

an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers.

(B) “Ask a doctor before use if [bullet] stomach bleeding warning applies to you [bullet] you have a history of stomach problems, such as heartburn [bullet] you have high blood pressure, heart disease, liver cirrhosis, or kidney disease [bullet] you are taking a diuretic”.

(C) “Stop use and ask a doctor if [bullet] you experience any of the following signs of stomach bleeding:” [add the following as second level of statements: “[bullet] feel faint [bullet] vomit blood [bullet] have bloody or black stools [bullet] have stomach pain that does not get better”].

(iv) *For products labeled only for children under 12 years of age.*

(A) *Warnings.* The labeling of the product states the following warnings under the heading “Warnings”:

(1) “Stomach bleeding warning [heading in bold type]: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if your child [bullet] has had stomach ulcers or bleeding problems [bullet] takes a blood thinning (anticoagulant) or steroid drug [bullet] takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) [bullet] takes more or for a longer time than directed”. The “Stomach bleeding warning” must appear after the “Reye’s syndrome” and “Allergy alert” warnings in § 201.66(c)(5)(ii)(A) and (c)(5)(ii)(B). If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers.

(2) “Ask a doctor before use if [bullet] stomach bleeding warning applies to your child [bullet] child has a history of stomach problems, such as heartburn [bullet] child has not been drinking fluids [bullet] child has lost a lot of fluid due to vomiting or diarrhea [bullet] child has high blood pressure, heart disease, liver cirrhosis, or kidney disease [bullet] child is taking a diuretic”.

(3) “Stop use and ask a doctor if [bullet] child experiences any of the following signs of stomach bleeding:” [add the following as second level of statements: [bullet] feels faint [bullet] vomits blood [bullet] has bloody or black stools [bullet] has stomach pain that does not get better”].

(B) *Directions.* The labeling of the product contains the following information under the heading “Directions”: “this product does not

contain directions or complete warnings for adult use” [in bold type].

(v) *For products labeled for adults and children under 12 years of age.* The labeling of the product states all of the warnings in paragraphs (a)(2)(iii)(A) through (a)(2)(iii)(C) of this section with the following modifications:

(A) The Stomach bleeding warning states “Stomach bleeding warning [heading in bold type]: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if the user [bullet] has had stomach ulcers or bleeding problems [bullet] takes a blood thinning (anticoagulant) or steroid drug [bullet] takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) [bullet] takes more or for a longer time than directed [bullet] is age 60 or older [bullet] has 3 or more alcoholic drinks everyday while using this product”. The “Stomach bleeding warning” must appear after the “Reye’s syndrome” and “Allergy alert” warnings in § 201.66(c)(5)(ii)(A) and (c)(5)(ii)(B). If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers.

(B) The labeling states “Ask a doctor before use if [bullet] stomach bleeding warning applies to user [bullet] user has history of stomach problems, such as heartburn [bullet] user has high blood pressure, heart disease, liver cirrhosis, or kidney disease [bullet] user takes a diuretic [bullet] user has not been drinking fluids [bullet] user has lost a lot of fluid due to vomiting or diarrhea”.

(C) The labeling states “Stop use and ask a doctor if [bullet] user experiences any of the following signs of stomach bleeding:” [add the following as second level of statements: [bullet] feels faint [bullet] vomits blood [bullet] has bloody or black stools [bullet] has stomach pain that does not get better”].

(b) *New warnings information statement.* The labeling of any drug product subject to this section that is initially introduced or initially delivered for introduction into interstate commerce before the effective date and within 12 months after the effective date of the final rule must bear on its PDP, as defined in § 201.60, the statement “See new warnings information.” This statement must appear highlighted (e.g., fluorescent or color contrast) or in bold type, be in lines generally parallel to the base on which the package rests as it is designed to be displayed, and be in one of the following sizes, whichever is greater: (1) At least one-quarter as large as the size of the most prominent

printed matter on the PDP, or (2) At least as large as the size of the “Drug Facts” title, as required in § 201.66(d)(2).

(c) *Requirements to supplement approved application.* Holders of approved applications for OTC drug products that contain internal analgesic/antipyretic active ingredients that are subject to the requirements of paragraph (a) of this section must submit supplements under § 314.70(c) of this chapter to include the required information in the product’s labeling. Such labeling may be put into use without advance approval of FDA provided it includes at least the exact information included in paragraph (a) of this section.

Dated: April 8, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Part 9

[TTB Docket No. 2008-0006; T.D. TTB-76; Re: Notice No. 87]

RIN 1513-AB42

### Establishment of the Lake Chelan Viticultural Area (2007R-103P)

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

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** This Treasury decision establishes the 24,040-acre “Lake Chelan” American viticultural area in Chelan County, Washington. It lies within the larger Columbia Valley viticultural area in north-central Washington. We designate viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

**DATES:** *Effective Date:* May 29, 2009.

**FOR FURTHER INFORMATION CONTACT:** Christopher Thiemann, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Room 200E, Washington, DC 20220; phone 202-927-8210.

**SUPPLEMENTARY INFORMATION:**

## Background on Viticultural Areas

### TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act requires that these regulations, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) contains the list of approved viticultural areas.

### Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been recognized and defined in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographical origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

### Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to 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 supports setting the boundary of the proposed viticultural area as the petition specifies;

- Evidence relating to the geographical features, such as climate, soils, elevation, and physical features, that distinguish the proposed viticultural area from surrounding areas;

- A description of the specific boundary of the proposed viticultural area, based on features found on United States Geological Survey (USGS) maps; and
- A copy of the appropriate USGS map(s) with the proposed viticultural area's boundary prominently marked.

