

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]

**BILLING CODE 4160-01-S**

## **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

approved viticultural area to be used as an appellation of origin in the labeling and advertising of wine.

On October 2, 1979, ATF published Treasury Decision ATF-60 (44 FR 56692), which added a new part 9 to 27 CFR, providing for the listing of approved American viticultural areas. Section 4.25a(e)(1), Title 27, Code of Federal Regulations, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been delineated in subpart C of part 9. Section 4.25a(e)(2) outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area. The petition should include:

(a) Evidence that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical features (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and

(e) A copy of the appropriate U.S.G.S. map(s) with the boundaries prominently marked.

#### Petition

ATF has received a petition from Mr. Ronald W. McManis, proposing to establish a new viticultural area in southern San Joaquin County, California, to be known as "River Junction." The viticultural area is located at the western edge of San Joaquin Valley (also known as the Central Valley) and the southernmost edge of the Sacramento-San Joaquin River Delta. It contains approximately 1,300 contiguous acres, of which 740 are currently planted to vineyards. Present agricultural use of the area is primarily 700 acres of Chardonnay grapes. An additional 40 acres are planted to Cabernet Sauvignon grapes.

#### Notice of Proposed Rulemaking

In response to this petition, ATF published a notice of proposed rulemaking, Notice No. 901, in the **Federal Register** on August 10, 2000 [65 FR 48653], proposing the establishment

of the River Junction viticultural area. The notice requested comments from interested persons by October 10, 2000.

#### Evidence That the Name River Junction Is Locally or Nationally Known

The origin of the name, "River Junction," refers to the junction of the Stanislaus River with the San Joaquin River. Mr. McManis states, "The name is in prominent use within the AVA, undoubtedly because of the significant prehistoric, historic, and ongoing influence of the rivers' confluence on the immediate area." The petitioner owns a vineyard in the AVA. The property, purchased in the early 1990's, was previously known as "River Junction Vineyards." A vineyard block map of his ranch shows the historical ownership of the vineyards by the designation "R" for "River Junction Vineyards." These vineyards are located within the AVA.

The name "River Junction" is also used for River Junction Reclamation District No. 2064, a State of California Special District dating from at least 1925. River Junction Reclamation District includes Bret Harte Gardens subdivision, filed October 11, 1922. Since this subdivision assumes reclamation within the District, it seems likely that "River Junction," as a District name, dates at least to 1922. The name is also used for River Junction Farms subdivision no. 2 within the River Junction Reclamation District.

#### Evidence of Boundaries

The viticultural area is bounded on the north by an old river terrace shelf delineated by Division Road; on the northwest by a drainage boundary enhanced and delineated by Airport Way; on the west and south by the San Joaquin River; and on the south and east by the Stanislaus River.

Following the Federal Swamp Land Act of 1850, reclamation of wetlands was begun. A portion of the River Junction AVA was designated as a State Reclamation District, River Junction Reclamation District No. 2064. Ronald McManis indicated that this portion of the AVA ". . . occupies the southern one-third of the California State Reclamation District No. 2064 and is the same as River Junction Farms Subdivision No. 2, except that it does not include 195 acres at the northeast corner of that subdivision."

As indicated, the petitioner owns a vineyard in the viticultural area. Most of the property, purchased in the early 1990's, was previously known as River Junction Vineyards and is located within the northwest and southwest

boundaries of the AVA, west of Two Rivers Road.

#### Geographical Features

##### Topography

The following topographical evidence shows that the area is distinct from surrounding areas:

(a) *South, east and west boundaries.* The River Junction viticultural area is bounded on the west by relatively steep slopes and the San Joaquin River, and is bounded on the south and east by gentle, nearly flat topography and the Stanislaus River. The area is locally unique in terms of topography: its gentle, persistent southwest slope and higher boundaries form a shallow, slightly tilted bowl about 18 to 25 feet in elevation at the center. Original natural boundaries to the west, south and east have been exaggerated by engineered, permanent levees that range from about 35 to 42 feet in elevation. Geographical analyses, provided by the petitioner, show a transect through the River Junction AVA and illustrate the elevation differences that distinguish it.

