



FROM THE OFFICE OF PUBLIC AFFAIRS

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TREASURY AND TTB LIMIT HEALTH CLAIMS RELATED TO CONSUMPTION OF ALCOHOLIC BEVERAGES

Today the Treasury Department and its Alcohol and Tobacco Tax and Trade Bureau (TTB) issued final regulations that provide new limitations on health-related statements appearing on labels of alcoholic beverages.

Over the past several years there has been a great deal of public attention and controversy over health claims related to alcoholic beverages. Some have sought permission (two entities unsuccessfully sued the government for it) to include health-related statements, other than the mandatory government warning label, on alcoholic beverage labels and in advertising for alcoholic beverages.

Although some studies have shown that moderate consumption of alcohol may have beneficial health effects for some, it is also clear that alcohol can have devastating effects on some individuals and any individual who regularly consumes large amounts. While the deleterious effects of alcohol lead many to strongly oppose allowing any statements that might encourage consumption, those concerns must be balanced against first-amendment protections of commercial free speech.

After lengthy consultation with the public and the Food and Drug Administration, the rule we are adopting provides that:

- Labels and advertisements may not contain any health claim that is untrue in any particular or tends to create a misleading impression.
- A health claim will be considered misleading unless it:
 - is truthful and substantiated by scientific or medical evidence;
 - discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and
 - outlines the categories of individuals for whom any alcohol consumption poses risks.
- "Directional" statements (statements that merely direct the consumer in a neutral manner to a third party for additional information) are presumed to be misleading in the labeling or advertising of alcoholic beverages unless accompanied by a disclaimer. The rule provides a model disclaimer: "This statement should not encourage you to drink or to increase your alcohol consumption for health reasons."
- TTB will consult with the Food and Drug Administration, 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 Food, Drug and Cosmetic Act, TTB will not approve the label. TTB will likewise evaluate specific health claims in advertisements and consult with FDA as appropriate, in reviewing advertisements that are voluntary submitted for pre-use clearance or discovered in use in the marketplace. Although advertisements are not covered by FDA's labeling regulations and are not subject to mandatory pre-approval by TTB, TTB can take administrative action and seek to have the advertisement withdrawn.

The text of the final regulations on the health claims for alcoholic beverages is attached and will be published in the Federal Register.

Related Documents:

- [Text of Final Regulations on the Health Claims](#)