

particular thing, and I would support their First Amendment right to utilize it. It's going to be up to them to find people that are, in fact, going to use it." (*Id.* at page 167).

C. Decision

After careful consideration of the record, TTB finds that the comments and testimony on this issue establish that the use of health claims in the labeling or advertising of alcohol beverages has the potential to mislead consumers as to the very serious health consequences associated with alcohol abuse and consumption. In particular, TTB finds that the rulemaking record overwhelmingly supports the conclusion that the type of detail, qualification, and balance required by the proposed rule would be necessary to avoid misleading consumers about the serious health risks associated with alcohol consumption.

Based on the comments on this issue, however, TTB is adopting certain changes to the final rule to set forth more specifically how a substantive health claim would comply with the requirements of the regulation. For example, TTB agrees with the NCADD comment that it has not been proven that alcohol itself lowers the risk of heart disease in certain people; this comment is consistent with the 1999 "Alcohol Alert" published by NIAAA. The 2000 Dietary Guidelines state only that "[d]rinking in moderation may lower risk for coronary heart disease, mainly among men over age 45 and women over age 55." The final rule provides that a specific health claim would not be approved unless it is truthful and adequately substantiated by scientific or medical evidence. Thus, TTB would not approve any claim implying that alcohol consumption itself caused a reduced risk of heart disease in the absence of scientific or medical evidence substantiating such a claim.

TTB also agrees with those commenters who suggested that the effects on health of alcohol consumption vary from person to person, and that any labeling or advertising statement that failed to take this into account would mislead consumers. Consistent with the 2000 Dietary Guidelines, many commenters noted that moderate consumption provided little, if any, health benefit for younger people, who are at low risk of heart disease. As noted above, the Dietary Guidelines provide that "[d]rinking in moderation may lower risk for coronary heart disease, mainly among men over age 45 and women over age 55."

In consideration of these comments, the final rule specifically provides that a claim will not be approved unless it is sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies. For example, assuming that the evidence continues to indicate that the potential health benefits associated with moderate alcohol consumption are mainly associated with men over age 45 and women over age 55, then the claim would have to specifically set forth this qualification. Furthermore, the concerns expressed in the comments regarding the definition of the term "moderate" would also be addressed by requiring, where necessary, sufficient detail in the claim itself regarding the meaning of this term. This level of detail could include specific information as to what constitutes "moderate" levels of consumption, possibly including separate definitions for men, women, and the elderly.

Many commenters suggested that there are safer ways to reduce the risk of heart disease without the negative health consequences associated with alcohol consumption. Again, this is a point noted in the 2000 Dietary Guidelines, which remind consumers that "there are other factors that reduce the risk of heart disease, including a healthy diet, physical activity, avoidance of smoking, and maintenance of a healthy weight." In reviewing whether a health claim tends to mislead consumers, TTB will certainly consider whether the health claim misstates the role played by these factors in reducing one's risk of heart disease.

Several commenters suggested that any health claim might be misinterpreted by alcoholics and other abusers of alcohol as a rationalization for their own consumption levels. TTB recognizes the possibility that certain consumers will selectively interpret data regarding the health consequences of alcohol consumption to justify their own behavior. We believe that summary health benefit claims that do not disclose the adverse health consequences of alcohol consumption would be particularly susceptible to this type of misinterpretation. We recognize the possibility that certain abusers of alcohol may use information regarding the potential cardiovascular benefits of alcohol consumption to justify alcohol abuse that clearly poses significant health risks. However, it is our conclusion that the best way to prevent this type of misinterpretation of a health claim, by both alcohol abusers as well as consumers who do not abuse alcohol, is to require detailed information regarding the health risks associated

with various levels of alcohol consumption.

Accordingly, the final rule provides that a specific health claim must adequately disclose the health risks associated with both moderate and heavier levels of alcohol consumption. It is misleading to imply that moderate alcohol consumption confers only health benefits; the administrative record establishes that there are significant risks associated with moderate consumption, including an increased risk of certain cancers. Even if a claim is made regarding only moderate consumption, consumers should be advised of the health risks of heavier levels of alcohol consumption. The record reveals that a high percentage of the alcohol consumed in this country is consumed at levels that exceed "moderate drinking." The Marin Institute comment states that alcohol is consumed at heavy levels (3 or more drinks per day, or more than 5 drinks at one time) in 78 percent of all drinking occasions. (Comment 324). Furthermore, Dr. Criqui testified that half of all the alcohol consumed in the United States is consumed by the 10% of men and the 5% of women who are alcohol-dependent. (May 23, 2000; San Francisco, CA, page 57). Finally, a study submitted by CEI and CA noted that "[i]n the United States, less than 10% of the population reports drinking more than two drinks per day, the cutoff for 'heavy drinking' in national survey research. This means that 'moderate' drinkers, because of their much greater numbers, probably account for well over half of all alcohol problems, a finding that led researchers at the Institute of Medicine to observe in a groundbreaking report that 'if all the clinically diagnosed alcoholics were to stop drinking tomorrow, a substantial fraction of what we understand as alcohol problems would still remain.'"¹³ These statistics make it clear that a specific health claim touting the potential health benefits of moderate alcohol consumption would be misleading without a referral to the health risks associated with both moderate and higher levels of alcohol consumption.

In addition, the administrative record establishes that there are certain categories of individuals for whom any alcohol consumption at all is not recommended. Accordingly, the final rule provides that any specific health claim must outline the categories of individuals for whom any levels of alcohol consumption may cause health risks. The Beer Institute commented that ATF's proposed standard on this issue made it unclear whether "disclaimers