

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

false. A claim that is supported by scientific evidence might still mislead the consumer without appropriate qualification and detail. Any such claim is considered misleading unless it is properly qualified and balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive effects on health would be outweighed by numerous negative effects on health.

II. Health Consequences of Alcohol Consumption

The risks associated with alcohol consumption are well documented. In Notice No. 884, ATF summarized these risks as set forth in an article by Charles H. Hennekens, M.D. as follows:¹

The hazards of heavy alcohol consumption are clear and substantial and have far-reaching health and social consequences. Alcohol is the second leading cause of preventable deaths in the United States as well as most industrialized countries, second only to cigarette smoking. Drinking increases the risk of cancer of the liver, mouth, tongue, and esophagus and has been implicated as a cause of 3 to 5 percent of all cancer deaths. Heavy alcohol consumption is also associated with increased risks of hemorrhagic stroke and cardiomyopathy, and it predisposes to hepatic cirrhosis, the ninth most common cause of death in the United States. In pregnant women, heavy alcohol consumption is associated with fetal alcohol syndrome. Alcohol drinking is also implicated in over 40 percent of all fatal traffic crashes, which are a chief cause of premature deaths in younger people, and it is associated with suicides, industrial accidents, sex crimes, robberies, and murders. It is estimated that 14 million U.S. residents suffer from alcohol abuse and dependence, and 76 million are affected by its presence in a family member. (Citations omitted).

It is true that heavier levels of alcohol consumption cause many of these health risks. It is also true that there are millions of Americans with alcohol dependency problems who find themselves unable or unwilling to control their consumption of alcohol. Given the serious health risks associated with higher levels of alcohol consumption, and given the fact that most medical studies agree that the effects of moderate consumption differ from individual to individual, it was ATF's longstanding, and is now our, position that any claim associating health benefits with moderate alcohol consumption must be carefully evaluated to ensure that it does not mislead the consumer about the various health consequences related to the consumption of alcohol beverages.

Prior to engaging in this rulemaking, ATF recognized that there were several scientific studies establishing a link

between moderate alcohol consumption and a reduced risk of coronary artery disease ("CAD").² However, it was ATF's conclusion that there was not significant scientific evidence to support an unqualified conclusion that moderate alcohol consumption has net health benefits for all or even most individual consumers. Some studies have suggested that only older drinkers will accrue any net health benefits from moderate alcohol consumption.³ This is because younger individuals have such a low risk for coronary artery disease, and are much more likely to be at risk from alcohol consumption, even at lower levels. This difference in risk factors has been explained as follows:⁴

The net outcome of all-cause mortality associated with a certain alcohol consumption level therefore also depends on the drinker's absolute risk of dying from these various causes. Accordingly, older people—who are at high absolute risk of coronary heart disease and ischemic stroke and at low risk for injury, cirrhosis, and other alcohol-related diseases—are most likely to benefit from low levels of alcohol consumption. In contrast, for men and women under age 40, who have relatively low absolute risk of dying from strokes, heart disease, and alcohol-related diseases but a high absolute risk of dying from injury, all-cause mortality will increase even at relatively low alcohol-consumption levels. * * *. Finally, the absolute risk of death from injury or coronary heart disease is lower in young women than in young men, leading to an increase in all-cause mortality even in young women who are light drinkers (less than two drinks every 3 days) compared with abstainers. (Citations omitted).

Overall, the available scientific literature establishes that there may be serious health risks associated with heavy as well as moderate alcohol consumption, depending on the individual.⁵

III. Industry Circular 93-8

On August 2, 1993, ATF published Industry Circular 93-8. The circular generally restated ATF's longstanding position regarding misleading curative and therapeutic claims. ATF explained that claims that set forth only a partial picture, representation, or truth might be as likely to mislead the consumer as those that are actually false. Thus, a statement that attributed health benefits to the moderate consumption of alcohol beverages, even if backed up by medical evidence, might have an overall misleading effect if such statement was not properly qualified, did not give all sides of the issue, and did not outline the categories of individuals for whom any such positive effect would be outweighed by numerous negative effects on health.

ATF also explained that its policy regarding health claims on labels had been reinforced by the 1988 enactment of the Alcoholic Beverage Labeling Act (ABLA), 27 U.S.C. 213 *et seq.* The ABLA contains a declaration of policy and purpose which states that the Congress finds that "the American public should be informed about the health hazards that may result from the consumption or abuse of alcoholic beverages, and has determined that it would be beneficial to provide a clear, nonconfusing reminder of such hazards, and that there is a need for national uniformity in such reminders in order to avoid the promulgation of incorrect or misleading information and to minimize burdens on interstate commerce." 27 U.S.C. 213. As a result of this concern, the ABLA requires that any alcohol beverage container held for sale or distribution in the United States must bear the following statement on the label:

Government Warning: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

It is clear that one of the purposes of the ABLA was to avoid confusing the American public about the health hazards associated with the consumption of alcohol beverages. In order to effectuate this goal, Congress prescribed specific language that must appear on the labels of alcohol beverage containers. To the extent that the overall message of any health claim is inconsistent with the message of the Government warning statement, then it may result in label information that is confusing and could mislead the consumer, and would thus be prohibited under the FAA Act.

In Industry Circular 93-8, ATF further noted that other Federal agencies, such as the Food and Drug Administration and the Federal Trade Commission, might have jurisdiction over certain aspects of advertising and labeling issues involving health claims. We will address this issue further in section IV ("Role of Other Federal Agencies with Respect to Specific Health Claims and other Health-Related Statements").

ATF also stated that the distribution of advertising materials that included the full text of the April 1992 edition of "Alcohol Alert," a publication of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), would not be in violation of current regulations. This NIAAA publication provides a comprehensive discussion of the health consequences of moderate alcohol consumption. The industry circular

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

acting on its petition. In 1997, CEI amended its complaint to challenge ATF's denial of the rulemaking petition. CEI also alleged that ATF had a "de facto" ban on the use of health claims, which violated the First Amendment and the FAA Act. In 1998, the district court granted the Government's motion for summary judgment on CEI's challenge to the denial of its rulemaking petition. Both parties filed motions for summary judgment on the remaining issues.

VII. Other Health-Related Statements on Alcohol Beverage Labels

On February 4, 1999, ATF approved two applications for certificates of label approval bearing directional health-related statements directing consumers to the Dietary Guidelines or their family doctor for information about the "health effects of wine consumption." ATF approved those labels based on its determination that the statements were not substantive health claims, but instead were neutral statements directing consumers to third parties for additional information regarding the effects on health of alcohol consumption. The first approved labeling statement read as follows:

The proud people who made this wine encourage you to consult your family doctor about the health effects of wine consumption.

The second labeling statement read as follows:

To learn the health effects of wine consumption, send for the Federal Government's *Dietary Guidelines for Americans*, Center for Nutrition Policy and Promotion, USDA, 1120 20th Street, NW., Washington, DC 20036 or visit its web site: <http://www.usda.gov/fcs/cnpp.htm>.

Prior to being approved, the two applications received a great deal of public attention. In July of 1997, both HHS and FTC urged ATF not to approve the labels until a consumer survey was conducted. In that same month, Senators Robert Byrd and Strom Thurmond wrote to the Secretary of the Treasury, also raising several concerns about the proposed labeling statements. ATF also received several letters from public health organizations concerned that the labels would encourage consumers to consume alcohol beverages for health reasons. In view of these concerns, ATF decided to defer final action on the labels pending the completion of a consumer survey by the Center for Substance Abuse Prevention (CSAP), a component of HHS.

In January of 1998, CSAP transmitted to ATF the main findings from its consumer survey. The survey found that most subjects reported that they do not

read wine labels, and that neither of the two labeling statements would likely induce wine drinkers to alter their drinking pattern, quantitatively or otherwise. However, several members of the focus groups reported that information about the positive effects on health of wine consumption from the media had led them to increase their wine intake.

While the CSAP survey did not establish that the labeling statements would influence the drinking patterns of wine drinkers, it did indicate that heavy drinkers may justify or increase their consumption levels based on their independent understanding of information regarding the alleged health benefits of moderate consumption. Furthermore, the survey established that consumers would be no more likely to seek additional health information after reading the proposed labeling statements.

Based on the evidence before it, including the consumer survey conducted by CSAP, ATF concluded that there was insufficient evidence in the record to establish that the directional statements tended to mislead consumers about the effects on health of alcohol consumption. Accordingly, the labels were approved.

The approval of these labels generated considerable interest from Federal health officials, members of Congress, and public advocacy groups, who expressed concern about consumer perception of the label statements. Of particular note, former Surgeon General David Satcher expressed concern that people might draw an incorrect message from these labels.

Moreover, ATF became aware of a number of press accounts interpreting the directional statements as actual health claims about the benefits of alcohol consumption. For example, on February 5, 1999, the "Wall Street Journal" wrote that the expected decision to approve the labels would allow "wine producers to put labels on bottles that point to the potential health benefits of their product." On February 5, 1999, the Associated Press reported the decision as follows: "Scientific studies have suggested it, and now winemakers finally may get a chance to tout it through their labeling: A glass or two of the grape each day could be good for you." On February 6, 1999, the "Los Angeles Times" reported that "[t]he federal government approved changes Friday that will allow winemakers for the first time to tout on labels the connection between drinking wine and better health." That same date, the "Washington Post" reported that ATF had "decided that winemakers may add

another label to the bottle to encourage consumers to learn more about the possible benefits of drinking wine." In an article dated February 9, 1999, the "San Francisco Examiner" stated that ATF's decision "would allow winemakers to carry bottle labels suggesting consumers check with their doctors or the government's nutritional guidelines on the possible health benefits of wine."

VIII. Notice of Proposed Rulemaking

On October 25, 1999, ATF invited comments on its current policy on health claims and health-related statements by publishing the policy as a proposed regulation in the **Federal Register** (Notice No. 884; 64 FR 57413). As proposed, labels or advertisements could not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, representing that consumption of alcohol beverages has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of an alcohol beverage would be misleading unless such claim was properly qualified and balanced, sufficiently detailed and specific, and outlined the categories of individuals for whom any positive effects on health would be outweighed by numerous negative effects on health.

ATF also sought comments on whether even balanced and qualified health claim statements should be prohibited because the negative consequences of alcohol consumption are so serious as to make any health-related statement on labels or in advertisements inherently misleading. In addition, ATF sought comments on whether health-related directional statements such as those approved in February 1999 tend to mislead consumers about the health consequences of alcohol consumption.

The comment period for Notice No. 884, initially scheduled to close on February 22, 2000, was extended until June 30, 2000, pursuant to Notice No. 896. (See following section, "Notice of Hearings.")

IX. Notice of Hearings

On December 9, 1999, ATF announced in a press release that after the close of the comment period, it would hold public hearings on the issue of health claims in the labeling and advertising of alcohol beverages. ATF stated that the hearings would provide it with a comprehensive record on

which to base final regulations on health claims.

Because it was seeking public comments on this very issue, ATF announced that it would suspend action on any new applications for label approval bearing similar health-related directional statements pending the completion of the rulemaking proceeding. ATF noted that due to the adverse consequences of alcohol consumption, it was concerned about any risk of misperception resulting from the two approved statements.

On February 28, 2000, ATF published a notice in the **Federal Register** announcing the dates and locations of five hearings that it planned to hold concerning the proposed regulations (Notice No. 892; 65 FR 10434). ATF subsequently canceled the hearings that were scheduled for Atlanta, Chicago, and Dallas, due to the low number of requests to present oral comments in those locations (Notice No. 896; 65 FR 24158). In addition, the hearings scheduled for Washington, DC and San Francisco, California, were limited to two days each. The hearing in Washington, DC was held on April 25–26, 2000, and the hearing in San Francisco was held on May 23–24, 2000. ATF also extended the close of the comment period regarding Notice No. 884 from February 22, 2000, to June 30, 2000. Written comments addressing testimony presented at the hearings could also be submitted up until June 30, 2000.

X. Recent Developments

A. 1999 Alcohol Alert

In 1999, NIAAA published an “Alcohol Alert” on “Alcohol and Coronary Heart Disease” (No. 45–1999). In this publication, NIAAA reaffirmed that “[r]esearch has revealed an association between moderate alcohol consumption and lower risk for CHD.” (Footnote omitted). However, NIAAA cautioned that “[a]n association between moderate drinking and lower risk for CHD does not necessarily mean that alcohol itself is the cause of the lower risk. For example, a review of population studies indicates that the higher mortality risk among abstainers may be attributable to shared traits other than the participants’ nonuse of alcohol.” (Footnote omitted). NIAAA noted that “[t]he role of exercise in the alcohol-CHD association requires additional study.”

NIAAA noted that “[t]he apparent benefits of moderate drinking on CHD mortality are offset at higher drinking levels by increasing risk of death from other types of heart disease; cancer;

liver cirrhosis; and trauma, including trauma from traffic crashes. Moderate drinking is not risk free. The trade-offs between risks and benefits can be exemplified by the fact that alcohol’s anticlotting ability, potentially protective against heart attack, may increase the risk of hemorrhagic stroke, or bleeding within the brain.” (Footnotes omitted).

In a commentary that appeared with the Alert, NIAAA Director Enoch Gordis, M.D., offered the following advice with respect to the health implications of alcohol consumption:

(1) Individuals who are not currently drinking should not be encouraged to drink solely for health reasons, because the basis for health improvements has not yet been established as deriving from alcohol itself;

(2) Individuals who choose to drink and are not otherwise at risk for alcohol-related problems should not exceed the one-to two-drink-per-day limit recommended by the U.S. Dietary Guidelines; and

(3) Individuals who currently are drinking beyond the U.S. Dietary Guidelines’ recommended limits should be advised to lower their daily alcohol intake to these limits.

B. Dietary Guidelines—Fifth Edition (2000)

In the summer of 2000, USDA and HHS published the “Dietary Guidelines for Americans, 2000.” The 2000 Dietary Guidelines contain more specific guidance about alcohol consumption, and summarize the current medical evidence regarding the risks associated with alcohol consumption as follows:

Alcoholic beverages supply calories but few nutrients. Alcoholic beverages are harmful when consumed in excess, and some people should not drink at all. Excess alcohol alters judgment and can lead to dependency and a great many other serious health problems. Taking more than one drink per day for women or two drinks per day for men * * * can raise the risk for motor vehicle crashes, other injuries, high blood pressure, stroke, violence, suicide, and certain types of cancer. Even one drink per day can slightly raise the risk of breast cancer. Alcohol consumption during pregnancy increases risk of birth defects. Too much alcohol may cause social and psychological problems, cirrhosis of the liver, inflammation of the pancreas, and damage to the brain and heart. Heavy drinkers are also at risk of malnutrition because alcohol contains calories that may substitute for those in nutritious foods. If adults choose to drink alcoholic beverages, they should consume them only in moderation * * * and with meals to slow alcohol absorption.

The 2000 Dietary Guidelines also contain a discussion of the possible health benefits of alcohol consumption; however, the following excerpt from this section emphasizes that these benefits accrue primarily to older

drinkers, and that there are other ways of reducing the risk of heart disease:

Drinking in moderation may lower risk for coronary heart disease, mainly among men over age 45 and women over age 55. However, 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. Moderate consumption provides little, if any, health benefit for younger people. Risk of alcohol abuse increases when drinking starts at an early age. Some studies suggest that older people may become more sensitive to the effects of alcohol as they age.

The 2000 Dietary Guidelines recommend that if adults choose to drink alcohol beverages, they should consume them only in moderation. The term “moderation” is defined as no more than one drink per day for women and no more than two drinks per day for men. The Dietary Guidelines also conclude that for some people, even moderate drinking is not recommended. Thus, many people should not drink alcohol beverages at all, including children and adolescents; individuals of any age who cannot restrict their drinking to moderate levels; women who may become pregnant or who are pregnant; individuals who plan to drive, operate machinery, or take part in other activities that require attention, skill, or coordination; and individuals taking prescription or over-the-counter medications that can interact with alcohol.

C. Recent Developments in the CEI Litigation

On June 18, 2001, the district court granted the Government’s motion for summary judgment on the remaining issues in the CEI litigation. The court ruled that the case was not ready for judicial review given the fact that ATF was in the middle of a rulemaking proceeding on the very issues raised by CEI in the litigation. The plaintiffs appealed this decision to the Court of Appeals. On May 10, 2002, the appellate court upheld the district court’s ruling that the case was not ripe (ready) for judicial review because ATF was nearing completion of a rulemaking proceeding on the use of health claims. Thereafter, the plaintiffs filed a petition for rehearing with the Court of Appeals that was denied.