(b) *Northern boundary.* The northern boundary of the area is an abrupt, natural elevation change at about the 29 foot contour, delineated by Division Road. Physical evidence indicates that Division Road was placed on the upper side of a pre-existing natural river terrace boundary. The topographic change marked by the road exactly follows geologic and soil type boundaries extending from the east to the center of section 7 on the Ripon, CA quadrangle map T3S/R7E and westward to Airport Way. The natural extension of "Red Bridge Slough" to the northwest is further evidence that this boundary is a natural river terrace.

(c) *Northwest boundary.* The northwest boundary of the River Junction AVA is delineated by Airport Way, a subtle natural high that is exaggerated by the raised roadbed. Elevation ranges from about 29 to 35 feet. Available geologic and historic evidence strongly supports the conclusion that, like Division Road, Airport Way follows a natural topographic high. The U.S.G.S. maps submitted by the petitioner show two separate sloughs draining from the Airport Way/Division Road intersection. An unnamed slough on the U.S.G.S. Ripon, CA quadrangle map drains southeast through the River Junction AVA, while the other slough, called "Red Bridge Slough" on the U.S.G.S. Vernalis, CA quadrangle map, flows in the opposite direction. A 1925 Reclamation District Map ("southern part") provided by the petitioner also

shows the two sloughs. These two sloughs coincide with occurrences of Merritt soils, which fan out to the northwest and southeast of the Airport Way/Division Road intersection. This provides further evidence that the intersection of Airport Way and Division Road has historically sat on naturally higher topography from which the soils accumulated downhill in two directions.

#### Soil

The following is evidence regarding the soil composition of the River Junction AVA:

(a) *Formation and distribution of local soils.* The River Junction AVA contains soils that are generally grouped as alluvial, and which formed on the geologic parent material of recent river channel deposits that are exposed in, and partly define, the area. Soils that formed on the stream channel deposits and derived from these deposits, are similar to one another in nature, and are characteristic of the parent sedimentary deposits. These soils are identified as "recent alluvial floodplains soils" and "delta and floodplains soils" in the U.S. Department of Agriculture soils reports for San Joaquin and Stanislaus counties.

Where the Stanislaus River joins the San Joaquin River, bounding topography is steeper to the west and flatter to the east, thus restricting the westward limits of soils. West of the San Joaquin River, northeast facing slopes limit alluvial soils to an area only about 1/2 mile or less in width. These soils, primarily Merritt—Columbia—Dello series and Dospalos—Bolfar complex, are bounded on the west by basin soils of the Willows—Pescadero series and terrace soils of the Capay series. Conversely, east of the San Joaquin River, flatter topography has allowed alluvial soils to accumulate to a width of 1 to 1 1/2 miles.

South of the Stanislaus River there are mostly Columbia—Temple series soils, bounded by basin soils of the Waukena—Fresno association, and alluvial fan soils of the Modesto—Chualar group that extend eastward.

North of the Stanislaus River, elevation is slightly higher than to the south, and topography is nearly flat but includes subtle northwest-facing and more strongly expressed southwest-facing slopes. Here the alluvial soils reach 1 1/2 miles in width and are composed of Merritt—Grangeville—Columbia series with lesser amounts of Dello and Egbert soils. They are bounded to the east by terrace soil groups, primarily of the Delhi—Veritas—Tinnin series.

(b) *Unique soil composition of area.* The River Junction viticultural area is a

mix of soils that differs from the surrounding areas. Among the total soils, nearly one-half are sandy types, and about one-fourth of the total is fine sandy loam of the Grangeville series. Soil types include about 25 percent Grangeville fine sandy loam; about 50 percent Merritt silty clay loam; nearly 25 percent Columbia fine sandy loams; and less than 1 percent Veritas silty clay loam. None of the surrounding areas has nearly as high a ratio between sandy loam to clay loam soils. Grangeville sandy loam is unusual in this part of the southern delta. The single other local occurrence of Grangeville sandy loam soil is west of the San Joaquin River, 1 1/2 miles northwest, and is less than 11 acres in area.

Grangeville and Columbia series are formed in alluviums derived from granitic rock sources and the Merritt series is formed in alluviums from mixed rock sources. The Grangeville, Merritt, and Columbia series of soils are characterized as "prime farmland." These soils are all very deep, less well drained, and have moderate to high water capacity. Permeability ranges from moderately slow in the Merritt series to rapid in the Columbia and Grangeville series. They occupy nearly flat areas at low elevation and are occasionally flooded. They are exceedingly fertile soils that are capable of supporting wine grapes, almonds, tomatoes, sugar beets, wheat and other crops. Grapes have been grown on Columbia soils, but apparently, in San Joaquin County at least, have not been previously grown on bottomlands with Grangeville and Merritt.

