

change of sponsor for a new animal drug application (NADA) from Parke-Davis, Division of Warner-Lambert Co., to A. H. Robins Co.

EFFECTIVE DATE: July 2, 1986.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: A.H. Robins Co., 1407 Cummings Dr., P.O. Box 26609, Richmond, VA 23261-6609, filed a supplement to NADA 106-111 (Telazol® injection, tiletamine hydrochloride and zolazepam hydrochloride, for dogs and cats) providing for a change of sponsor from Parke-Davis, Division of Warner-Lambert Co. Parke-Davis confirmed the change. FDA is amending the regulations to reflect the sponsor change.

List of Subjects in 21 CFR Part 522

Animal drugs.

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, Part 522 is amended to read as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 522 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

§ 522.2470 [Amended]

2. § 522.2470 *Tiletamine hydrochloride and zolazepam hydrochloride for injection* is amended in paragraph (b) by removing the sponsor number "000071" and inserting in its place "000031."

Dated: June 26, 1986.

Marvin A. Norcross,
Associate Director for New Animal Drug Evaluation.

[FR Doc. 86-14880 Filed 7-1-86; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-231; Ref. Notice No. 569]

Ozark Mountain Viticultural Area

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

ACTION: Final rule; Treasury decision.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) has decided to establish a viticultural area in Arkansas, Missouri, and Oklahoma to be known as "Ozark Mountain." This decision is the result of a petition submitted by Mr. Al Wiederkehr, a grape grower and winery proprietor in the area. The establishment of viticultural areas and the subsequent use of viticultural area names in wine labeling and advertising enables winemakers to label wines more precisely and helps consumers to better identify the wines they purchase.

EFFECTIVE DATE: August 1, 1986.

FOR FURTHER INFORMATION CONTACT: Steve Simon, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW., Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:

Background

ATF regulations in 27 CFR Part 4 provide for the establishment of definite 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.

Part 9 of 27 CFR provides 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 4.25(e)(2) outlines the procedures for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area.

Petition

ATF received a petition from Mr. Al Wiederkehr of Altus, Arkansas, proposing an area in southern Missouri, northern Arkansas, and northeastern Oklahoma as a viticultural area to be known as "Ozark Mountain." The area that was proposed contains about 55,000 square miles. There are about 4,280 acres of grapes planted in the area proposed by Mr. Wiederkehr, and approximately 35 wineries are operating within that area.

Notice of Proposed Rulemaking

In response to the petition, ATF published a notice of proposed rulemaking, Notice No. 569, in the *Federal Register* on Tuesday, September 17, 1985. That notice proposed establishment of the "Ozark Mountain"

viticultural area with boundaries generally as stated in the petition. The notice also solicited public comment concerning the proposed viticultural area.

Comments

The principal commenter was Mr. Robert G. Cowie, Secretary-Treasurer of the Arkansas Wine Producers Association and proprietor of a winery located just outside the boundaries proposed in Notice No. 569. Mr. Cowie requested extension of the boundaries in order to include an area south of the Arkansas River, in which his winery is located. This area is generally located between the Arkansas and Petit Jean Rivers and includes Mt. Magazine, the highest mountain in Arkansas. Mr. Cowie presented evidence to show that this area is locally known as being part of the "Ozark Mountain" region and contains the same distinguishing geographical features as the "Ozark Mountain" area proposed by the petitioner. Comments supportive of Mr. Cowie's request were received from two members of the Arkansas legislature, a geologist from the Arkansas Geological Commission, a geography professor at Arkansas Tech University, and eight others who are residents of Mr. Cowie's local area. The additional area proposed by Mr. Cowie contains about 800 square miles, of which about 60 acres are planted to grapes. At one time, as many as seven wineries were operating in that area, but at present the Cowie Wine Cellars is the only one left.