### Lake Chelan Petition

Alan J. Busacca, PhD, a geologist licensed in Washington State and a nationally certified professional soil scientist with Vinitas Vineyard Consultants, submitted a petition on behalf of the Lake Chelan Wine Growers Association to establish the 24,040-acre Lake Chelan American viticultural area in north-central Washington. Some of the petition evidence and documentation provided relies on the previous research and writings of Dr. Busacca. Additional petition resources include Government-published climatic, topographic, and soils data, as well as maps, municipal resources, commercial publications, personal correspondence, and anecdotal information.

The Lake Chelan Valley lies about 112 miles east-northeast of Seattle, according to USGS and commercial maps. The petitioner explained that the proposed Lake Chelan viticultural area lies entirely within the large, established Columbia Valley viticultural area (27 CFR 9.74). TTB notes that the Lake Chelan region lies to the east of the Puget Sound viticultural area (27 CFR 9.151) and to the north of other Washington State viticultural areas. The proposed Lake Chelan viticultural area neither borders nor includes any portion of any other Washington State viticultural area except the Columbia Valley viticultural area.

The petitioner explained that the proposed Lake Chelan viticultural area includes the southern and eastern portions of the large body of water known as Lake Chelan and its surrounding lands suitable for viticulture. According to the petitioner, at the time of the 2006 petition filing with TTB, the proposed viticultural area included 13 bonded wineries, 140 acres of vineyards, and another 50 acres to be planted to grape vines.

According to the petitioner, distinguishing features of the proposed Lake Chelan viticultural area include its geology, geography, soils, and climate as directly influenced by past alpine glacial activity of the Cascade region. Lake Chelan Valley is the only valley in

the Cascade Range in Oregon or Washington that holds a natural lake of its size. The climate of the agricultural and viticultural lands surrounding the lower (eastern) end of the lake is strongly moderated by the thermal effect of the lake on the air temperatures. The glacier that formed during the last ice age and traveled from the Cascade crest to the eastern end of the modern lake left a defining imprint on the landforms of the Lake Chelan Valley. In addition, the petitioner claimed that pumice and ash from eruptions of volcanoes in the Cascade Range, principally Glacier Peak to the west of the proposed viticultural area, formed soils that are ashier and more pumiceous than those in any other established viticultural area in Washington State.

We summarize below the supporting evidence submitted with the petition.

### Name Evidence

The “Chelan” geographic name derives from the name that Alexander Ross, an American fur trader, in about 1824 used to describe the “Tsill-anes,” a native people living along the south shore of Lake Chelan, according to “Chelan County—Thumbnail History,” an article from the Washington State Department of Archeology and Historic Preservation, The Online Encyclopedia of Washington State History at <http://www.historylink.org>.

The “Lake Chelan” name appears on the USGS Chelan, Manson, and Winesap quadrangle maps. The USGS Chelan map, sections 11 and 12, T27N and R23N, identifies an area to the north-northwest of the small town of Chelan as the “Lake Chelan Golf and Country Club.” The DeLorme Washington Atlas and Gazetteer identifies “Lake Chelan” on page 83, sections A7, B7, and B8. The American Automobile Association map, Oregon Washington State Series, identifies “Lake Chelan” as a long slender lake extending northwest from the North Cascades National Park southeast to the Chelan Dam, approximately 2 miles northwest of the Columbia River.

An article entitled “Chelan and Stehekin, WA,” dated August 12, 2006, on <http://www.nwsources.com>, a northwest travel and outdoors Web site, states that Lake Chelan is one of Washington's favorite summer recreation areas.

### Boundary Evidence

According to the petitioner and the written boundary description, the proposed Lake Chelan viticultural area encompasses the southernmost and easternmost 12 miles of the 55-mile-long lake and surrounding lands. A bedrock

ridge, with a pinnacle at a 1,526-foot elevation, divides the approximately 1,200-foot elevation of the south Lake Chelan region from the 707-foot elevation of the Columbia River, according to USGS maps of the area and the petitioner. Lands to the east and southeast of the proposed viticultural area are within the Columbia River airshed and watershed, and have different climates, geology, and soils.

The upper 43 miles of Lake Chelan and its shoreline lie outside of the proposed viticultural area, according to the written boundary description provided in the petition. According to the petitioner, in the northern lake region the surrounding Cascade Range provides significant downward cold air drainage from peaks to valley floor and blocks the sun from the adjacent valley lands. The cold air and shade combine with a steep shoreline terrain to create a region unsuitable for grape growing. Additionally, the North Cascades National Park surrounds the north end of Lake Chelan, and commercial agricultural development is prohibited within its borders.

Lands with viticultural potential in the Lake Chelan Valley area, the petitioner states, are generally at or below 2,000 feet in elevation. High mountains ridges, beyond the boundary of the proposed Lake Chelan viticultural area, rise over 5,000 feet in elevation to the north and west and to 3,800 feet to the south, cradling the Lake Chelan Valley region on three sides, according to the petitioner and USGS maps. The petition explains that these high mountains, which have cold climates and forested terrain, are unsuited to viticulture.

