

federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### VIII. Paperwork Reduction Act of 1995

FDA concludes that the final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, according to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

#### List of Subjects in 21 CFR Part 872

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 872 is amended as follows:

#### PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 2. Section 872.2050 is added to subpart B to read as follows:

##### § 872.2050 Dental sonography device.

(a) *Dental sonography device for monitoring*—(1) *Identification.* A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) *Classification.* Class I. The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to § 872.9.

(b) *Dental sonography device for interpretation and diagnosis*—(1) *Identification.* A dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls

Guidance Document: Dental Sonography and Jaw Tracking Devices."

■ 3. Section 872.2060 is added to subpart B to read as follows:

##### § 872.2060 Jaw tracking device.

(a) *Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla*—(1) *Identification.* A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to § 872.9.

(b) *Jaw tracking device for interpretation of mandibular jaw positions for the diagnosis*—(1) *Identification.* A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices."

Dated: October 23, 2003.

**Linda S. Kahan,**

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

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#### DEPARTMENT OF THE TREASURY

#### Alcohol and Tobacco Tax and Trade Bureau

##### 27 CFR Part 9

[T.D. TTB–7; Re Notice No. 965]

RIN: 1513–AA68

#### Expansion of the Russian River Valley Viticultural Area (2002R–421P)

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

**ACTION:** Final rule (Treasury decision).

**SUMMARY:** This final rule expands by 767 acres the eastern boundary of the Russian River Valley viticultural area in Sonoma County, California. 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:** This final rule is effective on February 2, 2004.

#### FOR FURTHER INFORMATION CONTACT:

N.A. Sutton, Specialist, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau (TTB), 6660 Delmonico Drive, #D422, Colorado Springs, CO 80919; telephone 415–271–1254.

#### SUPPLEMENTARY INFORMATION:

#### Homeland Security Act Impact on Rule Making

Effective January 24, 2003, the Homeland Security Act of 2002 divided the Bureau of Alcohol, Tobacco and Firearms (ATF) into two agencies, the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury and the Bureau of Alcohol, Tobacco, Firearms and Explosives in the Department of Justice. Regulation of wine labeling, including viticultural area designations, is the responsibility of the new TTB. References to ATF in this document relate to events that occurred prior to January 24, 2003, or to functions that the Bureau of Alcohol, Tobacco, Firearms and Explosives continues to perform.

#### 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