Soil samples collected on-site at the viticultural area during October 1997 include one sample from each of the dominant units. Brief low-power microscopic analysis from each of these samples indicated similar texture and composition. All samples contained abundant angular quartz grains and mica flakes, indicating granitic origin. These soils are mineralogically young and should be expected to be very high in available minerals.

(c) *Comparisons with surrounding areas.* The River Junction viticultural area is clearly distinct from all potentially comparable adjacent local tracts, including the Red Bridge Slough, Walthall Slough, and Northeast areas.

As would be expected of deposits formed along rivers, downstream alluvial soils have a wider distribution than does their parent alluvial substrate, due to stream transport, while upstream the derived soils are less widely distributed than the underlying stream channel deposits.

In the River Junction viticultural area, derived alluvial soils strictly overlap but do not extend beyond their parent recent river deposits. The strict relationship between the channel deposits and their derived soils in the area results in a strikingly distinct northern boundary.

The location of these soil changes corresponds to the location of a strongly expressed terrace (distinct change in elevation) which angles northwest from the Stanislaus River near its mouth. Its upper side is nearly exactly followed by Division Road. This terrace probably marks the highest flood stage in historically recent times and suggests that soils in the area are probably derived from Stanislaus River alluvium. This would explain the distinctively high granitic content of these soils as compared with the surrounding area.

In the Red Bridge Slough area (north of the AVA's boundary following Airport Way) overlap of alluvial soils with parent channel deposits is less exact and the soils are restricted to the west of the Slough. This tract has a slight northwest slope and, based on field observation, is wetter than the River Junction viticultural area. It has no strongly expressed northern or eastern boundaries, and thus would have less temperature extremes than the AVA due to the absence of topographic enclosure.

The Red Bridge Slough area also has soils that are different from the proposed River Junction AVA. It contains about 35 percent Columbia loam. At its center it includes 10 percent Egbert silty clay loam. No Grangeville sands are present. As indicated above, the tract is part of River Junction Reclamation District No. 2064, which was recorded as River Junction Farms subdivision no. 3 in 1925. Durham Ferry State Recreation Area occupies about 20 percent of the tract, and the remaining part is essentially flat at 20–25 feet elevation.

Southeast of Walthall Slough, located north of the Red Bridge Slough area, the relationship between channel deposits and derived soils is obscure. Here the soils occupy a larger expanse than do the underlying stream deposits. They include nearly 40 percent Columbia soils and about 20 percent Dello clay loam. No Grangeville sands are present. Topographically, this area is essentially flat to slightly northwest sloping. In terms of soils, and the microclimate that would be inferred from the flat and open topography, it is completely different from the AVA.

To the northeast, recent river alluvium still underlies the soils but soils in this area include about 20

percent Veritas and Manteca series. No Grangeville sands are present. Otherwise, the Merritt and Columbia soils percentages are comparable to the River Junction AVA. However, this area is higher and flatter, averaging about 30–35 feet elevation, and has no distinct topographic boundaries. Therefore, it undoubtedly has less temperature extremes than the AVA. This area comprises about 195 acres of the original River Junction Farms subdivision no. 2.

### Climate

The River Junction AVA is shown on a Sacramento-San Joaquin Delta map (“Base Map Source—Department Of Water Resources”). The AVA appears within the boundaries of the aforementioned delta, at the southeasternmost tip. The southernmost edge of the Sacramento-San Joaquin River Delta is more modified by inland weather patterns than other parts of the Delta. This part of the Delta experiences more extreme high and low temperatures, although still receiving maritime influence. It is subject to little rainfall (10 to 11 inches per year) and, at its southernmost part, lies within the rain shadow of the maritime influenced land to the west. This is the driest part of the Delta and can be considered as arid to semiarid with maritime influence.