#### History of Viticulture

According to the Chelan Valley Mirror dated May 1, 1947, Urban DeGrassi, a Jesuit priest, spent several years in the Lake Chelan region teaching Native Americans about agriculture. Based on Father DeGrassi's teachings, in 1881, John and Peter Wapato, Native Americans of Chelan Valley, started planting fruit eventually including grapes and cherries.

According to an article in the August 6, 1891, edition of the Chelan Falls Leader, Louis Conti, an Italian immigrant, owned a 60-acre vineyard in the Lake Chelan area. The article stated that a colony of Italian immigrants, living on the sunnier south side of the lake, planted grape vines on their claimed lands.

Two 1905 photographs from the Chelan County Historical Society show grapes growing in the Lake Chelan area. A photo of grapes on the vine is labeled

"Black Hamburg Grapes—Lake Chelan." The petitioner explains that the common name for those grapes is Black Muscat. The other photo, which shows a little boy sitting on the ground beside grapes hanging heavily from a vine, is labeled "Lake Chelan Grapes."

The Faletto family continued growing grapes into the early 1900's, according to an e-mail dated November 22, 2005, from family member Rich Faletto. Mr. Faletto stated of his grandfather, "Old John was the vintner and winery operator in the valley, producing great wine from [grapevines] brought to the area by a group of Italians."

The Chelan and Manson areas, within the proposed viticultural area, comprised 154 acres of producing vineyards, according to a November 17, 1949, newspaper article written by Harry R. McMullen. According to the article, that year grape growers received 2 cents a pound, or \$40 a ton, from the Welch Company.

#### Modern Viticulture

The petitioner states that in 1998, Steve Kludt and Bob Christopher replanted apple orchards to grapes within the proposed Lake Chelan viticultural area. Also, in 2000 the Kludt family opened the first bonded winery in the area and in 2001 started selling wine. Vineyard production in the Lake Chelan region increased from over 90 acres in 2004 to 140 acres by 2006. According to the petitioner, 13 bonded wineries operated in the Lake Chelan area as of the 2006 petition submission date.

#### Proposed Boundary Line

The petitioner explains that the proposed boundary line uses a 2,000-foot elevation line and USGS map section lines in conjunction with roads, mountain peaks, and other map markings in providing a clear, simple perimeter. The proposed Lake Chelan viticultural area boundary line includes lands adjacent to the southernmost 12 miles of the lake, according to the petition.

In determining the proposed boundary line, the petitioner included in the proposed viticultural area only the valley areas with a significant "lake effect" climate. The lake affects surrounding lands, the petitioner explains, by favorably moderating the climate, increasing the length of the growing season, and reducing the frequency of damaging or killing vine freezes. The petitioner states that the proposed boundary line excludes from the proposed viticultural area the surrounding mountainous areas and the northern 43 miles of the lake and

adjacent lands, all unsuitable for viticulture.

TTB notes that the northeast portion of the boundary of the proposed Lake Chelan viticultural area coincides with 17 miles of the 2,000-foot boundary line of the Columbia Valley viticultural area. When the petition was first submitted to TTB, the proposed northeast boundary line incorporated a series of map section lines and 90-degree turns. After discussions with TTB, the petitioner modified the northeast portion of the boundary line to coincide with the boundary line of the Columbia Valley viticultural area.

The petitioner provides an aerial photo of agriculture within and immediately outside of the proposed Lake Chelan viticultural area. The planted orchards and vineyards are clustered on the low, flat elevations adjoining the northern and southern shorelines of the lake. The petitioner explains that viticulture fails to thrive outside the proposed boundary line because of high elevations, steep terrain, cold temperatures, and the absence of a moderating lake-effect climate.

Other boundary line considerations include properties of the soil, the influences of the watershed and airshed, the elevations of the surrounding mountains, and the steepness of the terrain.

#### Distinguishing Features

##### Cascade Range Geographic Province

The proposed Lake Chelan viticultural area, a part of the Cascade Range geographic province, the petitioner explains, includes distinctive geology, geography, soils, and climate that contrast to those of the surrounding areas. The geology, the petitioner notes, includes the advance of Cascade alpine glaciers that occurred 14,000 to 18,000 years ago.

The Cascade Mountain Range runs north-south through Washington and Oregon and divides western and eastern Washington, the petitioner explains. The range creates, to the east, a rain shadow that limits precipitation in the Lake Chelan Valley and on the Columbia Plateau in eastern Washington. The range protects areas to its east from Arctic and Pacific winter storms and further moderates climate.

Lake Chelan Valley is the only valley that the Cascade glacier created in Washington and Oregon and that holds a large natural lake of Lake Chelan's size. The lake is the third deepest lake in the U.S., the petitioner emphasizes. The soils in the valley formed in glacial sediments layered below the more recent windblown deposition of

volcanic pumice and ash. Also, the large glacial lake acts as a heat reservoir to produce a unique climate of consistently moderated temperatures.

#### Columbia Plateau Geographic Province

Most Washington vineyards, the petitioner states, lie on the Columbia Plateau geographic province, the features of which contrast significantly in several important ways from the Lake Chelan Valley in the Cascade Range geographic province. The distinguishing features of the Columbia Plateau include the bedrock of Tertiary-age basaltic lavas, sediments derived from cataclysmic outburst floods of Lake Missoula, and bench-and-riser landforms that the recurrent Missoula Floods created through erosion of the lavas. The topography varies from near moonscapes to megasized gravel bars and slackwater terraces.