XI. Analysis of Comments Received in Response to Notice No. 884

In response to Notice No. 884, ATF received 535 comments. Comments were submitted by several United States Senators, two Federal agencies, an agency of a foreign government, consumers and consumer organizations,

medical professionals (including physicians, nurses, and local health departments), public health organizations, industry members, and others.

As previously noted, in Notice No. 884 ATF sought comments on whether the serious health risks associated with alcohol consumption meant that any health claim, even a balanced and qualified one, was inherently misleading to consumers. In response, approximately 45 commenters supported the use of substantive health claims or health-related statements in the labeling and advertising of alcohol beverages. On the other side, approximately 120 commenters opposed the use of either substantive health claims or health-related directional statements in the labeling or advertising of alcohol beverages. Many of these commenters suggested that health statements were inherently misleading when used to market alcohol beverages.

ATF specifically sought comments on whether health-related directional labeling statements such as the ones approved in February 1999 tended to mislead consumers about the health consequences of alcohol consumption. The vast majority of the commenters focused exclusively on this issue. Approximately 355 comments supported the use of health-related directional statements on alcohol beverage labels. The major issues raised by the commenters, as well as the individuals who testified at the public hearings, are summarized below.

XII. Is There a Need To Engage in Rulemaking on This Issue?

A. Issue

Four comments either opposed ATF's decision to engage in rulemaking on this issue or suggested that the notice of proposed rulemaking be withdrawn. These were comments submitted by the Beer Institute, a trade association for domestic and international brewers; the National Association of Beverage Importers (NABI), a trade association representing importers of beer, wine, and distilled spirits; the Distilled Spirits Council of the United States (DISCUS), a national trade association representing producers and marketers of distilled spirits and importers of wine; and a comment submitted jointly by CEI and Consumer Alert (CA).

DISCUS, the Beer Institute, and NABI all questioned the necessity for engaging in rulemaking on the issue of health claims and health-related statements in the labeling and advertising of alcohol beverages. (Comments 530, 396, and 522). These comments suggested that

the authorization of any directional statement on a label would be in violation of the ABLA. TTB does not agree with this legal analysis. This issue will be discussed further in section XIII.

DISCUS and Beer Institute also objected to the proposed advertising regulations. DISCUS suggested that ATF's proposal was "insurmountably vague and ambiguous. It only would serve to interfere with the rights of advertisers to engage in truthful, non-misleading speech about their products that are consumed responsibly by over a hundred million Americans." DISCUS suggested that "[a]n advertiser could run afoul of the provisions of BATF's proposed rule without making any type of curative or therapeutic claim," giving as an example an advertisement depicting attractive individuals relaxing in an enjoyable setting. The Beer Institute similarly suggested that the requirements for labeling and advertising should be separate, and that the proposed regulation complicated the existing advertising standard. The Beer Institute suggested that the current standard is readily understood and straightforward, and that instead of issuing new regulations, ATF should adopt a more formal review process of health statements on a case-by-case basis.

These commenters also suggested that large portions of the alcohol beverage industry had no interest in using health claims in the labeling or advertising of their products. For example, the Beer Institute comment suggested that there was no need to amend the malt beverage regulations, since to its knowledge, none of its constituents had ever used such claims in the past, and none had any intention to do so in the future. NABI raised similar concerns, and stated that it did not support the proposed amendment to the regulations "because any such support might imply the industry intends to make health-related statements on its labels and in its advertising." The comment from DISCUS stressed that "America's distillers do not recommend that consumers drink beverage alcohol for health reasons." (Comment 530).

CEI, a pro-market public interest group dedicated to advancing the principles of free markets and limited government, and CA, a free-market consumer advocacy group, suggested that the proposed rule should be withdrawn because the issuance of a regulation based on the proposal would restrict commercial speech in a way that violates the First Amendment. (Comment 326). These issues will be discussed further in section XIX.

B. Decision

After carefully considering the record, TTB has determined that it is important to issue a final rule on specific health claims and other health-related statements in the labeling and advertising of alcohol beverages. The rulemaking record confirms that alcohol abuse is an important public health issue. The use of health claims and health-related statements in the labeling and advertising of alcohol beverages requires a balance between a producer's First Amendment right to label and advertise its products in a truthful and non-misleading fashion and the public's right to be informed of the significant health risks associated with alcohol consumption. Specific regulations on the use of health claims and other health-related statements in the labeling and advertising of alcohol beverages will ensure that both the industry and the public are aware of the restrictions on the use of labeling and advertising statements that might tend to mislead the consumer about the serious health risks associated with alcohol consumption.

TTB recognizes that based on the administrative record, it does not appear that distillers and brewers are interested in using health claims or health-related statements in the labeling or advertising of alcohol beverages. However, as noted later in this preamble, both the Wine Institute and the American Vintners Association (AVA), two industry associations representing hundreds of wineries, supported ATF's proposed rule regarding substantive health claims. At least one individual testifying at the hearing, Mr. John Hinman, indicated that there were wineries interested in using a 664-word substantive health claim in advertising materials. The Wine Institute and AVA, as well as many individual wineries, commented in favor of allowing directional statements in the labeling of alcohol beverages. Thus, the record reflects that there may be some wineries interested in using substantive health claims in the advertising of alcohol beverages, and that many wineries are interested in using directional statements on labels. For this reason, TTB believes it is important to issue regulations that set forth the standards that must be met in the event that a specific health claim or other health-related statement is used in the labeling or advertising of alcohol beverages. As set forth later in section XVII, the same standards should apply to wines, distilled spirits, and malt beverages, even if there is no evidence that any members of the malt beverage or distilled spirits industries are

interested in using health claims or health-related statements. The rule does not require anyone to use such statements; it merely sets forth the standards that would apply in the event that an industry member wishes to use a specific health claim or a health-related statement on a label or in an advertisement.

TTB does not agree that the proposed regulations would inject uncertainty with respect to the use of advertisements that do not involve health claims or health-related statements, such as the example provided by DISCUS of an advertisement that shows people relaxing in an attractive setting. There is nothing in the proposed rule that would extend the definition of a health claim or curative or therapeutic claim to cover such advertisements. However, we agree that the lack of any definition of a "curative or therapeutic claim" or "health claim" in the proposed rule might give rise to some uncertainty as to what types of advertising claims would be covered by the regulation. Accordingly, the final rule includes definitions of the terms "health-related statement" (which includes statements of a curative or therapeutic nature), "specific health claims," and "health-related directional statements." We believe that these definitions should resolve any concerns by the commenters that the labeling or advertising regulations are intended to broaden ATF's traditional interpretation of a curative or therapeutic claim.

XIII. Does the ABLA Preclude the Use of Specific Health Claims or Other Health-Related Statements on the Labels of Alcohol Beverages?

A. Issue

Five commenters, including Senator Thurmond (Comment 526), DISCUS (Comment 530), the Beer Institute (Comment 396), NABI (Comment 522), and Remy Amerique, Inc. (Comment 531), suggested that the use of any health claims or other health-related statements on alcohol beverage labels was foreclosed by the provisions of the ABLA. They argued that it was Congress' intent to foreclose the use of any other health-related statements on alcohol beverage labels.

B. Decision

TTB does not agree with those commenters who suggested that the ABLA specifically precludes the voluntary use by industry members of any health-related statements on alcohol beverage labels other than the required warning statement. The ABLA was

enacted in 1988. Pursuant to 27 U.S.C. 215, alcohol beverage containers distributed or sold in the United States must bear a Government warning statement, which warns that alcohol consumption during pregnancy may cause birth defects; that alcohol consumption impairs one's ability to drive a car or to operate machinery; and that consumption of alcohol beverages "may cause health problems."

Some commenters argued that the ABLA provided ATF with authority to deny any statement on an alcohol beverage label that discusses the relationship between alcohol consumption and health. The ABLA provides that "[n]o statement relating to alcoholic beverages and health, other than the statement required by section 204 [27 U.S.C. 215] of this title, shall be required under State law to be placed on any container of an alcoholic beverage, or on any box, carton, or other package, irrespective of the material from which made, that contains such a container." This section of the law preempts State governments from each requiring their own version of a health warning statement on alcohol beverage containers. However, it in no way precludes producers from voluntarily placing either additional warning statements or health claims on alcohol beverage labels. *See also* 27 U.S.C. 213 (setting forth Congress' policy to ensure that the public is adequately reminded about any health hazards that may be associated with alcohol consumption or abuse, and not impeded by "diverse, nonuniform, and confusing requirements for warnings or other information on alcoholic beverage containers with respect to any relationship between the consumption or abuse of alcoholic beverages and health").

Some commenters argued that 27 U.S.C. 217 provides the exclusive method for allowing additional statements regarding alcohol consumption and health on the label. Section 217 provides that if the Secretary, after consulting with the Surgeon General, determines that there should be a change in the mandatory health warning statement, or if such statement should be deleted, he shall report such information to the Congress together with specific recommendations for necessary amendments to the ABLA. After soliciting public comments on this issue, ATF determined in 1993 that there was no need to seek changes to the required health warning statement. However, this provision applies only to the required health warning statement, not to voluntary statements that producers seek to place on alcohol

beverage labels. Thus, it is clear that the statute does not specifically preclude the voluntary use of additional health-related statements on alcohol beverage labels.

XIV. What Are the Effects on Health of Alcohol Consumption?

A. Issue

Most of the commenters who addressed this issue agreed that there was a link between moderate alcohol consumption and a reduced risk of heart disease in certain individuals. However, some commenters concluded that the risks associated with alcohol consumption greatly outweighed any purported cardiovascular benefits, while other commenters emphasized the benefits associated with moderate consumption.

CEI and CA presented a review of the medical evidence summarized by Michael Gough (Ph.D.), which concluded that most adults would benefit from moderate alcohol consumption. Dr. Gough stated that "with the exception of those well-defined groups of people who should avoid alcohol, there is clearly convincing evidence for the health benefits of moderate alcohol consumption." Dr. Gough acknowledged that individuals in their 20s and 30s do not accrue net benefits from consuming alcohol since they are at low risk for heart disease; however, he suggests that "[b]ased on understanding of the biological basis for the protective effects of alcohol, it is likely that moderate alcohol consumption in the 20s and 30s is important to the beneficial effects seen in later years."

CEI attached numerous medical studies regarding the effects on health of alcohol consumption. In most important respects, the studies were consistent with ATF's summary of the medical evidence in Notice No. 884. Several of the studies reported an association between light to moderate alcohol consumption and a reduced risk of heart disease. However, many of these same studies supported the conclusion that the health benefits of alcohol consumption do not apply to certain groups.

For example, the authors of one study began by noting that "[m]en and women who drink alcoholic beverages regularly have, in comparison with abstainers, higher death rates from injuries, violence, suicide, poisoning, cirrhosis, certain cancers, and possibly hemorrhagic stroke, but lower death rates from coronary heart disease and thrombotic stroke. The net balance of

risks and benefits is likely to differ in different age groups and populations.”⁶ (Footnotes omitted). One of the conclusions of the study is that “the balance of adverse and beneficial effects of drinking on mortality from all causes depends not only on the amount of alcohol consumed but also on age and background cardiovascular risk.”⁷

Another article noted that it has not yet been determined how alcohol reduces the risk of coronary heart disease. The authors stated that:⁸

Several possible mechanisms for a protective role of alcohol against coronary disease have been hypothesized, including alcohol-mediated increases in HDL cholesterol levels. * * * Knowledge of the basic mechanisms by which alcohol exerts a protective effect against coronary heart disease is critical to assessing the potential importance of moderate alcohol consumption to the public health, particularly if the beneficial effects of alcohol can be achieved through other interventions. Because heavy consumption of alcohol has been implicated in accidents, cirrhosis, cancer, and other adverse outcomes, the difference between drinking small-to-moderate quantities of alcohol and drinking large amounts may mean the difference between preventing and causing disease. Any clinical recommendations based on this epidemiologic evidence should therefore be cautious. (Footnotes omitted).

Among the more recent studies submitted by CEI and CA was one that focused on the effects on health of alcohol consumption on women. The authors noted that before beginning the study, it was unclear “[w]hether the apparent overall benefit of light-to-moderate alcohol intake among men” could be extrapolated to women, noting that “[a]s compared with men, women have a lower risk of coronary heart disease, attain higher blood alcohol concentrations for a given amount of alcohol consumed, and are more susceptible to alcoholic liver disease. Moreover, women who consume moderate quantities of alcohol have an increased risk of breast cancer.”⁹ (Footnotes omitted). The results of the study showed that light to moderate female drinkers had a reduced risk of heart disease, with women who drank one to three drinks per week having the lowest risk of mortality.¹⁰ However, the study concluded that “the apparent benefit of light-to-moderate alcohol consumption was mainly confined to women at greater risk for coronary heart disease, specifically older women and women with one or more coronary risk factors.”¹¹

The Wine Institute, representing over 500 California winery and associate members, also submitted summaries of several medical studies that established

a link between moderate alcohol consumption and reduced risk of cardiovascular disease (Comment 401). In its summary of these studies, the Wine Institute asserted that moderate drinkers have a 40–50 percent reduction in coronary artery disease risk compared with individuals who are abstinent, with a lower overall mortality rate as well.

As ATF stated in Notice No. 884, the serious health risks associated with alcohol consumption are well established, and ATF received many comments from public health organizations that focused on those adverse consequences. The major points made by these commenters are summarized below.

Many of the commenters focused on the serious public health risks associated with alcohol abuse. The National Council on Alcoholism and Drug Dependence, Inc. (NCADD) commented that “[w]hile most people who choose to drink do so without negative health or life consequences, there are 13.8 million Americans over the age of 18 who have problems with drinking, including 8.1 million people who are alcoholic. Millions of others, because of a family history or the addictive potential of alcohol, are at risk for developing an addiction.” (Comment 15). NCADD noted that alcohol contributes to 100,000 deaths annually, making it the third leading cause of preventable mortality in the United States, after tobacco and diet/activity patterns. While there are fewer deaths from alcohol-related causes than from cancer or heart disease, alcohol-related deaths tend to occur at much younger ages.

Some commenters focused on the cost to society associated with alcohol abuse. For example, the Center for Science in the Public Interest (CSPI) commented that “[a] substantial body of evidence has shown a positive relationship between the aggregate consumption of alcohol in society and population rates of alcohol-related diseases, accidents, criminal violence, and suicide. According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), alcohol abuse and alcoholism cost society more than \$166 billion annually and each year over 110,640 deaths have alcohol-related causes.” (Comment 400). (Footnotes omitted).

Many of the commenters set forth the serious risks associated with higher levels of alcohol consumption. NCADD noted that “[h]eavy and chronic drinking can harm virtually every organ and system in the body, and is the single most important cause of illness and death from liver disease. It is also

associated with cardiovascular diseases such as cardiomyopathy, hypertension, arrhythmias and stroke.” The Marin Institute identified similar health risks associated with alcohol consumption. (Comment 324).

Many recognized experts on the effects on health of alcohol consumption testified at the public hearings held by ATF in Washington, DC and San Francisco, California. Dr. David Satcher, former Assistant Secretary for Health and Surgeon General, testified about the public health dangers associated with alcohol consumption as follows:

Although the majority of Americans who consume alcoholic beverages do so safely, alcohol is one of the nation’s leading causes of preventable injury and premature death. Each year, over 100,000 premature deaths result from alcoholism and alcohol abuse. Alcohol represents, therefore, the third leading cause of premature death, right behind tobacco and physical inactivity. Traffic crashes involving alcohol killed more than 16,000 people in 1997, and one in four victims of violent crime report that the offender had been drinking alcohol prior to committing the crime. Fetal alcohol syndrome continues to be the leading preventable cause of mental retardation. I think we fail to appreciate that the roots of alcoholism and alcohol abuse have their origins in adolescence and that children are especially vulnerable to its dangers. Alcohol is the nation’s number one drug problem among youth, and it is involved in teen automobile crashes, homicides, and suicides, the three leading causes of teen death. (April 25, 2000; Washington, DC, pages 72–73).

Other physicians testified regarding the effects on health of alcohol consumption. Dr. Carlos Camargo, an emergency room physician and alcohol researcher, testified at the invitation of CSPI. He stated that “there is persuasive evidence that moderate alcohol consumption reduces risk of coronary heart disease in some people. There is also persuasive evidence that even moderate drinking carries significant health risks for many people.” (April 25, 2000; Washington, DC, page 94).

