

responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

## VI. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Section 866.3940 is added to subpart D to read as follows:

#### **§ 866.3940 West Nile virus serological reagents.**

(a) *Identification.* West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals who have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile virus.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance entitled "Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus." See § 866.1(e) for the availability of this guidance document.

Dated: October 8, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 03-27294 Filed 10-29-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Part 9

[T.D. TTB-6; Notice No. 963]

RIN 1513-AA36

#### Bennett Valley Viticultural Area (2002R-009T)

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

**ACTION:** Treasury decision, final rule.

**SUMMARY:** This Treasury decision establishes the Bennett Valley viticultural area in Sonoma County, California. It is entirely within the North Coast viticultural area and predominantly in the Sonoma Valley viticultural area, except for a small overlap into the Sonoma Coast viticultural area. The Alcohol and Tobacco Tax and Trade Bureau believes the use of viticultural area names as appellations of origin in wine labeling and advertising helps consumers identify the wines they may purchase. It also allows wineries to better designate the specific grape-growing area in which their wine grapes were grown.

**EFFECTIVE DATE:** December 29, 2003.

**FOR FURTHER INFORMATION CONTACT:** N. A. Sutton, Specialist, Regulations and Procedures Division (Oregon), Alcohol and Tobacco Tax and Trade Bureau, 946 Northwest Circle Blvd., #286, Corvallis, OR 97330; telephone: 415-271-1254.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background on Viticultural Areas**

##### *TTB Authority*

The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's identity, while prohibiting the use of deceptive information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out the Act's provisions. The Secretary has delegated this authority to the Alcohol and Tobacco Tax and Trade Bureau (TTB).

Regulations in 27 CFR part 4, Labeling and Advertising of Wine, allow the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Title 27 CFR part 9, American Viticultural Areas, contains the list of approved viticultural areas.

##### *Definition*

Title 27 CFR, section 4.25(e)(1), defines an American viticultural area as a delimited grape-growing region distinguishable by geographic features whose boundary has been delineated in subpart C of part 9. The establishment of viticultural areas allows the identification of regions where a given quality, reputation, or other characteristics of the wine is essentially attributable to its geographic origin. We believe that the establishment of viticultural areas allows wineries to describe more accurately the origin of their wines to consumers and helps consumers identify the wines they purchase. Establishment of a viticultural area is neither an approval nor endorsement by TTB of the wine produced there.

##### *Requirements*

Section 4.25a(e)(2) outlines the procedure for proposing an American viticultural area. Anyone interested may petition TTB to establish a grape-growing region as a viticultural area. The petition must include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that the boundaries of the proposed viticultural area are as specified in the petition;
- Evidence that the proposed area's growing conditions, such as climate, soils, elevation, physical features, etc., distinguish it from surrounding areas;
- A description of the proposed viticultural area's specific boundaries, based on features found on maps approved by the United States Geological Survey (USGS); and
- A copy of the appropriate USGS-approved map(s) with the boundaries prominently marked.

##### *Impact on Current Wine Labels*

With this viticultural area's establishment, bottlers who use brand names like Bennett Valley may be affected. If you fall in this category, you must ensure that your existing products are eligible to use the name of the viticultural area as an appellation of origin. For a wine to be eligible, at least 85 percent of the grapes in the wine must have been grown within the viticultural area.

If the wine is not eligible for the appellation, you must change the brand name and obtain approval of a new label. Different rules apply if you label a wine in this category with a brand name traceable to a label approved prior