The petitioner states that another distinguishing feature of the Columbia Plateau is the predominant east-west trending valley-and-ridge system that affects the elevation, slope, aspect, heat accumulation, winds, and air drainage of the plateau. Also, plateau elevations vary from 460 feet at the Wahluke Slope viticultural area (27 CFR 9.192) to 970 feet at the Walla Walla Valley viticultural area (27 CFR 9.91), a topography with a significantly lower elevation than that of the Lake Chelan area of the Cascade Range.

The separate climates of the Columbia Plateau viticultural areas share low winter temperatures with complete vine dormancy and significant fall daytime and nighttime temperature variations. The viticultural areas of the Columbia Plateau lie within the rain shadow of the Cascade Range, and have a drier climate as compared to western Washington. The combination of distinguishing features in the viticultural areas on the Columbia Plateau, the petitioner concludes, creates a unique annual growing season that contrasts with the Lake Chelan Valley region in the Cascade Range geographic province.

#### Geology

The petitioner explains that the most recent ice-age events of the Earth, 14,000 to 18,000 years ago, played significant roles in creating the differing

geological records within the Cascade Range and the Columbia Plateau.

The region encompassing the proposed Lake Chelan viticultural area, according to the petitioner, includes camel-backed bedrock landforms that the Cascade Range alpine glaciers eroded into the dominantly granitic bedrock of the Lake Chelan area, lake sediments that the alpine glaciers deposited, and bedrock that consists of Cretaceous-age igneous and older metamorphic rocks. The glaciers crushed bedrock in the Lake Chelan region, creating glacial till and outwash sediments that have coarse sandy textures and that are rich in biotite mica. The glacial lake sediments, silty to clayey in texture, include substantive amounts of quartz and mica. As a result, the soil's deep rooting zone for grape vines has distinguishable textures, mineralogy, and nutrients.

The petitioner provides a geologic map of the proposed Lake Chelan viticultural area from the USGS Miscellaneous Investigations Series Map I-1661, Geologic Map of the Chelan, 30-Minute by 60-Minute Quadrangle, Washington, accessed online on June 26, 2006. The map identifies the Cretaceous-age bedrock and the Quaternary-age surface sediments in the Lake Chelan Valley area. The Cretaceous-age units consist of dark, intrusive igneous tonalites, the petitioner explains. TTB notes that tonalite is an igneous plutonic (intrusive) rock having greater than 20 percent quartz and quartz diorite with 5 to 20 percent quartz. Also, the Quaternary-age units consist of glacial moraines, terraces, lake deposits, and postglacial landslides and alluvial sediments.

According to the petitioner, the Columbia Plateau geologic history, in contrast, stems from the force of a lobe of the western Canadian ice sheet that blocked the Clark Fork River in Idaho and created the huge glacial Lake Missoula in Montana. When the glacial ice dams repeatedly failed, the largest floods of water ever documented on Earth occurred. The floods overwhelmed the Columbia River and flowed across eastern Washington, eroding channels in the basalt bedrock and depositing gravel bars in the main basins and fine sandy and silty sediments in the river valleys.

#### Geography

Elevations vary from approximately 1,100 feet at lake level to 3,276 feet at an unnamed peak in the northwest portion of the proposed Lake Chelan viticultural area, 1.8 miles northwest of Lake Chelan State Park on the USGS Manson quadrangle map. The lower elevations, which have gently rising slopes, are along the southern and eastern shoreline of Lake Chelan, as shown on the USGS maps of the region. The petitioner explains that the lower lakeside elevations are known for successful fruit growing. The higher elevations enveloping the Lake Chelan Valley region generally correlate with steep terrain, as shown on the USGS maps of the proposed viticultural area.

According to the petitioner, when the Cascade alpine glaciers descended from the mountain crests to lower elevations, they created the distinctive U-shaped Lake Chelan Valley topography, including the lake depression. The term "camel-backed" describes the landforms of the Lake Chelan Valley at low elevations and adjacent surrounding mountains. The Cascade alpine glaciers created other valleys in the region with similar landscapes, including camel-backed topography, and layers of glacial sediment, but not lake basins. Thus, only Lake Chelan Valley, in contrast to the other regional glacial valleys, has a climate-moderating lake effect.

#### Climate

According to local growers and temperature statistics, a lake effect moderates air temperature extremes in both summer and winter in the proposed Lake Chelan viticultural area. The combination of moderating summer high and winter low temperatures creates a suitable environment for both viticulture and tree fruit agriculture. According to the petitioner, the strong lake effect moderates the air temperatures of planted areas adjacent north and south of the eastern part of the lake. In those areas, the waters of Lake Chelan create a heat reservoir that absorbs warming solar energy in summer and then reradiates heat energy into cold air in winter. The table below compares the climate in the areas along Lake Chelan to that in similar areas nearby but without lakes.

CLIMATIC INDICES FOR WINE GRAPES FOR THREE SITES IN WASHINGTON STATE, 1994–2003

Area *	Distance from Lake Chelan (miles)	Cool climate viticulture suitability index ** (days)	Number of days a year <32 °F	Number of days a year >95 °F
Lake Chelan .....	0 .....	244	89.6	7.1

## CLIMATIC INDICES FOR WINE GRAPES FOR THREE SITES IN WASHINGTON STATE, 1994–2003—Continued

Area *	Distance from Lake Chelan (miles)	Cool climate viticulture suitability index ** (days)	Number of days a year <32 °F	Number of days a year >95 °F
Methow Valley .....	30, north .....	176	147.9	13.6
Wenatchee Valley .....	30, south .....	230	102.3	14.1

\* Based on data from the National Climate Data Center.