Dr. Michael Criqui, a physician, epidemiologist, and professor, also expressed concerns regarding the use of any health-related statement in connection with the labeling of alcohol beverages. Dr. Criqui stressed that when evaluating the potential health benefits associated with alcohol consumption, it is important to look at the effects of various diseases on the potential years of life lost before age 75. He noted that while heart disease is the single largest cause of death in developed countries, it usually occurs at older ages. Motor vehicle crashes and suicides together cause the loss of more potential years of

life in men than heart disease, and both are linked to alcohol use. In women, breast cancer and motor vehicle accidents each account for more potential years of life lost before age 75 than heart disease. (May 23, 2000; San Francisco, CA, pages 53–54).

Dr. Criqui also stressed the importance of evaluating the patterns of consumption among drinkers. He said that in the United States, about 80% of men and 70% of women drink alcohol, with 50% of drinkers reporting temporary problems with alcohol. (*Id.* at page 55). About 10% of men and 5% of women are alcoholics. Furthermore, Dr. Criqui stated 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.” (*Id.* at page 57).

Other medical professionals stressed the health benefits associated with moderate drinking for persons who do not belong in the categories of individuals for whom alcohol consumption is contraindicated. Dr. Curtis Ellison, a Professor of Medicine, testified that “science clearly indicates that moderate drinkers have much lower risk of coronary heart disease and ischemic stroke. Because these are the number one and number three causes of death, it is not surprising that moderate drinkers will live longer in the United States.” (April 26, 2000; Washington, DC, page 109). Dr. Ellison suggested that “if I am withholding from a patient information that may reduce that individual’s risk of a heart attack by 30 or 40 percent and do not tell him about it, I am doing him a disservice.” (*Id.* at page 110).

B. Decision

The evidence presented by the medical experts, as well as the studies presented with some of the comments, indicate that there are differences of opinion as to how the relative risks and benefits of alcohol consumption should be weighed. The evidence reflects a broad consensus that heavy levels of alcohol consumption pose serious health risks. The record also reflects that there is a broad consensus that certain categories of people should not consume any alcohol. With regard to those individuals for whom alcohol consumption is not contraindicated, there was some difference among the experts as to how to weigh the relative risks and benefits of moderate consumption, with some experts stressing the protection against cardiovascular disease, and other experts stressing the increased risk of injury and certain cancers.

Because TTB is not an expert on public health issues, we (and our predecessors) have generally deferred to the findings of the Department of Health and Human Services, including NIAAA, FDA, CSAP, and the Surgeon General, on issues related to the effects on health of alcohol consumption. In the case at hand, TTB finds that the evidence in the rulemaking record supports the findings of NIAAA’s 1999 “Alcohol Alert” and the 2000 Dietary Guidelines published by USDA and HHS. The main points of these findings can be summarized as follows:

- Alcohol beverages are harmful when consumed in excess, and some people should not drink at all. Excess alcohol alters judgment and can lead to dependency and many other serious problems. Heavy levels of alcohol consumption cause social and psychological problems, cirrhosis of the liver, inflammation of the pancreas, and damage to the brain and heart.
- Taking more than one drink per day for women or two drinks per day for men can raise the risk for motor vehicle accidents, other injuries, high blood pressure, stroke, violence, suicide, and certain types of cancer. Even one drink per day can slightly raise the risk of breast cancer.
- Alcohol consumption during pregnancy increases the risk of birth defects.
- Certain individuals should not drink any alcohol; for these individuals, even moderate levels of alcohol consumption may cause health risks. Included in this category are children and adolescents; individuals of any age who cannot restrict their drinking to moderate levels; women who may become pregnant or who are pregnant; individuals who plan to drive, operate machinery, or take part in other activities that require attention, skill, or coordination; and individuals taking prescription or over-the-counter medications that can interact with alcohol.
- Moderate levels of alcohol consumption are associated with a reduced risk of coronary artery disease for certain individuals, but causation has not been conclusively established.
- To the extent that moderate consumption is linked to a lowered risk for coronary heart disease, the link appears mainly among men over 45 and women over age 55. Moderate consumption provides little, if any, health benefit for younger people.
- The effects on health of alcohol consumption vary from individual to individual, depending on the individual’s health profile and history, as well as the levels of consumption.

Risk of alcohol abuse increases when drinking starts at an early age. Some studies suggest that older people may become more sensitive to the effects of alcohol as they age.

Based on the above, it is TTB’s conclusion that the medical data still supports ATF’s longstanding (and now our) position that notwithstanding the data linking moderate alcohol consumption to a reduced risk of heart disease in some individuals, there are significant health risks associated with all levels of alcohol consumption. The medical data submitted by the commenters, as well as the testimony presented by experts at the public hearings, suggest that there is a link between moderate alcohol consumption and a reduced risk of heart disease in certain individuals; however, causation has not been conclusively established. The risk/benefit ratio varies with the individual’s own health profile and the level of consumption. For example, moderate alcohol consumption confers few, if any, benefits on people at low risk for heart disease. The evidence also establishes that there are serious risks associated with higher levels of alcohol consumption, and that even moderate consumption poses health risks for certain individuals. Finally, there are certain categories of individuals for whom any level of alcohol consumption is not recommended.

XV. Are Health Claims and Health-Related Statements in the Labeling and Advertising of Alcohol Beverages Inherently Misleading?

A. Comments in Opposition to the Use of Health Claims and/or Health-Related Statements

Approximately 120 comments opposed the use of health claims and/or health-related statements (including directional statements) in the labeling and advertising of alcohol beverages. Many of these commenters, including the American Medical Association, the American Cancer Society, and the Center for Science in the Public Interest, commented in support of a complete ban on the use of such statements in the labeling or advertising of beverage alcohol. The primary arguments made by these commenters are summarized below.

1. It Has Not Been Proven That Moderate Alcohol Consumption Lowers the Risk of Heart Disease

NCADD commented that the evidence for the alleged health benefits of alcohol consumption was “far from concrete,” noting that the 1999 NIAAA report concludes that while there is “an

association between moderate drinking and a lower risk of CHD, science has not confirmed that alcohol itself causes the lower risk." "Alcohol Alert," National Institute on Alcohol Abuse and Alcoholism, No. 45, October 1999. (Comment 15). Most other commenters, however, acknowledged that there was a link or association between moderate alcohol consumption and reduced risk of heart disease in some individuals.

2. Because the Negative Health Consequences of Alcohol Consumption Outweigh the Potential Benefits, Health Claims and Health-Related Statements Are Inherently Misleading and Should Be Banned

Many of the commenters stated that health claims for alcohol beverages were inherently misleading because the health risks associated with alcohol consumption outweigh the purported cardiovascular benefits. For example, the American Cancer Society commented in favor of a ban on all health benefit claims and health-related statements in the labeling and advertising of alcohol beverages. (Comment 527). They noted that "[w]hile moderate intake of alcohol has been shown to reduce the risk of coronary heart disease in middle-aged adults, 100,000 deaths each year are attributed to alcohol-related diseases."

The American Medical Association (AMA) strongly urged ATF to reject any type of beneficial claim for alcohol products on container labels, noting that such claims would be misleading, and for many persons, inaccurate. (Comment 534). AMA stated that "[w]hile some research indicates that moderate drinking is associated with a decreased risk of some diseases, other research shows that such risks actually substantially increase for certain people."

Senator Strom Thurmond opposed the use of any health-related statements on alcohol beverage labels. (Comment 526). He testified that health claims were inherently misleading because of the serious health risks associated with alcohol consumption; because the supposed health benefits of moderate drinking have not been conclusively established; and because any explanatory statements are simply insufficient to clarify a misleading health claim. (April 25, 2000; Washington, DC, pages 14-16).

CSPI argued that health claims are inherently misleading for five reasons:

(1) There are serious health risks associated with alcohol consumption, even moderate consumption;

(2) the health benefits of moderate alcohol consumption do not apply universally, but only to a discrete segment of the population;

(3) there are many groups of people who should abstain from, or minimize, their consumption of alcohol;

(4) allowing health claims would undermine the Government warning label; and

(5) explanatory statements are insufficient to clarify a misleading health claim. (Comment 400).

CSPI noted that researchers for the Centers for Disease Control and Prevention (CDC) found that, after decreasing during the late 1980s, alcohol consumption among pregnant women in the United States began to increase after 1991, and the lead author hypothesized that the increased consumption might be due to the media attention to the reports on the health benefits of moderate drinking. At the Washington, DC hearing, Mr. George Hacker, director of CSPI's Alcohol Policies Project, testified in opposition to the use of health claims. Mr. Hacker stressed the health risks associated with even moderate alcohol consumption, and stated that "[a]lcohol is a potentially dangerous, potentially addictive, and potentially deadly drug. Any positive health statement about such a drug must be presented, if at all, only in a balanced and non-misleading manner." (April 25, 2000; Washington, DC, page 56).

On behalf of its three million members and supporters, Mothers Against Drunk Driving (MADD) commented in favor of banning any health claims or directional statements in the labeling and advertising of alcohol beverages. (Comment 20). MADD commented that "[t]he negative consequences and the risk associated with alcohol consumption greatly outweigh any purported 'health benefits.'" MADD quoted Gen. Barry McCaffrey, former Director of the Office of National Drug Control Policy, as telling an alcohol policy conference in 1997 that, "Undoubtedly, alcohol is the principal drug abuse problem in America today."

MADD also noted that in 1998, 15,935 people were killed in alcohol-related traffic crashes and an estimated 850,000 were injured. These alcohol-related crashes result in an annual cost of \$114,800,000 in the United States.

The National Association for Children of Alcoholics commented that "the health risks of alcohol far outweigh the health benefits" and advocated a complete ban on health-related claims on alcohol beverage containers. (Comment 29). This comment noted that 76 million Americans, about 43% of the

U.S. adult population, have been exposed to alcoholism in the family. Almost one in five (18%) of American adults lived with an alcoholic while growing up. Its comment also noted the negative impact of alcoholism on family and marital relationships, the association between alcoholism and violent crime and child abuse, and the devastating impact of alcoholism on the children of alcoholics.

The Marin Institute for the Prevention of Alcohol and Other Drug Problems ("Marin Institute") commented in favor of a complete ban on all health-related statements (other than the required warning statement) in the labeling and advertising of alcohol beverages. (Comment 324). The Marin Institute commented that "[s]tatements attributing positive health effects to the consumption of alcoholic beverages (as is the case with the previously approved wine labels) are misleading and potentially dangerous because media and marketing messages can be misinterpreted as public health recommendations." They stated that "[s]implistic and misleading messages about the health effects of alcohol are dangerous to the health and safety of Americans and could increase the enormous toll of alcohol-related problems in this country. Because of the evidence regarding the risks associated with alcohol consumption, alcoholic beverages should not be held to a lower standard of accountability regarding health messages than well-regulated prescription drugs. Banning all health claim-related statements on labels or in advertising of alcoholic beverages assures that public health information is accurate and free of potentially harmful misinformation."

Other public health organizations strongly urged a ban on health claims. See, Pacific Drug Policy Institute, Inc. (Comment 34); American Council on Alcohol Problems (Comment 37); and West Los Angeles Alcohol Policy Coalition (Comment 384).

Many individuals made similar comments, noting the serious health risks associated with alcohol consumption. Some shared personal experiences with alcoholism or alcohol abuse. See comments 23, 28, and 35.

Many of the individuals testifying at the public hearings also emphasized the human costs associated with alcohol abuse. For example, Barrett Duke, Ph.D., testified on behalf of the Ethics and Religious Liberty Commission, the moral concerns agency for the Southern Baptist Convention. He shared his concerns from the perspective of the faith community, and noted that "[m]ost faith communities deal with the

devastating consequences of alcohol abuse on a regular basis in their churches, missions, and benevolent ministries. * * * Families have been destroyed. Lives have been lost. Careers have been ruined. Men and women have left the ministry as a direct result of alcohol abuse. Furthermore, alcohol is often a primary contributing component to poverty, forcing faith communities to use precious limited resources to assist the alcohol abuser as well as the abuser's intended or unintended victims." (April 25, 2000; Washington, DC, page 151).

Ms. Suzanne Harrington-Cole, Chair of the Vallejo Alcohol Policy Coalition, testified in favor of a complete ban on the use of health claims on alcohol beverage containers. She stated that alcohol is present in more than 50% of all incidents of domestic violence (May 24, 2000; San Francisco, CA, page 245), and noted that "[w]e do not need a government sanction on more drinking in the name of health." (*Id.* at page 243).

3. The Issue Is Too Complex To Be Summarized on an Alcohol Beverage Label Because the Effects on Health of Alcohol Consumption Vary From Person to Person

Many of the commenters stated that a summary statement of health benefits on an alcohol beverage label would mislead consumers because the effects on health of alcohol consumption vary from person to person, based on various factors. These commenters also suggested that the issue was too complex to be summarized on an alcohol beverage label, rendering all such labeling statements inherently misleading. Thus, the American Cancer Society noted that the potential health impact of alcohol consumption varied from individual to individual, and that a "brief message on any beverage container cannot provide a consumer with adequate information to make an informed decision about drinking 'for health related reasons.'" (Comment 527).

NCADD urged ATF to "prohibit labels and advertisements that make claims regarding potential health benefits associated with the consumption of alcoholic beverages, because it would be impossible to adequately and appropriately convey the negative health consequences." (Comment 15). NCADD noted that elderly consumers have special concerns, and that NIAAA's definition of moderate drinking for women and men over the age of 65 is no more than one drink a day. They cited a study showing that among persons older than 65, moderate and heavy drinkers were 16 times more

likely than nondrinkers to die of suicide.¹²

Senator Thurmond also testified that the effects of alcohol consumption vary from individual to individual, and any clarifying statement along those lines would "have to address factors such as age, sex, family, medical history, diet, weight, and activity." (April 25, 2000; Washington, DC, page 16). MADD noted ATF's historic policy of requiring balance in health claims, and suggested that in "order to 'appropriately qualify and balance' the alleged health claim benefits with the negative consequences, the alcohol label would have to be the size of a billboard and advertising messages would be longer than the State of the Union Address." (Comment 20). Accordingly, MADD suggested that to avoid misleading consumers, such claims should be banned entirely.

The United Communities Against Drug & Alcohol Abuse commented that "[n]o brief message on any beverage container can possibly provide a consumer with adequate information to make a decision about drinking 'for health-related reasons.'" Instead, they suggested that in order to balance a health message, "consumers would need to be provided with a detailed multi-page document (similar to those now provided by manufacturers of prescription medication) in order to make [an] informed choice about whether or not a decision to consume an alcoholic-beverage for health reasons would be, on balance, a good or a bad decision." (Comment 31). The Marin Institute (Comment 324) agreed, commenting that "[d]etailed, balanced and cautionary information about potential harmful effects would be required (as it is with advertisements of prescription drugs) in order to offset the demonstrated confusion of the general public about the health effects of alcohol. The volume of information needed could hardly be legible if it were displayed on a bottle of wine or beer."

4. Even if Moderate Alcohol Consumption Is Linked to a Reduced Risk of Heart Disease, There Are Safer Ways To Achieve the Same Reduction Without the Risks Associated With Alcohol Consumption

Many commenters suggested that even if alcohol consumption resulted in health benefits for certain individuals, there were less risky ways to obtain those benefits. For example, the Central Nebraska Council on Alcoholism, Inc. (Comment 14) noted that "[t]here are simply less risky ways to attain the same health benefits that consuming small amounts of alcoholic beverages

provide to a limited group of people. It would be irresponsible for the government to allow a health-claims statement on alcoholic beverages that urge the most risk laden way of obtaining those benefits."

CSPI also suggested that there were safer methods of reducing one's risk of heart disease, stating that the "discrete category of people who may benefit from moderate drinking could also lower their risk of heart disease by other less risky alternatives, such as quitting smoking, reducing fat in the diet, getting regular exercise, taking a daily low dose aspirin, or reducing stress. All of those methods are much less likely to cause accidents or other health problems than consuming alcohol, even in moderation." (Comment 400).

The Tangipahoa Alcohol and Drug Abuse Council (Comment 24) noted that consumers often look for "the easy way out," and that many may believe that drinking alcohol will get the same benefits as an overall healthy lifestyle. The Pacific Drug Policy Institute, Inc. commented that "smoking cessation, good diet, exercise, and stress management techniques provide cardiac benefits with much lower risk of adverse consequences. When there are low risk ways to attain the health benefits attributed to wine, it would appear absurd to allow advertisement of medicinal value in high-risk alcohol consumption." (Comment 34).

Ted Miller, PhD, an economist, testified at the hearings that a more cost-effective way to obtain the purported benefits associated with consumption of wine would be to walk a mile, drink a glass of juice, or eat one cup of vegetables every day. (April 25, 2000; Washington, DC, pages 179-183).

