

bioequivalency or similar data as suggested in the guidelines for submitting NADA's for DESI reviewed generic drugs. The guideline is available from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 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 (address above).

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### List of Subjects in 21 CFR Part 546

Animal drugs, Antibiotics, tetracycline.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i) and (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b(i) and (n)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 546 is amended as follows:

#### PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

1. In § 546.110d, by revising the section heading and by revising paragraphs (a)(1) and (c)(2), (3), (5), and (6) to read as follows:

##### § 546.110d Chlortetracycline tablets and boluses.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Chlortetracycline hydrochloride tablets and boluses, tetracycline hydrochloride tablets, and tetracycline tablets are tablets and boluses composed of crystalline chlortetracycline hydrochloride, tetracycline hydrochloride, tetracycline, or tetracycline phosphate complex, with or without one or more suitable and harmless buffer substances, preservatives, diluents, binders, lubricants, colorings, and flavorings. The potency of the drug is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of

milligrams it is represented to contain. The moisture content of the tablets is not more than 3 percent, unless the person who requests certification has submitted to the Commissioner information adequate to prove that the drug is stable when it has a moisture content not exceeding 6 percent. The moisture content of the boluses is not more than 6 percent.

\* \* \*

(2) *Sponsors.* (i) See No. 000010 in § 510.600(c) of this chapter for use of the 250-milligram chlortetracycline hydrochloride bolus.

(ii) See No. 010042 in § 510.600(c) of this chapter for use of the 25-milligram tablet and the 500-milligram bolus.

(3) *Special considerations.* The quantities of antibiotic in paragraph (c)(6) of this section refer to the activity of the master standard.

\* \* \*

(5) *NAS/NRC status.* The conditions of use specified in paragraph (c)(6) of this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(6) *Conditions of use.* Administer orally as chlortetracycline hydrochloride tablets or boluses to calves as follows:

(i) *Amount.* 250 milligrams per bolus.

(a) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klebsiella* spp., and *Hemophilus* spp.

(b) *Limitations.* Administer 1 bolus (250 milligrams) per 50 pounds of body weight twice a day for 3 to 5 days; administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(ii) *Amount.* 25 milligrams per tablet.

(a) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(b) *Limitations.* Administer 1 tablet (25 milligrams) for each 5 pounds of body weight every 12 hours daily for 3 to 5 days; administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk

replacer, administration 1 hour before or 2 hours after feeding is recommended; do not administer within 24 hours of slaughter.

(iii) *Amount.* 500 milligrams per bolus. (a) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(b) *Limitations.* Administer 1 bolus (500 milligrams) per 100 pounds of body weight twice a day for 3 to 5 days; administer directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

\* \* \*

#### § 546.110h [Removed]

2. By removing § 546.110h *Chlortetracycline boluses.*

Effective date February 6, 1984.

(Sec. 512(i) and (n), 82 Stat. 347., 350-351 (21 U.S.C. 360b (i) and (n)))

Dated: January 26, 1984.

Lester M. Crawford, Director,  
Bureau of Veterinary Medicine.

[FR Doc. 84-3070 Filed 2-3-84; 8:45 am]

BILLING CODE 4160-01-M

## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Part 9

[T.D. ATF-165; Ref: Notice No. 471]

#### Establishment of the Walla Walla Valley Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Treasury.

ACTION: Final rule, Treasury decision.

**SUMMARY:** This final rule establishes a viticultural area in southeast Washington and northeast Oregon known as "Walla Walla Valley." The establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising will help consumers better identify wines they purchase. The use of this viticultural area as an appellation of origin will also help winemakers distinguish their products from wines made in other areas.

**EFFECTIVE DATE:** March 7, 1984.

**FOR FURTHER INFORMATION CONTACT:** James P. Ficaretta, FAA, Wine and Beer

Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW., Washington, DC 20226 (202-566-7626).

#### 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 definitive viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

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, the names of which may be used as appellations of origin.

Section 4.25a(e)(1), Title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features. 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.

Mr. Richard L. Small, President of the Walla Walla Valley Winegrowers Association, petitioned ATF for the establishment of a viticultural area in southeast Washington and northeast Oregon, east of Lake Wallula, to be known as "Walla Walla Valley." In response to this petition, ATF published a notice of proposed rulemaking (Notice No. 471) in the Federal Register on June 27, 1983 (48 FR 29541), proposing the establishment of the Walla Walla Valley viticultural area.

##### General Description

The Walla Walla Valley viticultural area consists of approximately 178,560 acres, contains two bonded wineries, and about 60 acres of grapes from several vineyards. Grape-growing and winemaking, as described by Joe J. Locati in the *Horticultural History of Walla Walla County*, dates back to 1871.