\*\* Number of days between <29 °F in spring and the first temperature <29 °F in fall.

The petitioner uses a cool-climate viticultural suitability index (CCVSI) formulated at Cornell University as an analytical tool for the Lake Chelan Valley climate. The CCVSI emphasizes the impact of temperature moderation on viticulture. The petitioner explains that the CCVSI compiles the sum of the days from the last occurrence of 29 degrees Fahrenheit or lower in spring until the first occurrence of 29 degrees Fahrenheit or lower in fall. The larger total numbers, in days, generally correlate to the better viticultural regions.

For the Lake Chelan Valley region, the CCVSI 10-year average of 244 days is significantly higher than the glacially formed Methow Valley in the Cascade Range to the north and higher than the Wenatchee Valley to the south.

In another measure of the lake effect on the proposed Lake Chelan viticultural area, the petitioner uses the annual average number of days with temperatures of 32 degrees Fahrenheit or lower in winter and 95 degrees Fahrenheit or higher in summer. The petitioner compares the climates in Lake Chelan Valley, Methow Valley, and Wenatchee Valley using this method. All three valleys are located within 60 miles of each other, were created partially or wholly by Cascade alpine glaciers, and have other similar geographic features. Lake Chelan Valley averages 7 days a year above 95 degrees Fahrenheit, and Methow Valley and Wenatchee Valley average 14 days a year, according to data from the National Climate Data Center included with the petition. Fewer hot days in the Lake Chelan Valley correlate with better fruit quality, because temperatures above 95 degrees shut down most photosynthesis in grapes, according to the petitioner. The Lake Chelan Valley averages only 90 days a year colder than 32 degrees Fahrenheit in winter, while the Methow Valley averages 148 days and the Wenatchee Valley averages 102 days.

Northwest of the proposed viticultural area, temperatures are too low for

viticulture because of cold air drainage from the high Cascades and severe shading from steep mountainsides close to the lake. To the east and northeast of the proposed viticultural area, a ridge holds the lake-affected air masses in the lake basin. That ridge is used as the proposed eastern boundary.

To further demonstrate the moderating lake effect, the petitioner provides evidence concerning vine-killing freezes which, according to the petitioner, occur less frequently in the proposed Lake Chelan viticultural area than in other viticultural areas in eastern Washington State. Winemaker Charles Ray Sandidge III, in an October 2, 2006, e-mail to the petitioner, states that he conducted a study of weather data in the period 1934–84 in the regions of Wahuake Slope, Walla Walla, Chelan, East Wenatchee, and Roosevelt. Results, based on cold temperature readings, indicated that the Lake Chelan area averaged a killing freeze once in 17 years, while the other Washington viticultural areas studied averaged 6 to 8 years between vine-killing freezes.

Mr. Sandidge states that Lake Chelan averages a heavy crop loss and a light vine loss every 17 years. Also, fall temperatures cool more rapidly and rains arrive about a week earlier than in areas to the south. Mr. Sandidge theorizes that while the Lake Chelan area experiences milder winter temperatures, the later spring bud break relates to the close proximity of the proposed viticultural area to the surrounding mountains.

#### Soils

According to the petitioner, the soils of the Lake Chelan Valley include layers of glacial debris, sediment from normal stream erosion and deposition after the glacial age, and airborne volcanic and nonvolcanic sediments. The lower parts of the deeper soils, 20 to 60 inches below the surface, predominantly formed in glacial sediments. The upper part of the soils formed in a mixture of large amounts of airborne volcanic pumice and ash from Glacier Peak and

very small amounts of loess (wind-transported material) overlying the glacial sediments. Thus, the soils downwind from Glacier Peak and the north Cascades, including the soils in the proposed Lake Chelan viticultural area, are rich, about 3 to 40 percent by volume, in volcanic pumice and ash from a massive eruption of the Glacier Peak volcano about 12,000 years ago.

The petitioner explains that bedrock in the proposed Lake Chelan viticultural area consists of Cretaceous-age granitic rocks and older metamorphic rocks, including amphibolite, schist, and biotite gneiss. Glaciers shattered and crushed the Cascade crystalline bedrock, creating glacial till and glacial outwash sediments that include biotite mica-rich cobbly, bouldery, gravelly, and coarse sandy materials.

The soils in Lake Chelan Valley that are close to the surface, according to the petitioner, include sand- and fine gravel-sized pumice from the volcanic eruption of Glacier Peak to the northwest. Soils that have significant amounts of volcanic ash and pumice or clays weathered from glass have an unusually high available water capacity. The petitioner believes that the high content of volcanic material in the soils is a significant contributory factor to the successful regional viticulture and pomology over the past 100 years.

The United States Department of Agriculture, National Cooperative Soil Survey, has identified 11 soil series within the proposed Lake Chelan viticultural area. Eight of these series consist of soils derived from volcanic glass, including ashy, cindery, pumiceous, glassy, vitrandic, medial, and amorphous soils, the petitioner explains. Only the Margerum and Dragoon series are silt loam, which is common on the Columbia Plateau. The information in the soil table below is from the Official Soil Series Descriptions accessed on October 18, 2006, at the U.S. Department of Agriculture Web site, at: <http://soils.usda.gov/technical/classification/osd/index.html>.