After considering the evidence presented by the commenters, ATF has determined that it would be proper to extend the boundaries of the "Ozark Mountain" area. Accordingly, this document prescribes boundaries for the "Ozark Mountain" viticultural area that include the area advocated by Mr. Cowie.

Name

The following evidence demonstrates that the viticultural area established by this Treasury decision is known by the name of "Ozark Mountain":

(a) Wine labels from Wiederkehr Wine Cellars and others have borne the appellation "Ozark Mountain" since as far back as 1959.

(b) This area has been referred to as the "Ozark Mountain" region in many geographical books, including *Natural Regions of the United States and Canada* by C.B. Hunt (W.H. Freeman & Co., San Francisco, 1974) and *The Ozarks* by Richard Rhodes (Time-Life Books, New York, 1974).

(c) The Ozark Mountain area is well-known as a wine making region, as is shown by this quote: "Like all of the other American wine regions, the Ozarks [Mountains] are quietly seething with new ideas, new personalities, new grape varieties and a new sense of direction." (*Restaurateurs' Guide to American Wines, Part IV: The Wines and Wineries of the Ozarks*. "Dining," April-May 1973, p. 58.)

Geography

The following evidence demonstrates that the viticultural area is distinguished geographically from the surrounding areas:

(a) In his book, *The Ozarks*, Richard Rhodes states (pp. 19, 22), as quoted by the petitioner:

Stretching from the forests of southern Missouri outside St. Louis through northern Arkansas to the Oklahoma plains near Tulsa, the 55,000 square miles of the Ozarks are bounded by five major rivers: the Mississippi, the Missouri, the Osage, the Neosho, and the Arkansas. The Ozark highlands, the only extensive elevated area in the United States between the Appalachians and the Rocky Mountains, consist of low mountains and hills shaped by springfed streams and rivers . . . cutting their way through the elevated bed rock . . .

. . . These boundaries do not merely locate the Ozarks on the map, but also serve to isolate some of the region's plant and animal life . . .

The Ozarks mark the farthest western extension of the great deciduous forest that once covered the eastern United States. Their western border is the beginning of the prairie that runs from Western Missouri to the Rockies and from Texas to Canada. Their northern border, the Missouri River, is about as far south as the glacier of the ice age came . . . And the hot, lush alluvial lands of the Mississippi begin at the Ozarks' abrupt southeastern edge, in the Missouri bootheel.

With four different climatic regions pressing against them, the Ozarks serve as a sanctuary for a selection of plants and animals from all sides . . .

(b) Geologically, the Ozarks are regarded as an upland plateau, in which mountains and valleys have been carved out by numerous streams and rivers. The land is hilly to mountainous, and the soils are characteristically stony and well-drained. The distinctive soil of the Ozark region is "Clay from deeply weathered, well consolidated sedimentary and deeply weathered volcanic rocks." (Hunt, op. cit., pp. 122-123.) Most of the land remains forested, as it was before the arrival of civilization, in contrast to the neighboring plains country.

(c) The primary effect which the mountainous terrain has on the climate of the Ozarks is to divide the region into innumerable small microclimatic

temperature zones. This is demonstrated by the following quote from Milton D. Rafferty in *The Ozarks, Land and Life* (University of Oklahoma Press, Norman, 1980), p. 29:

Within the Ozarks, temperatures will vary widely with the orientation of slope, nature of surface materials, relief, and presence of water. South and west-facing slopes receive the greatest amount of sunlight and are subject to higher rates of evaporation . . . In winter, perhaps the most noticeable effect of temperature differences within a small area is the duration of snow and icicles on the north-facing slopes.

Air drainage creates the most readily observed temperature differences in summer. Nights are notable for the cool breeze that drains down the slopes, beginning an hour or two before sunset . . .

. . . As a rule, frosts occur in the valleys several weeks earlier in fall and later in spring than they do on the uplands, especially in the case of the larger valleys lying in the hill regions. The margins of the uplands have the best air drainage and are least subject to frosts.