##### Evidence of the Name

The Walla Walla Valley has been known as such since it was settled in the 1850's, even prior to the creation of the States of Oregon and Washington. The Walla Walla River flows through the valley into Walla Walla County, Washington.

U.S.G.S. 7.5 minute quadrangle map titled Walla Walla identifies the area as the Walla Walla Valley.

##### Boundaries and Geographical Evidence

In *The Horticultural Heritage of Walla Walla County, 1818-1977*, Joe J. Locati makes reference to the Walla Walla Valley as "including Touchet and Milton-Freewater \* \* \* the Walla Walla River Basin."

The *Geology and Groundwater Resources of the Walla Walla River Basin, Washington-Oregon*, published in 1965, states that the "Walla Walla Valley, descends from about 1,500' at the foot of the mountain slopes to about 500' where the river cuts through the bedrock ridge near Divide, astride the Oregon/Washington border."

The U.S.D.A. in the *Soil Survey of Umatilla County, Oregon*, describes the Walla Walla Valley as extending from the northeast part of Umatilla County into the State of Washington.

The Walla Walla Valley receives 10-20 inches of precipitation per year (average 12.5 inches), while the Columbia Basin to the west and north receives less than 10 inches per year, and the Blue Mountains to the east and southeast receive 25-45 inches.

The growing season within the proposed area is between 190 and 220 days, longest within the surrounding six counties.

The average maximum and minimum temperatures within the proposed area are 65°/42°F, while the surrounding areas range from a high of 66°F to a low of 34°F.

The soils of the valley are all basically loess derived soils. Most are classed as I or II irrigated capability units by the Soil Conservation Service. This is in contrast to the soils west of the Touchet River and along the Snake and Columbia Rivers which are droughty and are classified as Classes IV and VI. Soils to the west around Wallula Gap on the Columbia River, and to the east in the Blue Mountains are considered not suitable for cultivation.

##### Public Comment

In response to Notice No. 471, nine comments were received, all in support of the proposed viticultural area.

##### Miscellaneous

ATF does not wish to give the impression by approving Walla Walla Valley as a viticultural area that it is approving or endorsing the quality of the wine from the area. ATF is approving this area as being distinct and not better than other areas. By approving the area, wine producers are allowed to claim a distinction on labels an advertisements as to origin of the grapes. Any commercial advantage gained can only

come from consumer acceptance of Walla Walla wines.

##### Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this final rule because no requirement to collect information is imposed.

##### Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to a final regulatory flexibility analysis (5 U.S.C. 604) are not applicable to this final rule because it will not have a significant economic impact on a substantial number of small entities. The final rule will not impose, or otherwise cause, a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The final rule is not expected to have significant secondary or incidental effects on a substantial number of small entities.

Accordingly, it is hereby certified under the provisions of Section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this final rule will not have a significant economic impact on a substantial number of small entities.

##### Compliance With Executive Order 12291

In compliance with Executive Order 12291, the Bureau has determined that this regulation is not a major rule since it will not result in:

- (a) An annual effect on the economy of \$100 million or more;
- (b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- (c) Significant adverse effects on competition, employment, investment, productivity, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

##### Disclosure

A copy of the petition and the comments received are available for inspection during normal business hours at the following location: ATF Reading Room, Room 4407, Office of Public Affairs and Disclosure, 12th and Pennsylvania Avenue, NW., Washington, DC.

##### Drafting Information

The principal author of this document is James P. Ficaretta, Specialist, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

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

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

**Authority:** This regulation is issued under the authority in 27 U.S.C. 205. Accordingly, 27 CFR Part 9 is amended as follows:

**PART 9—AMERICAN VITICULTURAL AREAS**

**Paragraph 1.** The table of sections in 27 CFR Part 9, Subpart C, is amended to add the heading of § 9.91 to read as follows:

**Subpart C—Approved American Viticultural Areas**

Sec.

\* \* \* \* \*

9.91 Walla Walla Valley.

**Par. 2.** Subpart C is amended by adding § 9.91 to read as follows:

**Subpart C—Approved American Viticultural Areas****§ 9.91 Walla Walla Valley.**

(a) *Name.* The name of the viticultural area described in this section is "Walla Walla Valley."