Soil series	Soil order	Excerpt from official description
Margerum .....	Mollisols .....	Considerable pumice.
Chelan .....	Mollisols .....	Volcanic ash and pumice.
Springdale .....	Inceptisols .....	Volcanic ash in the upper part.
Kartar .....	Inceptisols .....	Volcanic ash in the surface.
Entiat .....	Mollisols .....	Volcanic ash.
Dinkelman .....	Mollisols .....	A component of volcanic ash.
Tyee .....	Mollisols .....	Volcanic ash.
Swakane .....	Mollisols .....	Volcanic ash in the upper part.
Psuga .....	Spodosols .....	Volcanic ash.
Mansonina .....	Mollisols .....	Volcanic ash and pumice.
Draagoon .....	Mollisols .....	Volcanic ash.

The petitioner explains that many agricultural soils on the Columbia Plateau are silt loam throughout the soil profile, and are unlike those with a high content of volcanic pumice and ash in the Lake Chelan area and Cascade Range. Also, the mineralogy of the Columbia Plateau basalt sediments, deposited as alluvium derived from basaltic lavas, includes neither quartz nor mica, which are commonly found in the sediments in the Lake Chelan Valley area.

A sampling of soils taken by the petitioner across the Columbia Plateau shows that the dominant parent materials are loess and dunes and have an average content of only 12 percent volcanic glass. This is substantially different from the high glass content of soils in the proposed viticultural area. The Pasco and Umatilla Basins, to the south of the proposed viticultural area, were the origins of most of the loess throughout the Columbia Plateau. Over the millennia the Lake Chelan Valley, outside the path of most of the wind transporting the loess, has received only minor deposits of loess. The petitioner asserts that the differences in soil between the Lake Chelan Valley and the Columbia Plateau impact infiltration and runoff of water, aeration of the soils, root penetration, and available water capacity.

#### *Notice of Proposed Rulemaking and Comments Received*

TTB published Notice No. 87 regarding the proposed Lake Chelan viticultural area in the **Federal Register** (73 FR 46836) on August 12, 2008. In that notice, TTB invited comments by October 14, 2008, from all interested persons. We solicited comments on the sufficiency and accuracy of the name, boundary, climatic, and other required information submitted in support of the petition. We also solicited comments on the proposal to identify "Lake Chelan" and "Chelan" as terms of viticultural significance. We expressed particular interest in receiving comments on whether the proposed area name, Lake

Chelan, would result in a conflict with currently used brand names. We received four comments from individuals in response to that notice. All four comments supported the establishment of the Lake Chelan viticultural area as proposed. Further, TTB is not aware of any conflict with existing brand labels that would occur if the viticultural area is established as proposed.

#### **TTB Determination**

When the Columbia Valley viticultural area was established in 1984, it was recognized as having the following distinguishing geographical features: (1) A growing season of over 150 days per year, with a high of 204 days per year; (2) a total degree day average of over 2,000; (3) annual rainfall of 15 inches or less; and (4) a topography described as a broadly undulating or rolling surface, cut by rivers and broken by long sloping basaltic uplifts extending generally east-west. Although the proposed Lake Chelan viticultural area shares some of these characteristics, due to lake effect temperature moderation its growing season is significantly longer at an average of 244 days annually and its lakeside topography is significantly different. TTB believes these differences justify recognition of Lake Chelan as a distinct viticultural area within the Columbia Valley viticultural area.

Accordingly, after careful review of the petition and the comments received, TTB finds that the evidence submitted supports the establishment of the proposed viticultural area. Therefore, under the authority of the Federal Alcohol Administration Act and part 4 of our regulations, we establish the "Lake Chelan" viticultural area in Chelan County, Washington, effective 30 days from the publication date of this document.

#### *Boundary Description*

See the narrative boundary description of the viticultural area in the

regulatory text published at the end of this document.

#### *Maps*

The maps for determining the boundary of the viticultural area are listed below in the regulatory text.

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

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. With the establishment of this viticultural area and its inclusion in part 9 of the TTB regulations, its name, "Lake Chelan," is recognized under 27 CFR 4.39(i)(3) as a name of viticultural significance. The text of the new regulation clarifies this point.

In addition, based on the evidence submitted, we believe that "Chelan" standing alone is locally and/or nationally known as referring to the region in Washington State encompassed by the proposed "Lake Chelan" viticultural area, and we therefore believe that consumers and vintners could reasonably attribute the quality, reputation, or other characteristic of wine made from grapes grown in the proposed "Lake Chelan" viticultural area to the name "Chelan" itself. Therefore, the part 9 regulatory text set forth in this document specifies both "Lake Chelan" and "Chelan" as terms of viticultural significance for purposes of part 4 of the TTB regulations.

Once this final rule becomes effective, wine bottlers using "Lake Chelan" or "Chelan" in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the viticultural area's full name as an appellation of origin.

For a wine to be labeled with a viticultural area name or with a brand name that includes a viticultural area name or other term identified as being viticulturally significant in part 9 of the TTB regulations, at least 85 percent of the wine must be derived from grapes grown within the area represented by

that name or other term, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with the viticultural area name or other viticulturally significant term and that name or term appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the viticultural area name or other viticulturally significant term appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Accordingly, if a previously approved label uses the name "Lake Chelan" or "Chelan" for a wine that does not meet the 85 percent standard, the previously approved label will be subject to revocation, upon the effective date of the establishment of the Lake Chelan viticultural area.