5. Health Claims and Health-Related Messages Would Be Misconstrued by Consumers, Particularly Those With a History of Alcoholism or Who Are Susceptible to Alcohol Abuse Problems, as an Endorsement To Consume or Abuse Alcohol

Many professionals in the field of addiction medicine commented that health claims and health-related messages were likely to be misinterpreted by those most susceptible to problem drinking. Many of these commenters were particularly concerned with the risk that recovering alcoholics would use information about the purported health benefits of alcohol consumption to justify their continued use of alcohol. For example, a physician who has worked in the alcohol and substance abuse treatment field for 18 years stated that any message about purported health benefits sends the

wrong message to the public, especially the alcohol abuser or alcoholic. He expressed concern that such a message “would only encourage the alcoholic to drink more to ‘help his heart’” and feared that “many current alcoholics who are in total recovery and abstinence may use this as a justification to begin drinking alcohol again, thinking they can control it.” (Comment 381). Another doctor made a similar point, (Comment 385) as follows:

The American public has become accustomed to warning labels on harmful products * * *. A label touting health benefits of use of alcoholic beverages in controlled and low amounts, is likely to be misinterpreted by problem drinkers, especially by alcoholics, whose belief systems about their drinking distort reality with respect to the relative benefits and risks of consumption. * * * I do not deny the scientific validity of reports of health benefits of consumption of one glass of wine per day for females or two glasses of wine per day for males. However, the risk of misinterpretation by the drinking public is far greater than any public health or public information benefit that may be alleged to accrue from adding labels to products that promote health benefits from drinking.

The National Association for Children of Alcoholics (Comment 29) also suggested that health claims can lead to confusion among children of alcoholics about the role of alcohol, and can reinforce and perpetuate the denial process of the alcohol-addicted person.

6. The Use of the Term “Moderate” in a Specific Health Claim Would Be Misleading Unless the Term Is Defined

Many public health organizations commented that the use of the term “moderate” in a health claim could mislead consumers who did not understand the definition of the term. The United Communities Against Drug & Alcohol Abuse noted that “moderate” drinking was poorly defined. It noted that the Substance Abuse and Mental Health Services Administration (SAMSHA) study showed that “virtually all drinkers define their personal level of consumption as ‘moderate,’ whether they consume one drink per week or five per day.” (Comment 31). CSPI also noted that consumers had varying definitions of the term “moderate.” (Comment 400). Rather than recommending moderate consumption, CSPI suggested that any health claims should provide specific quantities of alcohol that constitute moderate consumption, including a recommendation that consumers drink no more than one drink per day.

Nancy Piotrowski, PhD, testified that she had been conducting research on alcohol consumption for the past 16

years, and is in the middle of ongoing research on the perceptions of drinkers regarding moderate alcohol consumption. She noted that previous studies had shown that perceptions of moderate drinking were clearly related to drinkers’ current drinking patterns and their history of problems relating to drinking. (May 23, 2000; San Francisco, page 37).

B. Comments in Favor of Health Claims

A few commenters specifically supported ATF’s proposal to allow qualified, detailed and balanced health claims in the labeling and advertising of alcohol beverages. One comment, from CEI and CA, specifically supported the use of summary health claim statements without qualification or disclosure of the adverse effects on health caused by alcohol consumption. Finally, approximately 45 commenters supported the general use of health claims with respect to alcohol beverages.

1. Comments in Favor of Allowing Balanced Health Claims, as Set Forth in the Proposed Rule

The comments in favor of the substantive health claim provisions of the proposed rule generally stated that ATF had struck an appropriate balance in dealing with a difficult issue. For example, the National Consumers League (NCL), a national nonprofit consumer advocacy organization that was founded in 1899 to represent consumers in the marketplace and workplace, recognized the difficult nature of the issue as follows:

NCL believes that the proposed rule raises a serious public policy question for which there is no easy answer. NCL understands ATF’s concern as to whether health claims should be permitted on alcoholic beverages at all. While there is a body of research showing that moderate consumption of alcohol reduces the risk of coronary heart disease (CHD), there is also evidence that moderate drinking may increase the risk of certain cancers. Moreover, as ATF notes, moderate drinking is risky for certain individuals who are prone to alcoholism, some of whom may not realize that they are. Excessive alcohol consumption is unquestionably harmful. Whether a properly qualified health claim should be permitted on alcoholic beverage labels is a serious policy question that has been debated by public health experts for years.

NCL concluded that while it “has reservations about authorizing any health claim for alcoholic beverages, we believe a properly qualified and balanced claim would be of value to many consumers. * * * A healthclaim that includes the elements specified in the proposed rule would provide these

consumers with useful information.” (Comment 388).

Two major associations representing the wine industry also commented in support of the substantive health claims provisions of the proposed rule. The Wine Institute commented “that the public should receive the whole story regarding the responsible consumption of wine and applaud[ed] ATF’s efforts, as reflected in the additional proposed regulation language, to refine and focus the conditions which must be met before any substantive claim regarding health benefits can be made on wine labels or in advertisements.” (Comment 401).

The AVA also stated it had no objection to the proposed amendment to the regulations to reflect current ATF policy, noting that “[a]s our members have been required to conform to these policies for some years, converting them to regulation would pose no further hardship.” (Comment 417).

A comment from the Washington Legal Foundation (WLF) focused primarily on legal issues, noting that if the rule was properly implemented, it would pass muster under the First Amendment. (Comment 390). This comment will be discussed further under section XIX.

2. Comment Supporting Summary Health Claims Without Qualification or Disclosure of Adverse Effects

Only CEI and CA specifically argued in favor of allowing summary health claims without qualification or disclosure of adverse effects in the labeling and advertising of alcohol beverages. CEI and CA opposed ATF’s notice on the grounds that it would serve to suppress truthful and non-misleading speech. (Comment 326). CEI and CA argued that the cardiovascular and overall health benefits associated with moderate alcohol consumption are amply supported by the medical evidence, and summary statements of these benefits are protected by the First Amendment.

CEI and CA suggested that those individuals who would not benefit from moderate drinking “know who they are and are unlikely to be misled.” CEI and CA also suggested that the CSAP survey supports a conclusion that consumers would not be misled by directional statements, that such statements would not change the drinking patterns of consumers, and that the population studied understands the risks of drinking, particularly that drinking is counter-indicated during pregnancy.

CEI and CA claimed that other Federal agencies have approved summary health statements without the

extensive qualifications that would be required under ATF's proposed rule. As examples, they pointed to health claims approved by FDA for diets low in saturated fat and cholesterol and diets low in sodium. They also suggested that the "balance" ATF is ostensibly seeking would automatically be provided by the mandatory health warning statement on alcohol beverage containers.

The CEI and CA comment suggested that the proposed rule would result in regulations that violated the First Amendment; thus, the proposed rule should be withdrawn. At the public hearing, Mr. Ben Lieberman testified on behalf of CEI and stated that CEI believed that the rulemaking should result in a "policy allowing a wide range of accurate summary statements about moderate drinking and health to appear on alcoholic beverage labels and ads." (April 25, 2000; Washington, DC, page 119). Mr. Lieberman also suggested that ATF had not accurately summarized the evidence demonstrating the health benefits associated with moderate alcohol consumption, but instead spent "much of its time identifying and somewhat exaggerating every conceivable category of individual who is not likely to benefit from moderate drinking, such as adults too young to be at risk for heart disease, pregnant women, and recovering alcoholics." (*Id.* at page 120).

In response to a question from the panel, Mr. Lieberman confirmed that it was CEI's belief that a health claim regarding cardiovascular benefits, such as "there is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of cardiovascular disease," could appear on a label with no disclaimer and still not mislead consumers. He stated that "it is well known that people understand the limitations of advertising and labeling and that they would be skeptical. They would also read the government warning, which does at least allude to the other side of this story." (April 25, 2000; Washington, DC, pages 133-134).

3. Other Comments in Favor of Health Claims

Approximately 45 comments supported the use of substantive health claims in the labeling and advertising of alcohol beverages. However, these commenters did not specifically support the type of summary health claim advocated by CEI and CA. Instead, they commented in favor of the general principle that health claims for alcohol beverages are not inherently misleading. In some cases, it was difficult to determine whether these commenters

meant to support directional statements only or whether they specifically supported the use of substantive health claims on labels or in advertisements.

Most of the comments that favored a rule allowing the use of substantive health claims reflected a general perception that consumers were entitled to information about potential health benefits associated with moderate alcohol consumption. For example, one individual suggested that "consumers have the right to know and can be trusted to handle this scientific information." (Comment 300). Another comment supported "the rights of wineries to list the health benefits of their product on the labels." (Comment 277).

Some of the individuals commenting in favor of health claims specifically supported the concept that the claims be balanced, although it was unclear whether they were suggesting that the balance would come from qualifications in the claims or the required Government warning statement. For example, one individual stated that "[i]t is only fair and proper that the labels on the bottle contain the positive health benefits as well as the proper health warnings." (Comment 143). Another commenter expressed his support for "producers of wine to be able to print both the adverse and the positive effects of consuming wine." (Comment 340).

Many of the commenters suggested that consumers need to be made aware of health-related information, including the positive and negative effects of alcohol consumption, in order to make informed decisions regarding its use. For example, one commenter, a psychologist and attorney, stated that it was "necessary to rationally accept that alcohol has benefits as well as dangers * * *. Since Americans can easily and legally drink, and most in fact do so, the need to inform them of the range of drinking consequences and the related drinking limits for each is both prudent and democratic." (Comment 243). A doctor commented as follows:

It makes more sense to put more information on the label in order for the consumer to make a better decision. As a physician, I implore my patients to read labels. There are certainly some potential health benefits to wine as well as potential downsides in individuals. (Comment 145).

Two commenters argued that alcohol producers have a First Amendment right to market the health benefits of alcohol consumption, provided that such information is presented in a non-misleading manner. However, neither of these comments suggested that industry members were entitled to use summary health claims without any qualification

or disclosure of adverse effects. The First Amendment issues raised by these commenters will be addressed separately in section XIX.

Among the medical experts who testified at the hearings in favor of allowing health claims or health-related statements on labels or in advertisements, some specifically noted that consumers should be made aware of both the risks and purported benefits of moderate alcohol consumption. For example, Dr. Ellison suggested that an appropriate message on a label would be "[w]hile light to moderate alcohol consumption can be consistent with a healthy lifestyle for most individuals and has been shown to dramatically reduce the risk of heart disease, certain individuals should not drink at all.' Then, you should go through the list of the people that we are advising not to drink." (April 26, 2000; Washington, DC, page 116).

Finally, Mr. John Hinman testified on behalf of the American Wine Alliance for Research and Education as well as the Coalition for Truth and Balance, a group of California wineries. Mr. Hinman suggested that it was the Government warning statement, rather than the directional statements, which misled consumers about the health consequences of alcohol consumption. (May 23, 2000; San Francisco, CA, page 149). Mr. Hinman was also one of the few individuals responding to ATF's question about whether it was possible to craft a balanced substantive health claim. He noted that he had submitted a 664-word statement to ATF for review in 1993, entitled "Wine and Health—Behind the French Paradox." (*Id.* at page 151). Mr. Hinman stated that "considering that 664 words makes for a very wordy wine label, we seriously doubt whether any wine maker really has an interest in providing such a statement on the bottle. However, the statement can and should be available to hand out to those customers who request more information or are interested in the subject matter." (*Id.* at page 152). Accordingly, Mr. Hinman stated he was resubmitting the statement to ATF for review, and later clarified in response to a question from the panel that he would put the statement on an application for label approval. (*Id.* at pages 152, 165).

In response to a question from the panel, Mr. Hinman stated that neither the American Wine Alliance nor the Coalition for Truth and Balance was "interested, to my knowledge, in necessarily using CEI's proposed label. * * * On the other hand, as a lawyer * * * that's an absolutely accurate statement that CEI is using on that

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

are required only for categories of individuals whose potential negative health effects are literally numerous or whether the potential negative health effects would be aggregated for the purposes of performing the balancing test envisioned by the proposed regulation.” (Comment 396). Accordingly, the final rule clarifies that this requirement is intended to cover the categories of individuals for whom alcohol consumption is not recommended (*e.g.*, pregnant women, individuals taking certain medications, *etc.*).

We do not agree with CEI and CA that it is unnecessary to set forth this information in conjunction with a health claim because these people know who they are. For example, it is not at all clear that most consumers know that alcohol can interact harmfully with a variety of prescription and over-the-counter medications. It is TTB’s conclusion that any labeling or advertising statement that makes a substantive health claim regarding alcohol consumption would mislead consumers if it does not set forth this important information about the adverse consequences of alcohol consumption. Notwithstanding the above, we find that the rulemaking record does not support a conclusion that health claims in the labeling and advertising of alcohol beverages are inherently misleading. Nor does the record support a conclusion that the potentially misleading nature of such claims cannot be cured with the appropriate use of disclaimers and qualifying statements.

Initially, it should be noted that none of the commenters who supported a total ban on the use of health claims in the labeling and marketing of alcohol beverages presented consumer data on the use of substantive health claims in the labeling or advertising of alcohol beverages. Thus, we have no consumer data establishing that consumers would be misled by the use of properly qualified health claims that are sufficiently detailed and specific, and which disclose the adverse health consequences of alcohol consumption.

A complete ban on the use of health claims or health-related statements in the labeling and advertising of alcohol beverages would prohibit even the most qualified, detailed, and balanced discussion of health consequences in advertising materials. For example, in Industry Circular 93–8, ATF advised industry members that the regulations did not prohibit them from including the entire text of NIAAA’s April 1992 edition of “Alcohol Alert” in advertising materials. This NIAAA publication presents a comprehensive

overview of the benefits and risks associated with alcohol consumption. If the regulations imposed a complete ban on advertising materials that included health-related statements, then industry members would no longer be allowed to include this NIAAA publication in advertising materials. Yet TTB finds nothing in the record to establish that the inclusion of this type of comprehensive discussion of effects on health in an advertisement in any way misleads consumers as to the health risks of alcohol consumption. Accordingly, we find that the record does not support an overall ban on the use of specific health claims and health-related statements in the advertising of alcohol beverages.

A closer issue is presented by the labeling of alcohol beverages. As ATF noted in Industry Circular 93–8, we believe that it would be difficult to compose a health claim that is detailed and specific enough to meet our standards, yet short enough to fit on a traditional alcohol beverage label. In addition, TTB will not approve any labeling health claim that contradicts the message of the required Government warning statement.

TTB agrees with the commenters who suggested that a summary substantive health claim which does not include sufficient detail and qualification would mislead consumers about the serious health consequences of alcohol consumption. However, we do not believe that this provides a basis for banning all substantive health claims on alcohol beverage labels. Instead, as set forth above, TTB is making changes to the final rule to clearly provide that a specific health claim will not be allowed 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 levels of alcohol consumption may cause health risks.

We disagree with the arguments made by CEI and CA, the only commenters who specifically favored allowing industry members to make summary statements regarding health benefits that contained no qualification, balance, or disclosure of adverse effects. In the first place, the record did not establish that there was any concrete interest on the part of the alcohol beverage industry in using the summary health claim proposed in the CEI petition. Secondly, we find that statements such as the one

proposed by CEI would mislead consumers by not disclosing the significant adverse effects on health associated with alcohol consumption, which are set forth in great detail in this rulemaking record.

TTB has not drafted a model health claim for use on alcohol beverage labels because this extensive rulemaking record has revealed little, if any, interest on the part of industry members in using substantive health claims on alcohol beverage labels. In fact, industry members not only failed to express such an interest, in many cases, they specifically disavowed any interest in using substantive health claims. Furthermore, as discussed further in section XVIII, any such claim might well subject the product to regulation as a drug under FDA regulations.

Accordingly, TTB will leave it to any interested industry members to seek approval of a substantive health claim through the label approval process. The final rule sets forth the standards that would apply to any such labeling statement. If an industry member wishes to use a substantive health claim on a label in compliance with the standards set forth in the final rule, it should apply for a certificate of label approval.

ATF announced in Industry Circular 93–8 that dissemination of the full text of the April 1992 edition of “Alcohol Alert” as published by NIAAA, would not be in violation of the regulations. The final rule does not change this policy. Furthermore, dissemination of the entire Dietary Guidelines as advertising materials by industry members, or dissemination of the two pages from the current Guidelines dealing with alcohol beverages (pages 36 and 37) would not violate the final rule. Both of these materials provide a comprehensive discussion of the health consequences of alcohol consumption. The information in these materials regarding the health consequences of alcohol consumption is truthful and supported by scientific evidence. The information is sufficiently detailed, qualified and specific, and sets forth the health risks associated with both moderate and heavier levels of alcohol consumption. Both of these publications further set forth the categories of individuals for whom any level of alcohol consumption may pose health risks. Accordingly, these materials comply with the standards set forth in the regulations.

