

DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau****27 CFR Parts 4, 5, and 7**

[TTB T.D.–1; Ref: ATF Notice Nos. 884, 892, and 896]

RIN: 1512–AB97

Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages (99R–199P)

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

ACTION: Final rule, Treasury decision.

SUMMARY: TTB is amending the regulations to prohibit the appearance on labels or in advertisements of any health-related statement, including a specific health claim, that is untrue in any particular or tends to create a misleading impression. A specific health claim on a label or in an advertisement is considered misleading unless the claim is truthful and adequately substantiated by scientific evidence; properly 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. In addition, TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of specific health claims on labels. If FDA determines that a specific health 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 such statement on a label.

Health-related statements that are not specific health claims or health-related directional statements will be evaluated on a case-by-case basis to determine if they tend to mislead consumers. The final rule provides that health-related directional statements (statements that direct or refer consumers to a third party or other source for information regarding the effects on health of alcohol consumption) will be presumed misleading unless those statements include a brief disclaimer advising consumers that the statement should not encourage consumption of alcohol for health reasons, or some other appropriate disclaimer to avoid misleading consumers. TTB believes that the final regulations will ensure

that labels and advertisements do not contain statements or claims that would tend to mislead the consumer about the significant health consequences of alcohol consumption.

DATES: This rule is effective June 2, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Please note: References to “ATF” are to the Bureau of Alcohol, Tobacco and Firearms as it existed before January 24, 2003. The new Alcohol and Tobacco Tax and Trade Bureau (TTB) has taken over the former ATF’s responsibilities for alcohol beverage labeling regulations.

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Authority and Issuance

I. Background

The Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e) and (f), authorizes TTB to issue regulations on the packaging, labeling and advertising of alcohol beverages in order to prohibit deception of the consumer, and to prohibit, irrespective of falsity, statements relating to analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer. The FAA Act generally requires bottlers and importers of alcohol beverages to obtain certificates of label approval prior to the bottling or importation of alcohol beverages for sale in interstate commerce. Pre-approval of advertising is not required by the FAA Act.

Regulations that implement the provisions of section 205(e) and (f), as they relate to the labeling and advertising of wine, distilled spirits, and malt beverages, are set forth in Title 27, Code of Federal Regulations (CFR), parts 4, 5, and 7, respectively. These current regulations prohibit the appearance on labels or in advertisements of any statement, design, representation, pictorial representation, or device representing that the use of wine, distilled spirits, or malt beverages has curative or therapeutic effects if the representation is untrue in any particular or tends to create a misleading impression. This standard originated more than 60 years ago with the initial labeling and advertising regulations issued under the FAA Act.

TTB and its predecessor agencies have historically taken a very strict view of the regulatory prohibition on false or misleading curative or therapeutic claims about alcohol beverages. This strict interpretation is based on the view that “distilled spirits, wines and malt beverages are, in reality, alcoholic beverages and not medicines of any sort, * * *.” FA–129, dated January 5, 1938.

In view of the undisputed health risks associated with alcohol consumption, we and our predecessors have always taken the position that statements attributing positive effects on health to the consumption of alcohol beverages are misleading unless such statements are appropriately qualified and properly balanced. TTB views statements that make substantive claims regarding health benefits associated with alcohol beverage consumption (e.g., “moderate alcohol consumption is good for your health”) as making curative or therapeutic claims. Claims that set forth only a partial picture or representation might be as likely to mislead the consumer as those that are actually