Different rules apply if a wine has a brand name containing a viticultural area name or other term of viticultural significance that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

#### Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of a viticultural area name is the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

#### Executive Order 12866

This rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, it requires no regulatory assessment.

#### Drafting Information

Christopher Thiemann of the Regulations and Rulings Division drafted this notice.

#### List of Subjects in 27 CFR Part 9

Wine.

#### The Regulatory Amendment

■ For the reasons discussed in the preamble, we amend title 27 CFR, chapter I, part 9, as follows:

### PART 9—AMERICAN VITICULTURAL AREAS

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

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

#### Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9.215 to read as follows:

##### § 9.215 Lake Chelan.

(a) *Name.* The name of the viticultural area described in this section is "Lake Chelan". For purposes of part 4 of this chapter, "Lake Chelan" and "Chelan" are terms of viticultural significance.

(b) *Approved maps.* The five United States Geological Survey 1:24,000 scale topographic maps used to determine the boundary of the Lake Chelan viticultural area are titled:

(1) Manson Quadrangle, Washington—Chelan Co., 1968, photorevised 1987;

(2) Cooper Ridge Quadrangle—Washington, 1968, photorevised 1987;

(3) Chelan Quadrangle—Washington, 1968, photorevised 1987;

(4) Chelan Falls Quadrangle—Washington, 1968, photorevised 1981; and

(5) Winesap Quadrangle—Washington, 1968, photorevised 1987.

(c) *Boundary.* The Lake Chelan viticultural area is located in Chelan County, Washington. The boundary of the Lake Chelan viticultural area is as described below:

(1) The beginning point is on the Manson map at the intersection of the east shore of Lake Chelan and the north boundary line of section 15, T28N/R21E, north of Greens Landing. From the beginning point, proceed straight east 1.6 miles along the northern boundary line of sections 15 and 4 to its intersection with the 2,000-foot elevation line, T28N/R21E; then

(2) Follow the meandering 2,000-foot elevation line generally southeast onto the Cooper Ridge map, crossing Purterman Gulch; continue southeast onto the Chelan map and follow the meandering 2,000-foot elevation line onto the Chelan Falls map, over the Cagle Gulch, and then return to the Chelan map; continue generally southeast onto the Chelan Falls map and follow the 2,000-foot elevation line to section 8, T27N/R23E, to a point 0.3 mile due north of BM 1404 at the intersection of U.S. Route 97 and State Route 151, T27N/R23E; then

(3) Proceed in a straight south-southeast line 1.35 miles to its intersection with the section 20 north boundary line and the 1,000-foot elevation line, T27N/R23E; then

(4) Proceed south-southwest along the 1,000-foot contour line to its intersection with the section 20 south boundary line, south of Chelan Station and immediately west of State Route 151, T27N/R23E; then

(5) Proceed straight west along the south boundary line of sections 20 and 19 for 0.75 mile to its intersection with the light-duty Gorge Road, as identified on the adjoining Chelan map, T27N/R23E; then

(6) Proceed northwest along Gorge Road, crossing onto the Chelan map, to the southeast corner of section 13, T27N/R22E; then

(7) Proceed straight west along the south boundary line of sections 13, 14, 15, 16, 17, and 18, and crossing onto the Winesap map in section 18, to its intersection with the R21E/R22E line, T27N; then

(8) Proceed straight north along the R21E/R22E line to its intersection with the south boundary line of section 13 and the 2,440-foot contour line, T27N/R21E; then

(9) Proceed straight west to the southwest corner of section 13, T27N/R21E; then

(10) Proceed straight north along the section 14 east boundary line to the northeast corner of section 14, T27N/R21E; then

(11) Proceed straight west along the section 14 north boundary line to the northwest corner of section 14, T27N/R21E; then

(12) Proceed straight north along the east boundary line of section 10 for 0.3 mile to its intersection with the 2,520-foot contour line and a 90-degree turn in the Wenatchee National Forest (WNF) boundary line, T27N/R21E; then

(13) Proceed straight west along the WNF boundary line 0.3 mile to its intersection with the 2,600-foot contour line and a 90-degree turn in the WNF boundary line, T27N/R21E; then

(14) Proceed straight south along the WNF boundary line 0.3 mile to its intersection with the south boundary line of section 10, T27N/R21E; then

(15) Proceed straight west along the south boundary lines of sections 10 and 9 to the southeast corner of section 8, T27N/R21E; then

(16) Proceed straight north along the east boundary line of section 8 to the northeast corner of section 8, T27N/R21E; then

(17) Proceed straight west along the north boundary line of section 8 to the northwest corner of section 8, T27N/R21E; then

(18) Proceed generally north along the east boundary line of section 6, crossing onto the Manson map, and continue along the east boundary lines of sections 31 and 30, to the northeast corner of section 30, T28N/R21E; then

(19) Proceed straight east along the north boundary lines of sections 29 and 28 to the intersection with the east shoreline of Lake Chelan; and

(20) Proceed generally northwest and northeast along the east shoreline of Lake Chelan to the point of beginning.

Signed: February 24, 2009.

**John J. Manfreda,**  
Administrator.

Approved: March 26, 2009.

