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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Narasin

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 Elanco Animal Health which provides for establishing a tolerance for residues of narasin in edible tissues of chickens.

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

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 118-980 that provides for the use of Monteban® (36, 45, 54, 72, or 90 grams per pound narasin activity), a Type A medicated article. The supplement provides for establishing a tolerance for residues of narasin in the abdominal fat of chickens. The supplement is approved as of April 11, 2001, and 21 CFR 556.428 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA is taking the opportunity to codify the acceptable daily intake for total residues of narasin which was previously established.

NADA-118-980

NFR-1

In accordance with the freedom of information provisions of 21 CFR part 20 and 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.

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 556.428 is revised to read as follows:

§ 556.428 Narasin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of narasin is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Chickens (abdominal fat)*. The tolerance for parent narasin (the marker residue) is 480 parts per billion.

(2) [Reserved]

Dated: 5/1/01

May 1, 2001.

Claire M. Lathers

Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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