As ATF stated in Industry Circular 93–8, we will continue to evaluate any additional text that accompanies these materials, such as editorializing, advertising slogans, or exhortations to consume the product, to determine

whether or not the advertisement as a whole presents truthful and non-misleading information regarding the risks associated with alcohol consumption. Furthermore, the use of any buttons, shelf talkers, table tents, and similar items that excerpt any portion of the NIAAA publication or the Dietary Guidelines, or that are based on any other publication or article about the health consequences of alcohol consumption, will be closely scrutinized to determine if they tend to mislead consumers about the serious risks associated with alcohol consumption.

XVI. Are Health-Related Directional Statements Misleading?

As previously noted, the vast majority of the commenters addressed the issue of health-related directional statements, such as the ones approved by ATF in 1999, rather than the issue of substantive health claims. Approximately 355 commenters expressed support for the use of directional statements on alcohol beverage labels. Many commenters stated that directional statements are not substantive health claims and that they merely refer consumers to other sources for information about the effects on health of alcohol consumption. As such, the commenters maintain that directional statements are not misleading to consumers. On the other hand, most of the approximately 120 comments in opposition to the use of health claims also opposed the use of health-related directional statements in the labeling and advertising of alcohol beverages.

A. Comments and Testimony in Favor of the Use of Health-Related Directional Statements

Most of the comments in support of directional statements shared the view set forth in the Wine Institute's comment as follows:

Directing consumers to consult with their doctors or to refer to the Dietary Guidelines regarding the health effects of wine consumption constitutes a responsible and neutral message. Far from misleading the public, such statements are designed to educate and empower each individual to make fully informed choices regarding the consumption of wine. (Comment 401).

The Wine Institute's comment also stated that health-related directional statements were "certainly not misleading because they do not constitute substantive health claims in the first instance." They cited the CSAP survey, which concluded that the drinking patterns of 88.3% of the participants would not be influenced by

directional statements, with an additional 3.9% indicating they would drink less.

In response to ATF's question of whether the negative consequences of alcohol consumption and abuse disqualified alcohol beverages from entitlement to health claims or health-related statements, the Wine Institute submitted extensive summaries of scientific studies on moderate consumption of wine and alcohol for the Dietary Guidelines Review Process. An updated compilation of that submission was attached to their comment. The Wine Institute stated that it "fully subscribes to an open and vigorous dialogue driven by the findings of the scientific community on the health effects of alcohol consumption."

The Wine Institute submitted a supplemental comment in which it stated that it wished "to underscore how critical it is to make the distinction between health-related statements and those in which a substantive claim of health benefits is advanced. A substantial number of submissions you have received to date appear to blur this crucial difference and argue against directional labels by incorrectly classifying such labels as health claims." (Comment 401b).

Mr. John DeLuca, President and CEO of the Wine Institute, testified at both the Washington, DC and San Francisco, California hearings. Mr. DeLuca stated that he believed that wineries have a First Amendment right to use the directional label, and pointed to the CSAP survey as evidence that consumers would not increase consumption as a result of directional statements. (April 25, 2000; Washington, DC, page 32). He urged the empowerment of the public through dissemination of information, and urged that the public should be trusted "to handle this information." (*Id.* at pages 32-33).

When asked about substantive health claims, Mr. DeLuca stated that "we are not trying to sell wine as health food or as a medicine." (*Id.* at page 37). He said that "we should be erring on the side of making it as hard as possible for someone to make a health claim. It really is not the province of the industry to be talking that way. We want third-party peer review journals research to be what is presented to the public, not what we put to the public." (*Id.* at page 38). In response to a question about whether the directional statements were perceived as health claims, Mr. DeLuca stated that the Wine Institute had withdrawn its original label submission, which included the phrase "health benefits," because they "knew it was

going to lead to a cascade of criticism" and that the phrase "health effects" came from the Appropriations Committee's language in appropriating funds for NIH and NIAAA to research the effects on health of moderate drinking. (*Id.* at page 40).

When asked about consumer reaction to the directional statements, Mr. DeLuca noted that only 17 companies had received approval from ATF for using directional statements before the moratorium went into effect—5 received approval for the Dietary Guidelines statement, and 12 utilized the family doctor statement. (May 23, 2000; San Francisco, CA, pages 14-15). Mr. DeLuca stressed that the Wine Institute did not encourage wineries to use the label, noting that "[w]e always thought of this as a voluntary option for our members. They were designed primarily for public policy, not for public relations, a distinction with an enormous difference." (*Id.* at 15).

The AVA, a trade association of American wineries representing approximately 600 members, also noted that it had been involved on behalf of one of its members in the ATF review process for the directional statements approved in 1999. (Comment 417). AVA stated that it agreed with the applicant, Mr. Patrick Campbell, that the directional statement "makes no claim, pro or con, therapeutic or curative, true or false. The COLA [certificate of label approval] makes no claim at all. It merely (and sensibly) encourages consumers to consult with their family doctor about their personal use of the product. * * * Since this COLA makes no claim, questions about its potential to mislead are irrelevant." (Comment 417). The President of AVA, Mr. Simon Siegl, testified at the public hearings in support of a winery's right to use a directional label. (April 26, 2000; Washington, DC, page 65).

Many winemakers also commented in support of the use of directional statements. Some emphasized the neutral content of the directional statements. The Associated Vintage Group asked "what can be a better message than referring them [consumers] to our own government's nutritional guides or, even better, checking with their doctors." (Comment 173). Mr. Kent Rosenblum commented that "[d]irectional labels do not constitute health claims, and government survey data indicate no changes in drinking patterns would occur." (Comment 151). He then went on to note that "[t]here is a developing scientific consensus that moderate wine and alcohol consumption can be part of

a healthy diet and lifestyle for those who choose to drink.”

Other wineries specifically referenced the directional statements as providing balance to the Government warning statement, or referring to the “benefits” of consumption. For example, De Rose Vineyards commented that “[t]he U.S. Dietary Guidelines for Americans constitutes a responsible and neutral message.” The winery also stated that “[t]here is a very substantial body of scientific data that verifies the efficacy and healthfulness of moderate wine consumption. Withholding this most helpful and beneficial information, and instead only emphasizing the harmful effects of wine consumption, is ludicrous and ultimately destructive and irresponsible. A forthright balance of both positive and negative simply educates an informed public and allows them to make responsible decisions.” (Comment 172). Two other wine producers made similar comments (Comments 214 and 387).

Many commenters who did not identify themselves as being part of the wine industry also supported the directional statements. Some supported the general concept of directing consumers to the Dietary Guidelines or their physician for more information about the effects on health of alcohol consumption. One suggested that “[t]he wording is neutral and *not* positive, thereby serving as education rather than propaganda.” (Comment 332). Several commenters referred to the consumer survey conducted by CSAP as evidence that the statements did not mislead consumers.

Some commenters argued that consumers have a right to know all the scientific information available on both the positive and negative effects of various levels of alcohol consumption, and that such information allows consumers to make informed decisions regarding alcohol consumption. For example, one commenter stated that “people are generally capable of making sensible decisions, if assisted by complete information. * * * Moreover, the small minority who do not make sensible decisions will not be deterred by suppressing the presentation of accurate, balanced information.” (Comment 423). An individual suggested that “in an era when we all are trying to eliminate governmental control of those areas of our lives where we can be treated as adults, it seems odd for you to be against a neutral statement that wine drinkers should consult their doctors about the possible health benefits of wine.” (Comment 136).

Many of the commenters suggested that the directional statements or other

positive health-related statements were necessary to “balance” the negative information provided by the Government warning statement. For example, one commenter supported the directional statements because the warning statement should be supplemented with “equally valid” information “explaining the benefits and positive effects of responsible consumption.” (Comment 296). Another individual supported the use of “positive health related statements” and stated that “[t]he wine industry deserves to be afforded an opportunity to address the latest beneficial health aspects of moderate wine consumption, as outlined in the U.S. dietary guidelines, on its products. The entire thrust of Government Warning labels has been entirely negative.” (Comment 240).

Finally, some commenters argued that the Government should encourage consumers to seek the best advice possible from the most credible sources available on any health issue. With respect to the consumption of alcohol beverages, the National Association of Beverage Retailers suggested that “[p]hysicians and the U.S. Dietary Guidelines are among the most credible sources available to give professional, objective, responsible and balanced advice on an important health issue.” (Comment 424).

At the hearings, several doctors testified in support of the directional labeling statements. Some specifically supported the statement encouraging consumers to consult with their physician. For example, Dr. Michael Apstein, a gastroenterologist and liver doctor, testified that advice regarding alcohol consumption should be targeted to specific populations rather than generalized for the entire population. He stated that “[t]hese are complex issues that can’t easily be summarized on a label that goes on a wine bottle. They need to be discussed with a person’s physician and individualized to that person’s situation. Therefore, I am in favor of a directional label that advises individuals to discuss this topic with their physicians, because I am hopeful that a directional label will stimulate another kind of educational experience, so people can use alcohol responsibly if they so desire and avoid it if they should be avoiding it.” (April 25, 2000; Washington, DC, page 167).

Similarly, Dr. Harvey Finkel, a physician and clinical professor of medicine, testified that both directional statements should be allowed, stressing the importance of advising consumers to consult their doctors, because the public has a right to be fully informed about the health consequences of alcohol

consumption. (April 26, 2000; Washington, DC, pages 30–33). Mr. George Linn, a consumer, also testified in support of the concept of referring consumers to their physicians for more individualized advice about alcohol consumption. (May 24, 2000; San Francisco, CA, page 256). On the other hand, Dr. Paul Scholten, an associate professor of obstetrics, gynecology, reproductive medicine, and nursing, testified in support of the directional statement referring consumers to the Dietary Guidelines, but expressed concerns about whether doctors were well trained to advise patients about the health consequences of alcohol consumption. (May 23, 2000; San Francisco, CA, pages 170–171).

Some individuals commented in support of the general concept of directional statements. Dr. Dwight Heath, a Professor of Anthropology, testified that while he opposed the use of substantive health claims, he favored the use of the directional statements on labels. (April 26, 2000; Washington, DC, page 13). Dr. Heath suggested that the more people know about alcohol consumption, the less likely they are to have alcohol-related problems. (*Id.* at page 5). Similarly, Professor R.L. Williams, of the Oenological Research Facility of Old Dominion University, stated that in his opinion, “the level of scientific information regarding the positive health effects of moderate consumption of wine is now quite overwhelming. * * * This information should be made more available to the consumers in regard to the directional health statements.” (April 26, 2000; Washington, DC, page 91). Mr. Archie Brodsky, a senior research associate in psychiatry and the law, testified in favor of the use of directional statements on alcohol beverage labels. He stated that the CSAP survey confirmed that the labels would have a “negligible” influence on consumers’ drinking habits. (April 26, 2000; Washington, DC, page 171).

Mr. Patrick Campbell of Laurel Glen Winery, who submitted the first directional statement to ATF for approval in 1995, testified on behalf of the Coalition for Truth and Balance. Mr. Campbell stated that discussion of the health benefits or risks of alcohol consumption was not relevant to a discussion of the directional statements, since “the approved messages do not constitute health-related statements or make substantive claims regarding health benefits.” (May 23, 2000; San Francisco, CA, page 75). He asserted that the message encouraging consumers to consult with their family doctors “is neither true nor false. It makes no claim

* * * positive or negative, therapeutic or curative, pro or con.” (*Id.* at 76). Mr. Campbell argued that the message was not misleading in that it “presumes nothing. It presupposes nothing. It in no way directs the outcome of any consultation the consumer may or may not undertake with his or her family physician. For all the winery knows, the doctor might tell all of his or her patients never to touch the stuff * * *. It’s a thoroughly neutral and impartial message.” (*Id.* at 76–77).

Mr. Campbell expressed surprise at the controversy over the message, and said he would have expected that “every health professional and governmental agency in the country would welcome it. * * * After all, if you can’t trust your family doctor for truthful and not misleading advice on health issues who can you trust?” (*Id.* at 78). Mr. Campbell noted that the American Heart Association “publishes a section on alcohol in their dietary guidelines that explicitly recommends that patients consult with their personal physician on questions of alcohol use * * *.” (*Id.* at 80).

Mr. Campbell stated that on June 3, 1999, before the moratorium on approving directional statements went into effect, ATF approved a version of the directional statement which omitted the language about “the proud people who made this wine” and instead read as follows: “We encourage you to consult with your family doctor about the health effects of wine consumption.” (*Id.* at page 74). He stated that he now preferred this version, since he believes that it fits better in the label, it’s not pompous, and it was an appropriate response to the people who argued that the “proud people” language constituted an implicit endorsement of alcohol consumption. (*Id.* at page 87).

In response to a question from the panel, Mr. Campbell stated that he had gotten no feedback from consumers as to how they viewed the directional statements. He said that “[n]obody’s said anything, it’s unbelievable. I mean, it cost a lot of money to put these on the label.” (*Id.* at page 88).

Mr. Jack Stuart testified on behalf of the Napa Valley Vintners Association. He stated that “we think that the directional warning is a good thing. We don’t consider it to be a positive health claim. If you take out the phrase ‘proud people,’ certainly it’s a neutral statement, it’s simply a way of getting information, and we think it’s a good idea for anyone who is proposing to drink, or who does drink, or who does any other thing having to do with food, their diet, their lifestyle, to consult their

physician about the choices they make in that regard.” (May 24, 2000; San Francisco, California, page 200). In response to a question from the panel, Mr. Stuart suggested that “to have a balanced message, to me the ideal would be to somehow combine both the warning and the directional message.” (*Id.* at page 210).

Mr. Mark Chandler, the Executive Director of the Lodi-Woodbridge Winegrape Commission, also testified in favor of the directional statements. He stated that “[g]rowers and wineries have no intention to market their products as health food. But, unlike other food products, we are prevented by regulation from even mentioning our product’s positive health attributes, thus the need for directional labels.” (May 24, 2000; San Francisco, CA, page 250). Mr. Gordon Murchie testified on behalf of the Virginia Wineries Association in favor of the use of directional statements, calling them public service announcements that “direct the concerned citizen to another source of professional non-biased, balanced information.” (April 26, 2000; Washington, DC, page 78). In response to a question from the panel, Mr. Murchie said his members would be interested in using directional statements on labels, but were reluctant to do so until they saw that the statements were accepted by the Government and the public. (*Id.* at pages 86–87).

Dr. Ellen Mack, a physician and part owner of a winery, testified that “[i]f wine were considered a medication—and I’m not at all advocating that it should be—it would be like most other medications, the dose is critical. Too little may not have the desired effect, and too much can be dangerous or even deadly.” (May 23, 2000; San Francisco, CA, page 132). Dr. Mack suggested that “the directional wine labels are effective agents in that the sources of information—the U.S. Dietary Guidelines and personal physicians—will clearly make the point that the beneficial health effects result from moderate consumption of alcohol, and these sources will define moderate as no more than one drink per day for women and no more than two drinks per day for men.” *Id.*

Various other individuals testified in favor of the directional statement. For example, Ms. Annette Shafer, author of “The Wine Sense Diet” testified in favor of a “more balanced message on the bottle,” suggesting that the warning label is “very one-sided.” (May 24, 2000; San Francisco, CA, page 212).

B. Comments and Testimony in Opposition to Directional Statements

Public health organizations and other commenters raised the following specific objections to the use of directional health-related statements in the labeling and advertising of alcohol beverages.

1. Directional Statements Are Implicit Health Claims That Reinforce the Inaccurate Perceptions of Consumers About Alcohol and Health

CSPI commented that the directional statements were actually implied health claims. Its comment argued that the “reference to the ‘health effects of wine consumption’ offers no useful information, but simply reinforces existing inaccurate knowledge about the health benefits of alcohol consumption, as spread through the media and the wine industry’s misleading publicity campaign, and implies that those benefits are substantial and universal.” (Comment 400).

The American Cancer Society noted that “[w]ith the publicity in the past few years about the health benefits of consuming alcoholic beverages, any less-detailed claim or reference to health impacts or benefits might be interpreted by the uninformed consumer as a suggestion that people should drink alcohol for their health. Sufficient information is needed to allow consumers to make a well-educated decision regarding their risk from consumption of this product.” (Comment 527). Accordingly, the American Cancer Society concluded that directional labels “may mislead the general public regarding the health benefits of alcohol consumption by providing inadequate information regarding the risks.”

