

However, personnel from other offices of the Bureau participated in developing this Treasury decision.

List of Subjects

27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, and Wine.

27 CFR Part 5

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, and Packaging and containers.

27 CFR Part 7

Advertising, Consumer protection, Customs duties and inspection, Imports, and Labeling.

Authority and Issuance

For the reasons discussed in the preamble, TTB amends 27 CFR Parts 4, 5, and 7 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

1. The authority citation for 27 CFR Part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

2. Section 4.39 is amended by revising paragraph (h) to read as follows:

§ 4.39 Prohibited practices.

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(h) *Health-related statements.* (1) *Definitions.* When used in this paragraph (h), terms are defined as follows:

(i) *Health-related statement* means any statement related to health (other than the warning statement required by § 16.21 of this chapter) and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, wine, or any substance found within the wine, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, wine, or any substance found within the wine, as well as health-related directional statements. The term also includes statements and claims that imply that a physical or psychological sensation results from consuming the wine, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the wine, alcohol, or any substance found within the wine, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between wine, alcohol, or any substance found within the wine, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption.

(2) *Rules for labeling.* (i) *Health-related statements.* In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(ii) *Specific health claims.* (A) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a wine label. If FDA determines that the use of such a labeling claim is a drug claim that is not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, TTB will not approve the use of that specific health claim on a wine label.

(B) TTB will approve the use of a specific health claim on a wine label only if the claim is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption is presumed misleading unless it—

(A) Directs consumers in a neutral or other non-misleading manner to a third party or other source for balanced information regarding the effects on health of wine or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(2) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

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3. Section 4.64 is amended by revising paragraph (i) to read as follows:

§ 4.64 Prohibited practices.

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(i) *Health-related statements.* (1) *Definitions.* When used in this paragraph (i), terms are defined as follows:

(i) *Health-related statement* means any statement related to health and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, wine, or any substance found within the wine, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, wine, or any substance found within the wine, as well as health-related directional statements. The term also includes statements and claims that imply that a physical or psychological sensation results from consuming the wine, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the wine, alcohol, or any substance found within the wine, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between wine, alcohol, or any substance found within the wine, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related