

paragraph (c) and by removing paragraph (d)(2)(iv).

#### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

9. The authority citation for 21 CFR part 558 continues to read as follows:

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

##### **§ 558.274 [Amended]**

10. Section 558.274 *Hygromycin B* is amended as follows:

- a. In paragraph (a)(2) by removing "016968 and";
- b. By removing and reserving paragraph (a)(3);
- c. In paragraph (a)(4) by removing "016968,";
- d. In the table in paragraph (c)(1) in the fifth column of the first entry in items (i) and (ii) by removing "016968,".

##### **§ 558.625 [Amended]**

11. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(17).

##### **§ 558.630 [Amended]**

12. Section 558.630 *Tylosin and sulfamethazine* is amended by removing and reserving paragraph (b)(4), and in paragraph (b)(10) by removing "021780,".

Dated: May 2, 2001.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 01-11621 Filed 5-8-01; 8:45 am]

**BILLING CODE 4160-01-S**

## **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 May 9, 2001.

**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.

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: May 1, 2001.

**Claire M. Lathers,**

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

[FR Doc. 01-11584 Filed 5-8-01; 8:45 am]

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## **DEPARTMENT OF THE TREASURY**

### **Bureau of Alcohol, Tobacco and Firearms**

#### **27 CFR Part 9**

[T.D. ATF 452]

RIN 1512-AA07

#### **River Junction Viticultural Area (98R-192P)**

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

**ACTION:** Final rule, Treasury Decision.

**SUMMARY:** The Bureau of Alcohol, Tobacco and Firearms (ATF) is establishing a viticultural area located in southern San Joaquin County, California, to be known as "River Junction." This viticultural area is the result of a petition filed by Mr. Ronald W. McManis. ATF believes that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising allow wineries to designate the specific areas where the grapes used to make the wine were grown and enable consumers to better identify the wines they purchase.

**EFFECTIVE DATE:** July 9, 2001.

**FOR FURTHER INFORMATION CONTACT:** Tim DeVanney, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226; Telephone (202) 927-8196.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR part 4. These regulations allow the establishment of definite American viticultural areas (AVAs). The regulations also allow the name of an