The viticultural area is distinctively cooler than the immediate surrounding area (Modesto, Stockton, Tracy Carbona, Tracy Pumping Plant, and Rivercrest Vineyards). Temperature data from 1995 and 1996 were recorded by a weather station located near the center of the River Junction AVA, at Rivercrest Vineyards. The monthly-averaged data show that minimum temperatures are consistently slightly cooler than elsewhere in the region, especially in summer. Average high temperatures are similar to Antioch and Lodi, which are significantly closer to the Suisun and San Francisco Bays and would be expected to experience more cooling from the maritime influence. Average low temperatures are generally the coolest among Tracy Carbona and Tracy Pumping Plant. Significantly, minimum August temperatures are 2 to 5 degrees cooler than Tracy, Stockton, and Modesto.

Grapes grown here are also subject to seasonally later frosts as pointed out by an unpublished agricultural analysis by Cook and Lider dated 1972.

### Comments on Notice of Proposed Rulemaking

ATF did not receive any comments in response to Notice No. 901. Having

analyzed and evaluated the evidence contained in the petition, ATF is adopting the River Junction viticultural area as proposed.

### Boundary

The boundaries of the River Junction viticultural area may be found on the following two 1:24,000 Scale U.S.G.S. topographical maps. They are titled: (1) Ripon, CA 1969, photorevised 1980; (2) Vernalis, CA 1969, photorevised 1980;

The boundaries are described in § 9.164.

### Executive Order 12866

It has been determined that this proposed regulation is not a significant regulatory action as defined by Executive Order 12866. Accordingly, this proposal is not subject to the analysis required by this Executive Order.

### Regulatory Flexibility Act

It is hereby certified that this proposed regulation will not have a significant economic impact on a substantial number of small entities. Any benefit derived from the use of a viticultural area name is the result of the proprietor's own efforts and consumer acceptance of wines from a particular area. No new requirements are imposed. Accordingly, a regulatory flexibility analysis is not required.

### Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j)) and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because no requirement to collect information is proposed.

### Drafting Information

The principal author of this document is Tim DeVanney, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

### List of Subjects in 27 CFR Part 9

Administrative practices and procedures, Consumer protection, Viticultural areas, and Wine.

### Authority and Issuance

Title 27, Code of Federal Regulations, part 9, American Viticultural Areas, is amended as follows:

### PART 9—AMERICAN VITICULTURAL AREAS

**Paragraph 1.** The authority citation for part 9 continues to read as follows:

**Authority:** 27 U.S.C. 205.

**Par. 2.** Subpart C is amended by adding § 9.164 as follows:

### Subpart C—Approved American Viticultural Areas

#### § 9.164 River Junction.

(a) *Name.* The name of the viticultural area described in this section is “River Junction.”

(b) *Approved maps.* The appropriate maps for determining the boundaries of the River Junction viticultural area are the following two 1:24,000 Scale U.S.G.S. topographical maps. They are titled:

- (1) Ripon, CA 1969, photorevised 1980;
- (2) Vernalis, CA 1969, photorevised 1980;

(c) *Boundaries.* The River Junction AVA is located in southern San Joaquin County, California. The boundaries are as follows:

(1) Beginning on the Vernalis, CA quadrangle map at the intersection of the secondary highway Airport Way and the San Joaquin River levee, near Benchmark 35 in T3S/R6E;

(2) Then in a southeasterly direction, follow the levee along the San Joaquin River onto the Ripon, CA quadrangle map;

(3) Then in a northerly direction around Sturgeon Bend in section 18 T3S/R7E;

(4) Then continuing in a generally southeasterly, then northeasterly direction along the levee adjoining the Stanislaus River through sections 19, 20 and 17 to the point where the levee intersects sections 17 and 8;

(5) Then continuing in a northerly direction along the levee in section 8 for approximately 1,000 feet;

(6) Then in a straight line in a northwesterly direction for approximately 100 feet to the intersection with Division Road;

(7) Then in a southwesterly, then northwesterly direction along Division Road through sections 8, 17, 18 and 7 to the intersection with the secondary highway Airport Way;

(8) Then in a southwesterly direction along Airport Way onto the Vernalis quadrangle map to the starting point at the intersection of Airport Way and the San Joaquin River levee T3S/R6E.

Dated: March 8, 2001.

**Bradley A. Buckles,**  
Director.

Approved: April 4, 2001.

**Timothy E. Skud,**  
Acting Deputy Assistant Secretary,  
(Regulatory, Tariff and Trade Enforcement).  
[FR Doc. 01–11675 Filed 5–8–01; 8:45 am]

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