

stated that if the advertising materials also contained editorializing, advertising slogans, or exhortations to consume the product, ATF would evaluate the additional text to determine whether or not the advertisement presented a balanced picture of the risks associated with alcohol consumption. In addition, ATF stated that the use of buttons, shelf talkers (additional product information placed on the retail shelf), table tents, and similar items that excerpt any portion of the NIAAA publication, contain health slogans or other inferential statements drawn from this publication, or are based on any other publication or article citing the health benefits of alcohol consumption, would be closely scrutinized to determine if they presented a balanced picture of the risks associated with alcohol consumption.

ATF reminded industry members in Industry Circular 93-8 that substantive health claims on labels are considered to be misleading unless they are properly qualified, present all sides of the issue, and outline the categories of individuals for whom any positive effects on health would be outweighed by numerous negative effects on health. Finally, ATF stated that it intended to initiate rulemaking on this issue; however, pending rulemaking, ATF would continue to evaluate claims in labeling and advertising on a case-by-case basis.

#### **IV. Role of Other Federal Agencies With Respect to Specific Health Claims and Other Health-Related Statements**

While TTB now has primary jurisdiction over the labeling and advertising of alcohol beverages, under certain circumstances the labeling and advertising of alcohol beverages may also be subject to the jurisdiction of the Food and Drug Administration (FDA) or the Federal Trade Commission (FTC). For example, since certain wine products containing less than 7 percent alcohol by volume are not wines subject to the FAA Act, the labeling of such products generally falls within FDA's jurisdiction. ATF always utilized, as TTB does now, the scientific and public health expertise of FDA in approving ingredients in alcohol beverages, requiring label disclosure of certain substances, and identifying adulterated alcohol beverages that are deemed mislabeled.

By letter dated April 9, 1993, FDA advised ATF that certain curative, therapeutic, or disease-prevention claims for an alcohol beverage might place the product in the category of a drug under the Federal Food, Drug and Cosmetic Act (FFDC Act), 21 U.S.C.

321(g)(1)(B). FDA evaluates health claims on food labels pursuant to its authority under the FFDC Act, as amended by the Nutrition Labeling and Education Act (NLEA), Pub. L. 101-535 (1990). The law provides that a food product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with certain procedures mandated by FDA. 21 U.S.C.

343(r)(1)(B). FDA's regulations provide that FDA will approve a health claim when it determines, "based on the totality of publicly available scientific evidence" that there is "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 CFR 101.14(c).

FTC's general jurisdiction over advertising extends to alcohol beverages. In a policy statement published in the **Federal Register** on June 1, 1994 (59 FR 28394), FTC stated that it is necessary to examine "whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community." The FTC policy statement stated that an unqualified health claim in the advertising of a food was likely to be deceptive if the food also contained a nutrient that increased the risk for another disease or health-related condition, and the risk-increasing nutrient was closely related to the subject health claim.

#### **V. Fourth Edition of the Dietary Guidelines for Americans (1995)**

The Fourth Edition (1995) of the "Dietary Guidelines for Americans" was published by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) in 1996. This edition of the Guidelines contained a detailed discussion of the health consequences of alcohol consumption.

The 1995 Guidelines acknowledged that "[c]urrent evidence suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals." The Guidelines then went on to discuss the "serious health problems" caused by higher levels of alcohol consumption, including increased risk for high blood pressure, stroke, and heart disease.

The 1995 Guidelines recommended that if adults chose to drink alcohol beverages, they should consume them only in moderation. The term

"moderation" was defined as no more than one drink per day for women and no more than two drinks per day for men. However, the 1995 Guidelines stressed that many people should not drink alcohol beverages at all, including children and adolescents, women who are trying to conceive or who are pregnant, individuals who plan to drive or take part in activities that require attention or skill, and individuals using prescription and over-the-counter medications. Finally, the 1995 Guidelines suggested that individuals of any age who could not restrict their drinking to moderate levels should not drink at all.

#### **VI. Competitive Enterprise Institute Petition**

On May 9, 1995, the Competitive Enterprise Institute (CEI) submitted a petition asking ATF to issue a rule allowing alcohol beverage labels and advertisements to carry statements regarding the purported benefits of moderate alcohol consumption. More specifically, CEI proposed that ATF issue a rule specifically allowing the following statement to appear on labels and in advertisements: "There is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of heart disease." By letter dated November 10, 1995, CEI submitted a survey purporting to show that less than 42 percent of the general public was "aware of the medical benefits of moderate consumption."

By letter dated January 13, 1997, ATF denied CEI's rulemaking petition. ATF determined that CEI's proposed claim was not appropriately qualified, in that it did not define the categories of individuals for whom there would be no appreciable benefits (such as younger individuals already at low risk of heart disease), or individuals for whom there would be significant risks associated with moderate alcohol consumption (such as recovering alcoholics and persons otherwise at risk for alcohol abuse, or people with certain medical conditions). The claim was not balanced, in that it did not explain the significant risks associated with higher levels of alcohol consumption, as well as the potential risks of moderate alcohol consumption for certain individuals. ATF found that the claim, taken in isolation, would tend to mislead the consumer about the significant health consequences of alcohol consumption.

Before ATF had issued its denial of CEI's petition, CEI had filed suit (October 29, 1996) in the United States District Court for the District of Columbia, challenging ATF's delay in