(b) *Approved Maps.* The appropriate maps for determining the boundaries of the Walla Walla Valley viticultural area are two U.S.G.S. maps, in the scale 1:250,000. They are entitled:

- (1) "Walla Walla," Wa.; Oregon 1953 (limited revision 1983)
- (2) "Pendleton," Or.; Wa. 1953 (revised 1973)

(c) *Boundaries.* The Walla Walla Valley viticultural area, located in the southeast portion of Washington State and the northeast portion of Oregon, consists of approximately 178,560 acres. The boundaries of the Walla Walla Valley viticultural area, using landmarks and points of reference found on the appropriate U.S.G.S. maps, are as follows: Beginning at a point just northeast of Dixie, Washington, in T8N/37E, at the intersection of Highway 3 and Mud Creek; Southwest along State Highway 3 approximately 4 miles to its intersection with the Northern Pacific Railroad in T7N/R37E; Follow the Northern Pacific in a generally westerly direction, through Walla Walla; Continue west, then northwest along the railroad line, past Pedigo Station until it intersects the secondary road in T8N/R34E; thence, southwest in a straight line approximately 12½ miles until it meets the Union Pacific Railroad at the intersection of T7N and R32E/R33E; South along R32E/R33E for 2 miles until it intersects the 1,000' contour line; Follow the 1,000' contour line in a southeast direction until it intersects the

Union Pacific Railroad at T5N/R35E; South along said track until it intersects Dry Creek in T4N/R35E; Southeast along Dry Creek until it intersects the 2,000' contour line; Continue in a northeast direction along the 2,000' contour line until it intersects Dry Creek in T7N/R38E; North along Dry Creek, approximately 3½ miles, until it intersects the Northern Pacific Railroad at T8N/R37E; Continue in a northeast direction along said track until it intersects Mud Creek; Follow Mud Creek in a northwest direction to the beginning point where it intersects State Highway 3.

Signed: December 12, 1983.

Stephen E. Higgins,  
Director.

Approved: January 12, 1984.

John M. Walker, Jr.,  
Assistant Secretary (Enforcement and Operations).

[FR Doc. 84-3145 Filed 2-3-84; 9:45 am]  
BILLING CODE 4810-31-M

**DEPARTMENT OF TRANSPORTATION****Coast Guard****33 CFR Part 144**

[CGD 82-075b]

**Exposure Suits; Requirements for Mobile Offshore Drilling Units**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rules.

**SUMMARY:** These rules require exposure suits for personnel on board mobile offshore drilling units including foreign mobile offshore drilling units engaged in activities on the Outer Continental Shelf of the United States. Units operating in waters where the water temperature does not present a severe threat of injury due to exposure would be exempted from the requirements. The need for this action arises from casualties in which some of the loss of life might have been prevented if the persons on board had been provided with exposure suits. These regulations are intended to prevent some of the loss of life when persons are forced to enter cold water after abandoning ship.

**EFFECTIVE DATE:** These amendments become effective on August 6, 1984.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert Markle, Office of Merchant Marine Safety (202) 426-1444.

**SUPPLEMENTARY INFORMATION:** A Notice of Proposed Rulemaking was published in the Federal Register of February 3, 1983 (48 FR 4833). The comment period on the proposal (CGD 82-075b) ended on

May 4, 1983. A total of 167 comments were received from 40 parties.

**Drafting Information**

The principal persons involved in drafting these regulations are: Mr. Robert Markle, Office of Merchant Marine Safety, and Mr. Michael Mervin, Office of the Chief Counsel.

**Discussion of Rules**

These rules require certain mobile offshore drilling units (MODUs) operating on the Outer Continental Shelf (OCS) of the United States to carry exposure suits for all persons on board. The rules apply to any MODU that is not inspected under the regulations in 46 CFR, Subchapter I-A, including foreign registered MODUs.

These rules are similar to those for exposure suits on MODUs that are inspected under 46 CFR, Subchapter I-A. Those rules are published under a separate document (CGD-075a) which appears elsewhere in this issue of the Federal Register. Comments on the notice of proposed rule making (NPRM) applicable to both these rules and the rules under 46 CFR, Subchapter I-A are discussed in the preamble to that final rule. The following discussion concerns comments that apply only to the rules published under this notice.

**Discussion of Comments**

Two comments noted that the proposed rules appeared to exceed the authority of the OCS Lands Act by allowing an exemption from the rules for MODUs operating between 35°N and 35°S latitudes. The U.S. OCS does not extend to 35°S, so the reference to 35°S has been removed from the final rules.

One comment suggested that the rules be revised to require that exposure suits stowed in or near the work stations be of an appropriate size for the persons assigned to that station at any particular time. This change is not needed since the exposure suits come in one "universal" adult size. Title 46 CFR Subpart 160.071 as modified under docket CGD-075a, does provide for approval of oversize adult suits, however, very few individuals need the oversize suits, so the rules do not need to be revised to take this unusual occurrence into account.

Two comments had observations on the requirements for foreign MODUs. Both supported allowing foreign MODUs to use suits approved by their national Administration. One of them stated that the Coast Guard should urge other nations to accept U.S. approved exposure suits on U.S. MODUs in their waters. A new revision to Chapter III of