Animal drugs, Foods.

■ 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 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. Section 556.760 is amended by revising paragraph (b) and by adding paragraph (c) to read as follows:

§ 556.760 Zeranol.

* * * * *

(b) *Tolerances.* The tolerances for residues of zeranol in edible tissues are:

(1) *Cattle.* A tolerance is not needed.

(2) *Sheep.* 20 parts per billion.

(c) *Related conditions of use.* See § 522.2680 of this chapter.

Dated: _____

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

BILLING CODE 4160-01-S