Senator Thurmond commented that the directional statements were inherently misleading. He stated that it was unlikely that consumers who read the directional statements would actually send for the Dietary Guidelines or consult their physicians. Instead, Senator Thurmond suggested that “consumers may be left with the impression that these statements refer to studies that suggest drinking alcohol may have some positive health benefits.” He noted that “[t]his impression may reinforce inaccurate assertions about the health benefits of alcohol consumption spread through the media. These statements may also be inappropriately viewed as the government’s endorsement of drinking. However, any suggestion that the government endorses drinking for health reasons is false.” (Comment 526).

2. Directional Statements Undermine the Mandatory Government Warning Statement and May Be in Violation of the Alcoholic Beverage Labeling Act

NCADD's comment stated that the directional statements approved by ATF in 1999 "are misleading and potentially confusing to consumers in juxtaposition to the federally mandated government warning on all alcoholic beverage containers sold in the United States." (Comment 15). Similarly, MADD commented that "[t]he public and particularly youth are being given a mixed message with the inclusion of 'health messages' in alcohol advertising and on warning labels and the net result is consumer confusion." (Comment 20). MADD also noted that "[w]arning labels on alcoholic beverages were created for a specific purpose—to make the consumer aware of the potential harm they could suffer as a result of the use or abuse of the product."

The United Communities Against Drug & Alcohol Abuse commented that "Congress has already required a warning statement on alcoholic-beverage containers. Any other reference to health impacts or benefits is likely to confuse consumers and undermine the impact of the existing warning statement." (Comment 31). The American Council on Alcohol Problems urged ATF "not to contribute to confusion by allowing any insinuation of health benefits from alcohol consumption." (Comment 37).

Dr. Thomas Greenfield, a psychologist, testified in opposition to the use of health-related statements. He stated he was principal investigator of the Impact of Alcoholic Beverage Warning Labels Research Project from 1991–1997. He stated that research showed that the mandatory Government warning statement had "fragile but beneficial effects" and that "one must be concerned that a vague health effects message, by implication positive, may wipe out the small gains in reminding the public of situational hazards of drinking when driving or pregnant, and also the health risks." (May 24, 2000; San Francisco, CA, pages 182–183). He suggested that in order to be truly neutral, a directional statement "should have a tone that would be to look at the health risks and health benefits, and potential health benefits. And one would have to do it in such a way that it emphasized that—which is, we believe, strongly the case—that the health benefits [are] * * * relatively small in comparison to the health harms." (*Id.* at page 191).

CSPI commented that if ATF allowed any health claim or health-related

statement on a label, it "should be worded and displayed in a manner that does not overshadow, contradict, or undermine the government warning label. For example, the claim should appear in the same type size and style as the government warning label, and should not contain any claim that contradicts any of the statements in the warning label." (Comment 400).

Senator Thurmond testified that the purpose of the ABLA was to provide "a clear, non-confusing reminder of the health hazards associated with alcohol consumption." (April 25, 2000; Washington, DC, page 17). Senator Thurmond suggested that "the two directional statements which the ATF approved last year dilutes the required warnings and, worse, may be seen as the government's endorsement of drinking. As one of the authors of the Alcoholic Beverage Labeling Act, let me stress that the intent of the legislation was to exclude such misleading statements." *Id.* In response to the First Amendment concerns raised by some individuals, Senator Thurmond suggested that at a minimum, "groups supporting health-related statements should be required to prove beyond any reasonable doubt that such claims are not misleading and do not detract from the government warning." (*Id.* at page 18).

In addition to Senator Thurmond's comment, a letter signed by Senators Thurmond, Byrd, and Helms supported a ban on all health-related statements and directional health statements on labels. (Comment 526). In this comment, the three Senators stated that the directional statements approved by ATF in 1999 "dilute the required government warning and mislead consumers. In fact, these labels might inappropriately be seen as the government's endorsement of alcohol consumption." The comment also noted the difficulty of presenting a balanced statement on the effects on health of alcohol consumption on an alcohol beverage label. The Senators stated that "Congress has spoken clearly on this important public health issue. The purpose of the ABLA should not be subverted."

3. Directional Statements Are Misleading Because Drinkers Are Unlikely To Seek Health Information

Many commenters suggested that the directional statements were misleading because the CSAP consumer survey established that consumers who read the directional labels were unlikely to seek additional information from their doctors or send for the Dietary Guidelines. For example, CSPI argued that "referring consumers to a government publication which offers

balanced information is only credible if there is a reasonable likelihood that such referral will in fact result." (Comment 400). CSPI suggested that "according to consumer research, few people would actually look at or write for the Dietary Guidelines on the basis of the label language." CSPI and others questioned whether consumers would get complete information from either the Dietary Guidelines or their doctors.

Similar points were raised in the testimony of Mr. James Mosher on behalf of the California Council on Alcohol Policy, a nonprofit membership organization dedicated to promoting public health approaches to the prevention of alcohol-related problems. Mr. Mosher argued that the directional labels were inherently misleading and thus did not constitute protected commercial speech under the First Amendment. Because the directional statements themselves make no claim about the effects on health of alcohol consumption, Mr. Mosher suggested that the key to determining whether they would mislead consumers depends upon "the sources to be consulted, the likelihood of consumers actually consulting them, and the possibility that the wording will lead to consumer confusion, misleading or deceptive impressions." (May 23, 2000; San Francisco, CA, page 92).

4. Directional Statements Are Misleading Because Drinkers Are Likely To Rationalize Their Consumption Patterns

As previously mentioned, several doctors who have been certified by the American Society of Addiction Medicine commented in opposition to the use of both health claims and health-related directional statements in the labeling and advertising of wines. These commenters suggested that health claims and directional statements could be misconstrued by problem drinkers in order to rationalize their own levels of consumption. For example, one doctor suggested that these statements could be misconstrued by consumers, because "consumers, especially those with a vulnerability to alcoholism, may take the message as an endorsement of excessive drinking." Accordingly, he urged that ATF "prohibit the alcoholic-beverage industry from making these misleading and potentially dangerous claims." (Comment 167).

Another medical doctor urged ATF to rescind approval of the directional labeling statements, stating that "[a] brief message on any beverage container will not provide consumers with adequate information about use of alcohol for health-related reasons. Due

to the publicity in the past few years about the health benefits of moderate alcohol consumption, a brief label may be interpreted by the uninformed consumer as a government-authorized statement supporting consumption of alcohol for health benefit.” (Comment 410).

NCADD also cited the CSAP study as establishing that focus group members were “generally aware” of the reports on positive effects on health of wine consumption, and that the heavier drinkers were more aware of the media reports. NCADD suggested that heavy drinkers would use these “beliefs” about the effects on health of wine consumption to justify their drinking levels. (Comment 15).

Ms. Joan Kiley, coordinator of the Alcohol Policy Network of Alameda County, testified in favor of a complete ban on health claims or health-related statements in the labeling or advertising of alcohol beverages. She stated that the directional statements were inherently misleading, since they were “incomplete statements that do not put research results in their proper context.” (May 24, 2000; San Francisco, CA, page 228). Ms. Kiley noted that “[c]onsumers are not always aware of the effect that images and attitudes promoted in advertising have on their own desires.” (*Id.* at page 232). In response to a question from the panel, Ms. Kiley said that in her experience, people with alcohol problems were “very skilled at finding good reasons to drink. They * * * can use a multiple number of reasons to drink, that might just be another one.” (*Id.* at page 239).

5. Directional Statements Could Be Interpreted as the Government’s Endorsement of Alcohol Consumption

The former Surgeon General, Dr. David Satcher, testified that it was important to “carefully consider any action, whether it involves the health warning or claims that could encourage underage drinking or mislead about the very real, adverse health consequences.” (April 25, 2000; Washington, DC, page 73). Dr. Satcher stated he was “concerned that references to the U.S. dietary guidelines on the labels of certain wine products could wrongly lead consumers to conclude that consumption of wine would reduce health risks or that it was recommended by guidelines or by family physicians. References to alcohol in the guidelines should not be construed as evidence of health benefits nor encouragement that consumers drink. * * * In fact, the Public Health Service does not recommend consumption of alcohol beverages.” (*Id.* at page 74).

The Marin Institute for the Prevention of Alcohol and Other Drug Problems (Comment 324) suggested that the directional statements attributed positive effects on health to the consumption of alcohol beverages, and were thus “misleading and potentially dangerous because media and marketing messages can be misinterpreted as public health recommendations.” The Marin Institute stated that the “60 Minutes” report on the possible heart protective effects of drinking red wine led to a 44 percent increase in red wine sales. They quoted the marketing manager of a winery as stating in “Impact” magazine in 1997 that information about health benefits was “increasing consumption more than anything else.” Ms. Hilary Abramson testified on behalf of the Marin Institute at the San Francisco hearing that the so-called French Paradox (“the apparent coexistence in France of a low heart disease rate and a diet rich in saturated fat, and the belief that alcohol [red wine] is the explanation for it”) had been overestimated, and the French heart disease statistics underestimated. She stated that after the 60 Minutes Broadcast in November 1991 on the French Paradox, “sales of red wine in the United States rocketed 44%, and a Gallup poll showed that 58% of Americans were aware of research linking moderate drinking to lower rates of heart disease.” (May 23, 2000; San Francisco, CA, pages 115–116).

Similarly, the Greater Spokane Substance Abuse Council’s Prevention Center commented that “[a]ny statement or labeling in reference to supposed ‘health benefits’ could be construed by an uninformed consumer population as a government endorsement to consume a likely harmful product.” (Comment 32). The American Council on Alcohol Problems also commented that “[i]f health claims are allowed on labels or even implied, many uninformed consumers would interpret this as a government sanctioned statement suggesting that people drink alcohol for their health. Quite to the contrary, research clearly shows that any measure which increases the level of alcohol consumption will result in increased levels of disease and accidents.” (Comment 37).

6. Other Testimony Against Directional Statements

Many of the medical experts who testified at the public hearings expressed concerns that the directional statements would mislead consumers about the effects on health of alcohol consumption. For example, Dr. Camargo concluded that “with all of these variety

of factors influencing the net health effect of alcohol, I think it is really quite foolhardy to believe that any one-sentence generic health claim about moderate wine consumption would serve public-health interests, or even provide reliable consumer advice. In addition to the gross simplification of a complex risk/benefit analysis, the labels will also lead to several other levels of confusion.” (April 25, 2000; Washington, DC, page 90). In particular, he noted that few consumers would actually consult the Dietary Guidelines for information on the effects of alcohol consumption, that many people who notice the label would interpret the phrase “health effects” as “healthy effects,” that there is considerable confusion about what constitutes moderate drinking, and that if consumers do consult their family physician, “it is very unlikely the physician will be in a position to provide accurate, up-to-date information about all of the risks and benefits of moderate drinking.” (April 25, 2000; Washington, DC, pages 91–92). Dr. Camargo also noted that “generic health claims are likely to be misinterpreted by those at greatest risk of alcohol problems, a group that would likely use the health claim to justify continued or increased consumption of excessive alcohol with all of its attendant health hazards.” (*Id.* at page 92).

Dr. Criqui also testified that because of the negative health consequences associated with alcohol consumption and abuse, the directional statements are inherently misleading. (May 23, 2000; San Francisco, CA, page 60). He stated that the approved directional statements appear to implicitly endorse the value of alcohol as a pharmacological protective agent. (*Id.* at page 59). Dr. Criqui offered his opinion that consumers interpret the approved statements as substantive health claims, which means that at least for most people drinking is good and has health benefits and that the Government endorses this position. Because the directional statements are recent and come in the context of media discussion about the possible benefits of alcohol consumption, Dr. Criqui stated that the statements are likely to be interpreted as implicitly endorsing alcohol consumption as being potentially healthy, since they do not emphasize or even mention the dangers of alcohol consumption. (*Id.* at pages 59–60).

Some people suggested that consumers would interpret the directional statements as making positive health-related claims simply because of an assumption that the industry would not use the statements

unless they were positive. For example, Dr. Duke, representing the Ethics and Religious Liberty Commission, the moral concerns agency for the Southern Baptist Convention, suggested that the directional statements were misleading because they “create an impression of endorsement of the health claims made by the alcohol industry. * * * The average person would not conclude that the alcohol industry would direct people to information damaging to their claim. Consequently, the average person will assume a doctor would agree that drinking alcohol is good for one’s health.” (April 25, 2000; Washington, DC, 154–155).

Ms. Diana Conti testified on behalf of the American Public Health Association in support of a ban on all health-related statements on labels and in advertisements, other than the required warning statement. Ms. Conti suggested that the directional statement regarding the Dietary Guidelines “provides no specific information, no definition of moderate drinking, and no cautions to those who should not drink. The message is confusing and it’s contradictory to the warning label.” (May 23, 2000; San Francisco, CA, page 106). She stated that “[t]he lack of substantive information creates the impression that the government says moderate wine consumption is good for your health, and few, if any, will actually read the guidelines for the more complete information.” (*Id.* at page 107).

C. Decision

When ATF approved the directional statements in 1999, it concluded that the record did not establish that the statements would mislead consumers about the risks associated with alcohol consumption. ATF relied heavily upon the CSAP consumer survey, which concluded that the directional statements would not encourage most consumers to alter their consumption levels or patterns.

After careful consideration of the comments and testimony on this issue, it is TTB’s conclusion that while the two directional statements approved in 1999 were worded in a way that was intended to represent a neutral referral to doctors or the Dietary Guidelines for additional information, the statements were capable of being interpreted in a very different fashion. In particular, the statements could be interpreted as encouraging the consumption of alcohol for health reasons.

While the CSAP survey established that the vast majority of consumers would not alter their consumption patterns after exposure to the two directional statements, it did not

explore whether consumers would interpret the statements as encouraging the consumption of alcohol for health reasons. Since TTB has no consumer data on this issue, we must rely upon the secondary data that is available to us, including the opinions of medical and public health experts in the field of alcohol and health.

Initially, TTB would note that many media reports about approval of the directional statements referred to these statements as health claims or references to health benefits. *See* section VII, *infra*. We recognize that these reports only indirectly reflect consumer reactions to the directional statements, and that they may have been influenced by the industry’s or the public health sector’s characterizations of the statements. Nonetheless, to the extent that these media reports both reflect and shape the perceptions of consumers, we believe that these reports are persuasive evidence that the directional statements are perceived by many as making a positive claim about the effects on health of alcohol consumption.

We are also persuaded by the opinions of many of the foremost public health experts in the nation. These public health experts believe that the allegedly neutral directional statements in fact communicated a message that the Government endorsed drinking for health reasons, or that the Dietary Guidelines or a family physician would endorse the consumption of alcohol for health reasons. For example, the former United States Surgeon General testified that he was “concerned that references to the U.S. dietary guidelines on the labels of certain wine products could wrongly lead consumers to conclude that consumption of wine would reduce health risks or that it was recommended by guidelines or by family physicians.” (April 25, 2000; Washington, DC, page 74). Similarly, the American Cancer Society noted that “[w]ith the publicity in the past few years about the health benefits of consuming alcoholic beverages, any less-detailed claim or reference to health impacts or benefits might be interpreted by the uninformed consumer as a suggestion that people should drink alcohol for their health” and concluded that directional labels “may mislead the general public regarding the health benefits of alcohol consumption by providing inadequate information regarding the risks.” (Comment 527). Other commenters, including the American Medical Association and the Marin Institute, supported a ban on directional statements for similar reasons.

TTB also finds persuasive the testimony of many of the foremost

experts on the medical research regarding alcohol and health. For example, Dr. Camargo testified that in his opinion, consumers would interpret the phrase “health effects” to mean “healthy effects.” (April 25, 2000; Washington, DC, pages 90–92). Dr. Criqui offered his opinion that the approved directional statements appear to implicitly endorse the value of alcohol as a pharmacological protective agent, and that consumers interpret the approved statements as substantive health claims meaning that at least for most people drinking is good and has health benefits and that the Government endorses this position. Because the directional statements are recent and come in the context of media discussion about the possible benefits of alcohol consumption, Dr. Criqui stated that the statements are likely to be interpreted as implicitly endorsing alcohol consumption as being potentially healthy, since they do not emphasize or even mention the dangers of alcohol consumption. (May 23, 2000; San Francisco, CA, pages 59–60).

TTB does not disregard the testimony of those medical professionals, including Dr. Apstein, Dr. Finkel, and Dr. Scholten, who testified in favor of the use of directional statements. We agree that industry members have the right to suggest, in labels or in advertisements, that consumers refer to third party sources for additional information regarding the effects on health of alcohol consumption. The question presented is how to make such referrals without misleading consumers.