Ozark viticulturists rely on their knowledge of local microclimatic conditions to select the best sites for their vineyards. Such sites possess generally similar conditions of soil and climate, thus giving Ozark viticulture a distinctive character. Favorable conditions for viticulture can be found at locations throughout the Ozarks, from Hermann in the north to Altus and Paris in the south. The reason for this is summarized succinctly by Milton D. Rafferty in the book mentioned above (p. 160): "The growing of grapes is well suited to the climate and soils of the Ozarks."

Boundaries

The boundaries of the viticultural area were proposed by the petitioner to largely follow the five major rivers mentioned above in the quote from Richard Rhodes (the Mississippi, Missouri, Osage, Neosho, and Arkansas). However, for reasons previously stated (under "COMMENTS"), these boundaries have been slightly modified, so that the southern boundary of the area established by this Treasury decision follows the Petit Jean River as well as the Arkansas River. These boundaries may be found on 11 U.S.G.S. maps in the scale of 1:250,000 titles St. Louis, Jefferson City, Springfield, Joplin, Tulsa, Fort Smith, Russellville, Memphis, Poplar Bluff, Paducah, and Rolla. The boundaries are as described in § 9.108, as added by this Treasury decision.

The following approved viticultural areas are entirely enclosed within the Ozark Mountain boundaries: Altus (§ 9.77) and Hermann (§ 9.71). In

establishing a large viticultural area based on geographical features which affect viticultural features, ATF recognizes that the distinctions between a small area and its surroundings are more refined than the differences between a large area and its surroundings. It is possible for a large viticultural area to contain approved viticultural areas, if each area fulfills the requirements for establishment of a viticultural area.

Miscellaneous

ATF does not want to give the impression by approving "Ozark Mountain" as a viticultural area that it is approving or endorsing the quality of the wine from this area. ATF is approving this area as being distinct but not better than other areas. By approving this area, ATF allows wine producers to claim a distinction on labels and advertisements as to the origin of the grapes. Any commercial advantage can only come from consumer acceptance of "Ozark Mountain" wines.

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 is not expected to have significant secondary or incidental effects on a substantial number of small entities. Further, 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.

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.

Executive Order 12291

In compliance with Executive Order 12291 of Feb. 17, 1981, the Bureau has determined that this final rule 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 geographical 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.

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.

List of Subjects in 27 CFR Part 9

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

Drafting information

The principal author of this document is Steve Simon, FAA Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

Issuance

Accordingly, 27 CFR Part 9 is amended as follows:

PART 9—AMERICAN VITICULTURAL AREAS

Paragraph A. The authority citation for Part 9 continues to read as follows:

Authority: 27 U.S.C. 205

Par. B. The table of sections in 27 CFR Part 9, Subpart C, is amended to add the title of § 9.108, to read as follows:

* * * * *

Subpart C—Approved American Viticultural Areas

Sec.	
* * * * *	
9.108	Ozark Mountain.
* * * * *	

Par. C. Subpart C of 27 CFR Part 9 is amended by adding § 9.108, which reads as follows:

§ 9.108 Ozark Mountain.

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

(b) *Approved maps.* The appropriate maps for determining the boundaries of Ozark Mountain viticultural area are 11 U.S.G.S. maps in the scale of 1:250,000. They are titled—

- (1) St. Louis, Missouri (1963, revised 1969);
- (2) Jefferson City, Missouri (1955, revised 1970);
- (3) Springfield, Missouri (1954, revised 1969);
- (4) Joplin, Missouri; Kansas (1954, revised 1974);

- (5) Tulsa, Oklahoma; Arkansas; Missouri; Kansas (1958, revised 1973);
- (6) Fort Smith, Arkansas-Oklahoma (1978);
- (7) Russellville, Arkansas (compiled in 1954);
- (8) Memphis, Tennessee; Arkansas; Missouri (1953, revised 1978);
- (9) Poplar Bluff, Missouri; Arkansas (1957, revised 1978);
- (10) Paducah, Kentucky; Illinois; Missouri; Indiana (1949, revised 1969); and
- (11) Rolla, Missouri; Illinois (1954, revised 1969).