**Timothy E. Skud,**  
Deputy Assistant Secretary, Tax, Trade, and  
Tariff Policy.

[FR Doc. E9-9847 Filed 4-28-09; 8:45 am]

BILLING CODE 4810-31-P

## DEPARTMENT OF THE TREASURY

### Fiscal Service

#### 31 CFR Part 363

#### Regulations Governing Securities Held in TreasuryDirect

**AGENCY:** Bureau of the Public Debt, Fiscal Service, Treasury.

**ACTION:** Final rule.

**SUMMARY:** TreasuryDirect is an account-based, book-entry, online system for purchasing, holding, and conducting transactions in Treasury securities. To date, TreasuryDirect has only been available for individual account owners. This final rule will permit certain specified entities to open accounts in TreasuryDirect.

**DATES:** *Effective date:* April 24, 2009.

**ADDRESSES:** You can download this final rule at the following Internet addresses:  
<http://www.publicdebt.treas.gov> or  
<http://www.gpoaccess.gov/ecfr>.

#### FOR FURTHER INFORMATION CONTACT:

Elisha Whipkey, Director, Division of Program Administration, Office of Retail Securities, Bureau of the Public Debt, at (304) 480-6319 or [elisha.whipkey@bpd.treas.gov](mailto:elisha.whipkey@bpd.treas.gov).

Susan Sharp, Attorney-Adviser, Elizabeth Spears, Senior Attorney, Edward Gronseth, Deputy Chief Counsel, Office of the Chief Counsel, Bureau of the Public Debt, at (304) 480-8692 or [susan.sharp@bpd.treas.gov](mailto:susan.sharp@bpd.treas.gov).

#### SUPPLEMENTARY INFORMATION:

TreasuryDirect is an online account-based system for individuals to purchase, hold, and conduct transactions in eligible Treasury securities. To date, only individuals have been permitted to open a TreasuryDirect account. This final rule will permit certain specified entities to open accounts in TreasuryDirect and conduct transactions in eligible Treasury securities. A sole proprietorship, partnership, corporation, limited liability company

or professional limited liability company, trust, decedent's estate, estate of an incompetent individual, and estate of a minor will be able to open a TreasuryDirect account. Treasury believes that these forms of registrations will serve most organizations and fiduciaries wishing to open a TreasuryDirect account. If, in the future, there is a demonstrated need for other forms of entity registrations, Treasury will consider adding additional registrations.

The account must be opened and managed by an individual known as an entity account manager who is authorized to act alone on behalf of the entity with regard to this account. Only an individual is permitted to act as an entity account manager. Initially, the entity account manager will be the individual who opens the TreasuryDirect account. If the entity subsequently wishes to change the individual who acts as its entity account manager, the entity account manager may be changed using procedures available on the TreasuryDirect Web site. Only one individual may act as entity account manager at any one time. The identity of the entity account manager will be verified using an online verification service; the identity of the entity may be verified using appropriate evidence. The entity account manager must certify online that he or she has the authority to act alone on behalf of the entity.

An entity will not be permitted to open a minor linked account. An entity cannot purchase gift savings bonds, and a gift bond cannot be delivered to an entity. However, an entity may transfer an existing bond, which is already registered in the entity's name, to another account (primary or linked) owned by either an individual or an entity. An entity may convert a definitive savings bond to book-entry form if the bond is registered in the name of the entity.

#### Procedural Requirements

This final rule does not meet the criteria for a "significant regulatory action" as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

Because this final rule relates to matters of public contract and procedures for United States securities, notice and public procedure and delayed effective date requirements are inapplicable, pursuant to 5 U.S.C. 553(a)(2).

As no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) does not apply.

We ask for no new collections of information in this final rule. Therefore, the Paperwork Reduction Act (44 U.S.C. 3507) does not apply.

#### List of Subjects in 31 CFR Part 363

Bonds, Electronic funds transfer, Federal Reserve system, Government securities, Securities.

■ Accordingly, for the reasons set out in the preamble, 31 CFR Chapter II, Subchapter B, is amended as follows:

#### PART 363—REGULATIONS GOVERNING SECURITIES HELD IN TREASURYDIRECT

■ 1. The authority citation for part 363 continues to read as follows:

**Authority:** 5 U.S.C. 301; 12 U.S.C. 391; 31 U.S.C. 3102, *et seq.*; 31 U.S.C. 3121, *et seq.*

■ 2. Amend § 363.5 by revising paragraph (c) to read as follows:

#### § 363.5 How do I contact Public Debt?

\* \* \* \* \*

(c) Letters should be addressed to the address provided on our web site at <http://www.treasurydirect.gov/write.htm>.

■ 3. Amend § 363.6 by:

■ a. Adding the definitions of "Entity," "Entity account manager," and "Incompetent individual or Incompetent person" in alphabetical order;

■ b. Revising the definitions of "Individual," "Owner," "Person," and "Verification" to read as follows:

#### § 363.6 What special terms do I need to know to understand this part?

\* \* \* \* \*

*Entity* means any owner of a TreasuryDirect account that is not an individual. Entity is a sole proprietorship, partnership, corporation, limited liability company or professional limited liability company, trust, the estate of a decedent, or the estate of a living person such as an incompetent or a minor.

*Entity account manager* is the individual who initially opens the TreasuryDirect account for an entity, or his or her replacement; who is authorized by the entity to act alone on its behalf to open, access, and conduct transactions with respect to the account; and who certifies that he or she is so authorized.

\* \* \* \* \*

*Incompetent individual or incompetent person* means an individual who has been declared by a court to be legally incompetent, incapacitated, or otherwise unable to manage his or her financial affairs.