We would also note that many of the comments in favor of the use of directional statements referred to the need to provide “balance” to the negative message of the health warning statement, and thus implicitly recognized that the directional statements were meant to convey a positive message about the effects on health of alcohol consumption. In this regard, it is noteworthy that in a comment submitted after the hearings were held, Beer Institute suggested that the position of several proponents of directional statements that such statements did not constitute health claims was inconsistent with those same proponents’ attempts “to defend the directional statements by relying on well-known published medical literature that attributes certain health benefits to the moderate consumption of alcohol beverages. Given the history of this issue and the evidence cited by supporters of the directional statements, it seems impossible to characterize the directional statements as anything but health claims subject to the automatic

qualifying provisions of the proposed new regulations.” (Comment 396b).

After careful consideration of the comments and testimony in the rulemaking record, it is TTB’s view that the directional statements approved in 1999 may be interpreted as advocating the consumption of alcohol beverages for health reasons. We recognize that producers of alcohol beverages have contended that they have a constitutionally protected right to advocate that consumers drink their products for health reasons. However, if such a claim is made on a label or in an advertisement, it must be made in a truthful and non-misleading fashion. Furthermore, such a claim would fall within the category of a specific health claim, and would be subject to the requirements in the final rule applicable to such claims. To the extent that producers instead wish to make a neutral referral to third parties for additional information regarding the effects on health of alcohol consumption, we believe that it is necessary to provide a disclaimer that clarifies that the labeling or advertising statement should not encourage consumption of alcohol for health reasons.

Accordingly, the final rule provides that directional statements will not be allowed in the labeling or advertising of alcohol beverages unless accompanied by a disclaimer. The final rule provides a model disclaimer that alcohol beverage producers may use in conjunction with a general statement that directs consumers in a neutral or other non-misleading manner to a third party for balanced information regarding the effects on health of alcohol (wine, distilled spirits, or malt beverage) consumption: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons.” It should be noted that in some cases, an acceptable disclaimer might be incorporated into the language of the directional statement itself; thus, if the directional statement makes it clear that it is not advocating consumption of alcohol for health reasons, then an additional disclaimer may not be necessary.

XVII. Should the Same Standards Apply to Wines, Distilled Spirits, and Malt Beverages?

A. Issue

The DISCUS comment opposed the Bureau’s suggested “case-by-case” approach, noting that the effects on health of alcohol consumption apply across the board to all beverage alcohol products. Accordingly, DISCUS

suggested that public policy and regulatory policy require fair and equal treatment for each form of beverage alcohol, and any label statement for a beverage alcohol container should apply equally to each type of beverage alcohol. (Comment 530).

B. Decision

Both the proposed and final rules make it clear that the same standards apply to wine, distilled spirits, and malt beverages. The rulemaking record does not provide a basis for setting forth different standards for these types of alcohol beverages. The two directional statements approved by ATF in 1999 were both submitted by wineries, and thus both referred to the effects on health of “wine consumption.” To the extent that a directional statement complies with the standards set forth in this final rule, it may be used in the labeling of a wine, distilled spirit, or malt beverage product.

XVIII. Should TTB Adopt the Procedures Set Forth in FDA’s Regulations?

A. Issue

Several commenters suggested that ATF should adopt the substantive standards already in place in FDA’s regulations governing the use of health claims in the labeling of foods. FDA also raised several concerns about consistency between ATF’s proposed regulations and its own health claim regulations.

FDA (Comment 327) commented that it was “imperative that [ATF] regulate these claims in a manner consistent with the provisions of the Federal Food, Drug, and Cosmetic Act (FFDC Act) to ensure the meaningful and non-misleading use of such claims.” FDA pointed out that pursuant to the Nutrition Labeling and Education Act (NLEA), a manufacturer may make a health claim on a food label only if FDA determines “based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), 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 U.S.C. 343(r)(3)(B)(i).

FDA also noted that the use of claims for foods that may have a negative health impact generally is not appropriate under the NLEA. The statute provides that a health claim may not be made for a food that contains, as

determined by regulation, any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet-related. 21 U.S.C. 343(r)(3)(A)(ii). FDA may grant an exception to allow foods with disqualifying nutrient levels to bear a health claim if the claim is accompanied by a disclosure statement regarding the disqualifying nutrient and FDA has determined by regulation that such a claim would assist consumers in maintaining healthy dietary practices. 21 U.S.C. 343(r)(3)(A)(ii) and 343(r)(2)(B). FDA requires rigorous evidence to support a conclusion that a health claim on a food with a disqualifying nutrient level would assist consumers in maintaining healthy dietary practices.

FDA expressed the following concern about the use of health claims on alcohol beverage labels:

Alcohol beverages are foods for which there is evidence of a substantial number of undisputed negative health effects. FDA has not evaluated the evidence supporting the putative health benefits of alcohol beverages. Therefore, we cannot say whether health claims for an alcohol beverage would be prohibited under FDA’s existing health claim authorization process, or if not prohibited, could be authorized with a disclosure statement of the type required by 21 U.S.C. 343(r)(2)(B). We are concerned, however, that the evidence for the well-known direct causative relationships between alcohol and numerous health risks would be a significant hurdle to our concluding that label information about a relationship between consumption of alcohol and a health claim could assist consumers in maintaining healthy dietary practices.

FDA also noted that the absence of any significant nutritive value of alcohol products would be another obstacle to FDA authorizing a health claim for alcohol beverages.

FDA stated that it was concerned that “certain therapeutic or curative claims sought by manufacturers of alcohol beverages may in fact be claims that would require regulation of the alcohol beverages as drugs.” It noted that FDA has authority and responsibility under the FFDC Act to regulate all products bearing drug claims, and that the term “drug” is defined by statute to include an article “intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.” 21 U.S.C. 321(g)(1)(B). FDA concluded that “[a]lcohol beverages could fall within this definition if their labeling contains drug claims.”

FDA expressed a concern that certain health claims that would be allowed under ATF’s proposed rule might render the product a drug subject to regulation under the FFDC Act. The FFDC Act

provides that any drug that is not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling, or that has not been used to a material extent or for a material time under such conditions, is a "new drug." 21 U.S.C. 321(p). A new drug may not be legally marketed unless FDA has approved a new drug application for such a drug. 21 U.S.C. 331(d) and 355(a). FDA noted that the FFDC Act requires substantial evidence of effectiveness and evidence that the drug is safe for its intended use before FDA will approve a new drug application. 21 U.S.C. 355(d). FDA suggested that this standard differed from the "not misleading" standard proposed by the ATF notice of proposed rulemaking.

FDA advised that ATF should explicitly articulate in its regulations the processes by which it would review claims intended for alcohol beverages. It stated that it was unable to determine, based on the proposed rule, whether the proposed process for a review of health-related statements would be consistent with FDA's statutory and regulatory authorities. Accordingly, FDA urged ATF to clarify the process and criteria it intends to use to substantiate the validity of any health claims or other health-related statements before finalizing the proposed rule.

The former Surgeon General, Dr. David Satcher, also testified in support of adopting standards "consistent with that relied upon by the Food and Drug Administration or for regulated health claims for foods and drugs." (April 25, 2000; Washington, DC, page 77). Accordingly, "[c]laims should be based on significant scientific agreement, and they should be qualified to identify those categories of persons for whom the claims are relevant, as well as to identify those for whom the negative consequences would outweigh any positive effect." (*Id.* at page 78). In response to a question from the panel, Dr. Satcher agreed that there were problems with consumers self-medicating without knowing all the facts, noting that "with alcohol, you also have the added effect that you are dealing with an addictive drug." (*Id.* at page 80). Senator Thurmond also commented that "[a]pplication of the FFDC Act to this issue would appear to prohibit any health-related statements on alcohol beverage labels. It is absurd that the government would prevent whole milk from making health-related claims but allow such claims by alcohol beverages." (Comment 526).

CSAP commented that "[a]lcohol abuse and alcoholism continue to be

among the most vexing public health problems facing the United States. Indeed, alcohol is the nation's number one drug problem among youth." While CSAP did not take a position on any of the issues on which comment was sought, it noted that "[o]ne of the key issues challenging our efforts is the mixed or misleading messages that consumers receive from a variety of sources. The addition of health related information on beverage alcohol labels must be carefully considered in relation to the general public's understanding of alcohol-related health risk." (Comment 430).

CSPI suggested that ATF adopt regulations similar to FDA's regulations under the NLEA, noting that USDA did so on a voluntary basis for health claims on meat and poultry. CSPI stated that under regulations similar to those of FDA, health claims would be prohibited because alcohol consumption increases the risk of other diseases, noting that "[t]o allow health claims for alcohol, America's most devastating drug, while health claims for foods such as whole milk are prohibited, would be indefensible and would make a mockery of the federal government's health-claim regime."

CSPI also noted that if an alcohol beverage label or advertisement claims that alcohol may reduce the risk of disease, the beverage may be regulated as a drug by FDA. CSPI argued that, "aside from its regulatory classification, alcohol is a drug. Depending on a variety of factors such as dose and schedule of use, individual metabolism, personality factors, and situation, alcohol is variously a stimulant and depressant, euphoric and soporific, irritant and anxiety reducer. Alcohol, like other intoxicants, can produce such dependency phenomena as persistent search behavior, withdrawal, relapse, and loss of control."

B. Decision

After giving careful consideration to these comments, and consulting with FDA, TTB does not agree that its health claim regulations should be identical to those of FDA. FDA regulations were promulgated pursuant to a very specific grant of authority by Congress under the NLEA. Because of the differences in statutory authority, as well as the differences in the products regulated under these two statutes, TTB's regulatory scheme for health claim labeling will differ from FDA's regulatory scheme.

However, TTB agrees with the FDA comment in several respects. Most importantly, we agree that it is important to ensure that alcohol

beverage producers do not violate the new drug provisions of the FFDC Act when seeking to use specific health claims on alcohol beverage labels. It would be where the use of that claim would render the product subject to FDA's jurisdiction over drugs. Furthermore, FDA's authority over new drugs has significant public health and safety consequences. TTB does not wish to create any confusion on the part of industry members regarding their obligations to comply with FDA's requirements over drug claims.

In the past, ATF merely advised industry members that they should be aware of the fact that the use of a health claim on an alcohol beverage label may subject the product to FDA's jurisdiction. However, after reviewing the comments on this issue, we met with FDA to discuss a process whereby TTB and FDA could consult on the use of specific health claims on alcohol beverage labels. In this way, FDA would have an opportunity to object to the use of a specific health claim, based on its jurisdiction over drugs, prior to any TTB action.

Accordingly, the final rule now provides that 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. There is no similar provision in the advertising regulations, since advertisers are not required to obtain prior approval from TTB. We will of course consult with FDA, as appropriate, if the question arises as to whether an advertisement is in violation of the FFDC Act.

XIX. Is the Final Rule Consistent With the First Amendment?

A. Issue

As previously noted, many commenters suggested that the proposed rule did not comply with the protection accorded truthful and non-misleading commercial speech under the First Amendment. CEI and CA argued that ATF is precluded from placing any restrictions on the dissemination of truthful information about health benefits in the labeling and advertising of alcohol beverages. Beer Institute, DISCUS, and NABI suggested that the proposed advertising regulations would restrict protected commercial speech. Mr. Rex Davis, representing the President's Forum of the Beverage Alcohol Industry, testified that he believes the proposed rule violates the First Amendment because it would

restrict the industry from communicating the benefits of alcohol consumption through labels and advertisements. (April 26, 2000; Washington, DC, pages 133–141). Many other commenters defended the constitutionality of a complete ban on the use of health-related statements in the labeling and advertising of alcohol beverages.

Some of the comments that (or commentators who) addressed the First Amendment issue suggested that while ATF would have authority to restrict the use of misleading health claims, a complete ban on the use of health-related statements would be unconstitutional. For example, the Washington Legal Foundation concluded that an outright ban on the use of truthful health claims would be unconstitutional, but stated that the proposed regulations, “if properly implemented, strike the appropriate balance in ensuring the First Amendment rights of industry and consumers, and the dissemination of important information regarding the health benefits proven to flow from moderate consumption of alcohol beverages.” (Comment 390). A comment submitted on behalf of the Oregon Winegrower’s Association also stated that a ban on the use of health claims on labels or in advertisements would be unconstitutional; however, the comment stated that the agency should instead “adhere to a policy of allowing labeling and advertising claims about such health-related benefits to be fairly and objectively evaluated for substantiation, balance and qualification.” (Comment 380).

A comment from Mr. Erik Bierbauer (Comment 395) attached a copy of a note that he wrote for the New York University Law Review as a third-year law student, entitled “Liquid Honesty: The First Amendment Right to Market the Health Benefits of Moderate Alcohol Consumption,” 74 N.Y.U.L. Rev. 1057 (1999). The note concludes that alcohol producers have a First Amendment right to market the health benefits of moderate drinking, as long as they do so accurately and include certain limited disclaimers. Mr. Bierbauer suggested that while such limited disclaimers would be constitutionally authorized, “the sort of disclosure described in ATF’s Industry Circular 93–8 probably would be too burdensome to comply with the First Amendment.” However, Mr. Bierbauer’s comment suggested that “[t]he Constitution would permit the government to require health-related alcohol advertisements and labels to mention lesser-known risks that are present at moderate levels of drinking.

For example, the government might legitimately require a disclaimer warning consumers of the possible link between moderate drinking and breast cancer, and also a statement warning certain vulnerable consumers not to drink at all.” Mr. Bierbauer concluded that “[a]ds and labels that merely direct the consumer to other sources of information, such as the wine labels approved by ATF in February 1999, clearly would enjoy First Amendment protection.”

B. Decision

As set forth in this final rule, TTB is not imposing a complete ban on the use of health claims or other health-related statements in the labeling and advertising of alcohol beverages. Accordingly, it is not necessary to consider whether such a ban would be constitutional. Instead, the final rule requires TTB to evaluate health claims on a case-by-case basis to determine if such claims would tend to mislead the consumer.

The final rule codifies ATF’s longstanding position that any substantive health benefit claim is 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 alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks. The final rule clarifies that the identified health risks must include those associated with both moderate and higher levels of consumption. Thus, the rule would require any such claim to include appropriate qualifications and disclaimers about the health risks associated with alcohol consumption. In addition, health-related directional statements that are not substantive health claims must nonetheless include a disclaimer to clarify that the statement does not advocate the consumption of alcohol beverages for health reasons, or some other appropriate disclaimer to avoid misleading consumers. The rule’s requirements for appropriate disclaimers and qualifications in order to avoid consumer deception about a health issue comport completely with the safeguards articulated by the Supreme Court to protect non-misleading commercial speech.

Commercial speech is defined as speech that proposes a commercial transaction. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976).

Information on alcohol beverage labels is considered commercial speech. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995). Commercial speech is generally protected by the First Amendment; however, it enjoys a more limited measure of protection. *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995). Nonetheless, the Government bears the burden of justifying a restriction on commercial speech. See *Greater New Orleans Broadcasting Ass’n v. United States*, 527 U.S. 173, 183 (1999).

In order to regulate commercial speech, the Government must satisfy a 4-prong test. *Central Hudson Gas & Electric Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 563–566 (1980). First, the expression is protected by the First Amendment only if it concerns lawful activity and is not misleading. Second, the Government must establish a substantial interest. Third, the regulation must directly advance the governmental interest asserted. Finally, the regulation must be no more extensive than necessary to serve the interest asserted.

In two recent cases involving alcohol beverages, the Supreme Court has struck down bans on truthful and non-misleading commercial speech. In *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995), the Supreme Court applied the *Central Hudson* analysis in striking down the FAA Act’s prohibition against statements of alcohol content on malt beverage labels unless required by State law. In *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), the Supreme Court struck down Rhode Island’s ban on advertising the price of alcohol beverages on First Amendment grounds. More recently, in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), the Supreme Court struck down certain restrictions imposed by the State of Massachusetts on the advertisement of tobacco products on First Amendment grounds. However, none of these decisions restricts the Government’s authority to regulate misleading or potentially misleading commercial speech.

If commercial speech is actually misleading, then it is not protected by the First Amendment. If commercial speech is potentially misleading, the Government may regulate such commercial messages if the restrictions are “no broader than reasonably necessary to prevent the deception.” *In re R.M.J.*, 455 U.S. 191, 203 (1982). Potentially misleading speech cannot be banned “if the information also may be presented in a way that is not deceptive” through the use of “disclaimers or explanation.” *Id.* Requirements for disclaimers have been

upheld as long as the disclaimers are “reasonably related to the State’s interest in preventing deception” and do not constitute an undue burden on the advertiser. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651–53 (1985).