(c) *Boundary*—(1) *General.* The Ozark Mountain viticultural area is located in Missouri, Oklahoma, and Arkansas. The starting point of the following boundary description is the point at which the Missouri River joins the Mississippi River north of St. Louis, Missouri (on the St. Louis map).

(2) *Boundary Description*—(i) The boundary proceeds from the starting point westward along the Missouri River until it meets the Osage River;

(ii) Then further westward along the Osage River (flowing through Lake of the Ozarks and the Harry S. Truman Reservoir) until it passes adjacent to Missouri Highway 82 in Osceola, Missouri (on the Jefferson City map);

(iii) Then southwestward along Missouri Highway 82 until it intersects U.S. Highway 54 in Eldorado Springs, Missouri (on the Joplin map);

(iv) Then westward along U.S. Highway 54 until it intersects U.S. Highway 71 near Nevada, Missouri;

(v) Then southward along U.S. Highway 71 until it intersects Interstate Highway 44, approximately 5 miles south of Carthage, Missouri;

(vi) Then westward and southwestward along Interstate Highway 44 into the State of Oklahoma, and continuing southwestward until Interstate Highway 44 crosses the Neosho River near Miami, Oklahoma (on the Tulsa map);

(vii) Then southward along the Neosho River (flowing through the Lake of the Cherokees, Lake Hudson, and Fort Gibson Lake) until it flows into the Arkansas River, approximately 2 miles west of Fort Gibson, Oklahoma (on the Fort Smith map);

(viii) Then southward and eastward along the Arkansas River (flowing through the Robert S. Kerr Lake) into the State of Arkansas, and continuing eastward until the Arkansas River is joined by Vache Grasse Creek, approximately 4 miles east of Barling, Arkansas;

(ix) Then southeastward and southwestward following Vache Grasse Creek to the place where it is crossed by Arkansas Highway 10, near Greenwood, Arkansas;

(x) Then westward along Highway 10 to U.S. Highway 71

(Note: Highway 10 is the primary highway leading from Greenwood to Hackett, Arkansas);

(xi) Then southward and eastward along Highway 71 until it crosses Rock Creek;

(xii) Then northeastward along Rock Creek to Petit Jean Creek;

(xiii) Then generally northeastward and eastward along Petit Jean Creek until it becomes the Petit Jean River (on the Russellville map);

(xiv) Then generally eastward along the Petit Jean River, flowing through Blue Mountain Lake, until the Petit Jean River joins the Arkansas River;

(xv) Then generally eastward along the Arkansas River to Cadron Creek;

(xvi) Then northeastward and eastward along Cadron Creek, for about 2½ miles, until it passes under U.S. Highway 64, approximately 3½ miles west of Conway, Arkansas;

(xvii) Then eastward along U.S. Highway 64 until it intersects U.S. Highway 67, near Beebe, Arkansas (on the Memphis map);

(xviii) Then northeastward along U.S. Highway 67 into the state of Missouri, then northward until U.S. Highway 67 intersects U.S. Highway 60, in Poplar Bluff, Missouri (on the Poplar Bluff map);

(xix) Then eastward along U.S. Highway 60 until it crosses the western boundary of Stoddard County

(Note: Here that boundary is the St. Francis River);

(xx) Then northward, northeastward, and eastward along the boundary of Stoddard County until it joins the southern boundary of Cape Girardeau County (on the Cape Girardeau map);

(xxi) Then northeastward along the Cape Girardeau county boundary until it meets the Mississippi River south of Cape Girardeau, Missouri;

(xxii) Then northward along the Mississippi River to the starting point.

Signed: June 10, 1986.

Stephen E. Higgins,
Director.