

interest in using substantive health claims in the labeling or advertising of alcohol beverages. One lawyer testified in support of a 664-word labeling statement regarding effects on health and asserted that members of the wine industry had the right to make such statements; however, in response to questioning, he conceded that such a long statement would not be likely to be used on a label.

In the absence of any concrete indications of industry interest in using substantive health claims on alcohol beverage labels, there is no reason for TTB to draft a model health claim for use by industry members. Discussions of whether the regulations would unduly burden the industry's ability to use qualified and truthful health claims in the labeling of alcohol beverages will be better informed if and when industry members submit such statements to TTB for review. Nothing in the regulation itself indicates that the requirements for qualification and balance are unduly burdensome. Furthermore, it must be concluded that the length of any required disclaimers and qualifications are directly related to the serious health risks associated with alcohol consumption, rather than any desire by the Government to suppress speech. In particular, the comparison made by CEI and CA with claims regarding diets low in saturated fat and cholesterol or diets low in sodium is not persuasive in the absence of any suggestion that such diets are associated with the types of documented health risks associated with alcohol consumption. Accordingly, TTB concludes that the requirements of the regulations do not unduly burden speech about the effects on health of alcohol consumption.

Because the directional statements do not make substantive health claims, but instead have been interpreted as implicitly encouraging the consumption of alcohol for health reasons, TTB does not believe it is necessary to require the same level of detail in the disclaimers required to ensure that such statements do not mislead consumers. In addition, there clearly is interest on the part of several industry members in using the directional statements. Accordingly, we have provided a model disclaimer that may be used by industry members in conjunction with such directional statements in order to avoid misleading consumers. This one-sentence disclaimer is not overly burdensome, and complies with the court cases allowing the Government to mandate disclosures necessary to prevent consumer deception. TTB will consider other disclaimers on a case-by-case basis.

Accordingly, the final rule is in accordance with the case law under the commercial speech doctrine. Because the rule does not ban any speech, but merely sets forth the type of qualification, detail, and disclosure required in order to set forth a non-misleading health-related statement in the labeling or advertising of alcohol beverages, the rule is completely consistent with the First Amendment protection accorded truthful and non-misleading commercial speech. On the other hand, the rule is also consistent with TTB's statutory responsibility to protect consumers from misleading commercial speech regarding the serious effects on health of alcohol consumption.

XX. Final Rule

Accordingly, this final rule amends the regulations to provide that labels and advertisements may not contain 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 an alcohol beverage label or advertisement will be considered misleading unless it 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 alcohol consumption poses risks. This information must appear as part of the specific health claim and, in the case of advertising, must also appear as prominent as the specific health claim. In addition, TTB will consult with 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 FFDC Act, TTB will not approve the use of such statement on a label.

The final rule provides that a health-related statement that is not a specific health claim or a health-related directional statement will be allowed in the labeling or advertising of alcohol beverages only if TTB determines that the claim is not untrue in any particular and does not tend to create a misleading impression as to the effects on health of alcohol consumption. We will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or other qualifying statement to dispel any misleading impression created by the health-related statement.

With regard to the "directional" statements approved by ATF in 1999, we recognize that the producers of alcohol beverages may have a protected right under the First Amendment to convey the message on labels and in advertisements that consumers should refer to their doctors or the Government's Dietary Guidelines for additional information about the effects on health of alcohol consumption, as long as that message is conveyed in a fashion that does not mislead consumers about the health consequences of alcohol consumption. As discussed above, TTB has also determined that without disclaimers, the directional statements approved in 1999 tended to mislead consumers about the health consequences of alcohol consumption.

Accordingly, the final rule provides that a health-related directional statement is presumed misleading unless it 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 alcohol consumption and includes as part of the health-related directional statement a brief disclaimer stating that the statement should not encourage consumption of alcohol for health reasons, or some other appropriate disclaimer to avoid misleading consumers.

As a clarifying change, the final rule uses the term "health-related statement" instead of "curative or therapeutic claim." However, the definition of a "health-related statement" in the final rule incorporates ATF's historic position on what constitutes a statement of a curative or therapeutic nature, as set forth in the preamble of its final rule concerning the labeling and advertising regulations under the FAA Act (T.D. ATF-180, 49 FR 31667; August 8, 1984). Accordingly, a health-related statement includes any claim of a curative or therapeutic nature that, expressly or by implication, suggests a relationship between the consumption of alcohol, wine, distilled spirits, malt beverages, or any substance found within the alcohol beverage, and health benefits or effects on health. The term "health-related statement" also includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, wine, distilled spirits, malt beverages, or any substance found within the alcohol beverage, 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 wine, distilled spirits, or