TTB recognizes that under the commercial speech doctrine, there is a preference for disclosure over suppression. See *e.g.*, *Zauderer and Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In *Pearson*, the Court of Appeals for the D.C. Circuit required the Food and Drug Administration to consider appropriate disclaimers for health claims on dietary supplement labels. The Court noted that “the government’s interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied—at least ordinarily—by inclusion of a prominent disclaimer setting forth those adverse effects.” 164 F.3d at 659.

Consistent with the Supreme Court cases cited above, as well as the DC Circuit’s ruling in the *Pearson* case, the final rule requires any industry member who wishes to make an explicit or implicit health claim on a label or in an advertisement to make a more complete disclosure of the adverse effects on health caused by alcohol consumption. The final rule does not impose any additional requirements on industry members who do not wish to make such claims. However, given the very serious health risks associated with alcohol consumption, TTB believes that the use of health claims without such qualifications and disclaimers would be misleading to consumers.

The final rule is completely consistent with the preference expressed by the courts for disclosure over suppression in the commercial speech arena. The Supreme Court has held that more speech, not less, is the preferred means of ensuring that consumers have sufficient information to make informed choices in the commercial arena. *In re R.M.J.*, 455 U.S. at 203. The final rule does not “ban” any type of speech regarding health claims or health-related statements in the labeling or advertising of alcohol beverages. Instead, the rule simply requires disclaimers for specific health claims and health-related directional statements.

CEI and CA suggested that there is no need for disclaimers in connection with health claims in the labeling or advertising of alcohol beverages. They point to the fact that the Government warning statement required on alcohol beverage containers already advises consumers that “Consumption of alcoholic beverages impairs your ability

to drive a car or operate machinery, and may cause health problems.” CEI and CA further suggest that consumers are well aware of the health risks associated with alcohol abuse, and there is no need to remind them of such risks.

TTB does not agree with this comment. The administrative record contains overwhelming evidence of the serious health risks associated with alcohol consumption. These risks are not merely hypothetical; they are well documented. Among other things, the comments established that over 8 million American adults are alcoholics; alcohol is a known human carcinogen; and alcohol contributes to the deaths of more than 100,000 Americans each year. Furthermore, alcohol abuse has devastating effects on innocent third parties. In 1998, 15,935 people were killed in alcohol-related traffic crashes, and an estimated 850,000 were injured. Mothers Against Drunk Driving commented that the NIH estimated that the overall societal costs of alcohol abuse and alcoholism in 1995 (\$167 billion) were more than 50 percent higher than the costs to society of illegal drug use (\$110 billion). The health risks associated with alcohol consumption are not simply hypothetical; on the contrary, they present a serious public health problem in this country. Accordingly, the record supports a conclusion that a health claim that does not include information about these serious health risks would tend to mislead consumers about the health consequences of alcohol consumption.

TTB also disagrees with the suggestion by CEI and CA that health-related statements presented a necessary “balance” to the warning presented by the mandatory Government warning statement. The warning statement was intended by Congress to present a clear and nonconfusing reminder of the health hazards associated with consumption or abuse of alcohol beverages. See 27 U.S.C. 213. The use of health claims or other health-related statements without qualification or disclosure of adverse effects to “balance” the mandatory warning statement not only undermines the intent of the ABLA; it also tends to confuse consumers about the very real health risks associated with alcohol consumption.

The administrative record contains significant evidence that truthful statements about certain health benefits associated with moderate consumption of alcohol beverages for certain individuals will tend to mislead consumers unless such statements are 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 disclose the health risks associated with both moderate and heavier levels of alcohol consumption; and outline the categories of individuals for whom any levels of alcohol consumption may cause health risks. Most consumers are unable to conduct or verify health research for themselves to determine whether a health claim is valid as to their own alcohol consumption, and are ill equipped to interpret the medical data, evaluate the potential benefits, or identify and weigh the other medical factors that may bear upon their individual decision to use alcohol for therapeutic reasons. See *In re R.M.J.*, 455 U.S. at 202 (the public’s comparative lack of knowledge regarding the product being advertised is an important factor in determining whether speech is misleading). A requirement for disclaimers of this nature in such a situation is clearly directly related to the Government’s interest in ensuring that consumers are not misled by health statements on alcohol beverage labels.

Some commenters suggested that the types of disclaimers and qualifications required by the proposed regulations would overly burden industry members who wish to make health claims about alcohol consumption, making such requirements unconstitutional. CEI and CA suggested that “summary” health claims for alcohol consumption are just as truthful as other short health claims allowed by FDA for diets low in saturated fat and cholesterol, as well as diets low in sodium. Other commenters suggested that because an alcohol beverage label is not large enough to include the volume of information necessary in order to give consumers a complete picture of the effects on health of alcohol consumption, such statements should be banned completely from alcohol beverage labels.

TTB agrees that the regulations make it difficult to present a substantive health claim (for example, one involving cardiovascular benefits associated with moderate alcohol consumption) on an alcohol beverage label, because of the level of qualification and explanation that would be necessary to set forth the risks associated with such consumption. TTB would also note that there seems to be an overwhelming lack of interest on the part of the alcohol beverage industry in using such health claims on alcohol beverage labels. The comments from major trade associations representing wineries, importers, brewers, and distillers did not indicate a concrete

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

malt beverages, as well as statements and claims of nutritional value. Statements concerning caloric, carbohydrate, protein, and fat content of alcohol beverages are not considered nutritional claims about the product. However, statements of vitamin content are considered nutritional value claims, and will be prohibited if presented in a fashion that tends to mislead consumers as to the nutritional value of the product.

The term "specific health claim" is defined as a type of health-related statement that, expressly or by implication, characterizes the relationship of the alcohol beverage (e.g., wine, distilled spirits, or malt beverage), alcohol, or any substance found within the alcohol beverage, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the alcohol beverage (wine, distilled spirits, or malt beverages), alcohol, or any substance found within the alcohol beverage, and a disease or health-related condition.

The term "health-related directional statement" is defined as a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of alcohol consumption.

The definitions in the final rule also clarify that TTB is not expanding its traditional interpretation of a curative or therapeutic claim to cover, for example, advertisements in which people are shown relaxing in an enjoyable setting while consuming alcohol beverages. Accordingly, the final rule in no way impinges on the right of industry members to advertise their products in a truthful and non-misleading fashion.

XXI. Applications for and Certificates of Label Approval

Upon the effective date of this final rule, applications for certificates of label approval must be in compliance with the regulations. In accordance with the provisions of 27 CFR 13.51 and 13.72(a)(2), upon the effective date of this final rule, certificates of label approval that are not in compliance with the regulations will be revoked by operation of regulation. Certificate holders must voluntarily surrender all certificates that are no longer in compliance and submit new applications for certificates that are in compliance with the new requirements.

XXII. Notes Appearing in Text of Supplementary Information

1. Hennekens, C.H., "Alcohol and Risk of Coronary Events," Research Monograph No. 31, "Alcohol and the Cardiovascular System" at 15 (National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD, 1996).

2. See, e.g., Boffetta, P. & Garfinkel, L., "Alcohol drinking and mortality among men enrolled in an American Cancer Society prospective study," "Epidemiology" 1(5):342-348, 1990; Stampfer, M.J.; Colditz, G.A.; Willett, W.C.; Speizer, F.E. & Hennekens, C.H., "A prospective study of moderate alcohol consumption and the risk of coronary disease and stroke in women," "New England Journal of Medicine," 319(5):267-273, 1988; Klatsky, A.L.; Armstrong, M.A.; and Friedman, G.D., "Alcohol and Mortality," "Annals of Internal Medicine," 117(8):646-654, 1992. See generally National Institute on Alcohol Abuse and Alcoholism, "Moderate Drinking," "Alcohol Alert," No. 16, April 1992, at 2, and studies cited therein.

3. See, e.g., Criqui, M.H., "Moderate Drinking: Benefits and Risks," "Alcohol and the Cardiovascular System," at 117-118 ("Clearly, younger persons cannot possibly benefit much from alcohol consumption, at least in the short term, because their risk of ischemic CVD events is low.")

4. DuFour, M.C., "Risks and Benefits of Alcohol Use Over the Life Span," "Alcohol Health & Research World," Vol. 20, No. 3:145-150 at 147, 1996.

5. See, e.g., Hennekens, C.H., "Alcohol and risk of coronary events," Research Monograph No. 31, "Alcohol and the Cardiovascular System" at 20 (National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD 1996) ("while the health risks of excessive drinking are clear, there may also be hazards associated with moderate intake that must be weighed, on an individual basis, against the apparent protection against CHD.")

6. Thun, M.J.; Peto, R.; Lopez, A.D.; Monaco, J.H.; Henley, S.J.; Heath, C.W.; and Doll, R.; "Alcohol Consumption and Mortality Among Middle-Aged and Elderly U.S. Adults," "The New England Journal of Medicine," 337(24):1705-1714 at 1705, 1997.

7. *Id.* at 1712.

8. Manson, J.E.; Tosteson, H.; Ridker, P.M.; Satterfield, S.; Hebert, P.; O'Connor, G.T.; Buring, J.E.; and Hennekens, C.H.; "The Primary Prevention of Myocardial Infarction," "The New England Journal of Medicine," 326(21):1406-1416 at 1412, 1992.

9. Fuchs, C.S.; Stampfer, M.J.; Colditz, G.A.; Giovannucci, E.L.; Manson, J.E.; Kawachi, I.; Hunter, D.J.; Hankinson, S.E.; Hennekens, C.H.; Rosner, B.; Speizer, F.E.; and Willett, W.C.; "Alcohol Consumption and Mortality Among Women," "The New England Journal of Medicine," 332(19):1245-1250 at 1245, 1995.

10. *Id.* at 1246.

11. *Id.* at 1249.

12. Grabbe, L.; Demi, A.; Camann, M.A.; *et al.* "The health status of elderly persons in the last year of life; A comparison of deaths

by suicide, injury, and natural causes." "American Journal of Public Health" 87(3):434-437, 1997.

13. Stampfer, M.J.; Rimm, E.B.; Walsh, D.C.; "Commentary: Alcohol, the Heart, and Public Policy," "American Journal of Public Health," 83(6): 801-804 at 803, 1993.

XXIII. How This Document Complies With the Federal Administrative Requirements for Rulemaking

A. Executive Order 12866

TTB has determined that this final rule is not a significant regulatory action as defined in E.O. 12866. Therefore, a regulatory assessment is not required.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. TTB has certified that this final rule will not have a significant economic impact on a substantial number of small entities. In general, the final regulations merely clarify TTB's existing policy concerning the use of health claims in the labeling and advertising of alcohol beverages and impose no burdens on the industry. With respect to health-related statements, TTB believes that the burden imposed by the additional wording required by a disclaimer or other qualifying statement is minimal. Accordingly, a regulatory flexibility analysis is not required.

C. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because no requirement to collect information is imposed.

Disclosure

Copies of the notice of proposed rulemaking, all comments, the hearing transcripts, and this final rule will be available for public inspection by appointment during normal business hours at: TTB Public Reading Room, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC; 202-927-7890.

Drafting Information

The originating drafter of this document is James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

However, personnel from other offices of the Bureau participated in developing this Treasury decision.

List of Subjects

27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, and Wine.

27 CFR Part 5

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, and Packaging and containers.

27 CFR Part 7

Advertising, Consumer protection, Customs duties and inspection, Imports, and Labeling.

Authority and Issuance

For the reasons discussed in the preamble, TTB amends 27 CFR Parts 4, 5, and 7 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

1. The authority citation for 27 CFR Part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

2. Section 4.39 is amended by revising paragraph (h) to read as follows:

§ 4.39 Prohibited practices.

* * * * *

(h) *Health-related statements.* (1) *Definitions.* When used in this paragraph (h), terms are defined as follows:

(i) *Health-related statement* means any statement related to health (other than the warning statement required by § 16.21 of this chapter) and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, wine, or any substance found within the wine, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, wine, or any substance found within the wine, 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 the wine, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the wine, alcohol, or any substance found within the wine, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between wine, alcohol, or any substance found within the wine, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption.

(2) *Rules for labeling.* (i) *Health-related statements.* In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(ii) *Specific health claims.* (A) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a wine label. If FDA determines that the use of such a labeling 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 that specific health claim on a wine label.

(B) TTB will approve the use of a specific health claim on a wine label only if the claim 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 levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption is presumed misleading unless it—

(A) 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 wine or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(2) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

* * * * *

3. Section 4.64 is amended by revising paragraph (i) to read as follows:

§ 4.64 Prohibited practices.

* * * * *

(i) *Health-related statements.* (1) *Definitions.* When used in this paragraph (i), terms are defined as follows:

(i) *Health-related statement* means any statement related to health and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, wine, or any substance found within the wine, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, wine, or any substance found within the wine, 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 the wine, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the wine, alcohol, or any substance found within the wine, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between wine, alcohol, or any substance found within the wine, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related

statement that directs or refers consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption.

(2) *Rules for advertising.* (i) *Health-related statements.* In general, advertisements may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement. Such disclaimer or other qualifying statement must appear as prominent as the health-related statement.

(ii) *Specific health claims.* A specific health claim will not be considered misleading if 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 levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim and in a manner as prominent as the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption is presumed misleading unless it—

(A) 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 wine or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement, and in a manner as prominent as the health-related directional statement, the following disclaimer: “This statement should not encourage you to drink or increase your alcohol consumption for health reasons;” or

(2) Includes as part of the health-related directional statement, and in a manner as prominent as the health-related directional statement, some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading

impression conveyed by the health-related directional statement.

* * * * *

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

4. The authority citation for 27 CFR Part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805; 27 U.S.C. 205.

5. Section 5.42 is amended by revising paragraph (b)(8) to read as follows:

§ 5.42 Prohibited practices.

* * * * *

(b) * * *

(8) *Health-related statements.* (i)

Definitions. When used in this paragraph (b)(8), terms are defined as follows:

(A) *Health-related statement* means any statement related to health (other than the warning statement required by § 16.21 of this chapter) and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, 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 the distilled spirits, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(B) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the distilled spirits, alcohol, or any substance found within the distilled spirits, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between distilled spirits, alcohol, or any substance found within the distilled spirits, and a disease or health-related condition.

(C) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other

source for information regarding the effects on health of distilled spirits or alcohol consumption.

(ii) *Rules for labeling.* (A) *Health-related statements.* In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(B) *Specific health claims.* (1) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a distilled spirits label. If FDA determines that the use of such a labeling 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 that specific health claim on a distilled spirits label.

(2) TTB will approve the use of a specific health claim on a distilled spirits label only if the claim 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 levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(C) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption is presumed misleading unless it—

(1) 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 distilled spirits or alcohol consumption; and

(2)(i) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(ii) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading

impression conveyed by the health-related directional statement.

* * * * *

Par. 6. Section 5.65 is amended by revising paragraph (d) to read as follows:

§ 5.65 Prohibited practices.

* * * * *

(d) *Health-related statements.* (1) *Definitions.* When used in this paragraph (d), terms are defined as follows:

(i) *Health-related statement* means any statement related to health and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, 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 the distilled spirits, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the distilled spirits, alcohol, or any substance found within the distilled spirits, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between distilled spirits, alcohol, or any substance found within the distilled spirits, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption.

(2) *Rules for advertising.* (i) *Health-related statements.* In general, advertisements may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects

on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement. Such disclaimer or other qualifying statement must appear as prominent as the health-related statement.

(ii) *Specific health claims.* A specific health claim will not be considered misleading if 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 levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim and in a manner as prominent as the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption is presumed misleading unless it—

(A) 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 distilled spirits or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement, and in a manner as prominent as the health-related directional statement, the following disclaimer: “This statement should not encourage you to drink or increase your alcohol consumption for health reasons;” or

(2) Includes as part of the health-related directional statement, and in a manner as prominent as the health-related directional statement, some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

* * * * *

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

7. The authority citation for 27 CFR Part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

8. Section 7.29 is amended by revising paragraph (e) to read as follows:

§ 7.29 Prohibited practices.

* * * * *

(e) *Health-related statements.* (1) *Definitions.* When used in this paragraph (e), terms are defined as follows:

(i) *Health-related statement* means any statement related to health (other than the warning statement required by § 16.21 of this chapter) and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, malt beverages, or any substance found within the malt beverage, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, malt beverages, or any substance found within the malt 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 the malt beverage, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the malt beverage, alcohol, or any substance found within the malt beverage, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between malt beverages, alcohol, or any substance found within the malt beverage, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of malt beverage or alcohol consumption.

(2) *Rules for labeling.* (i) *Health-related statements.* In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading

impression conveyed by the health-related statement.

(ii) *Specific health claims.* (A) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a malt beverage label. If FDA determines that the use of such a labeling 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 that specific health claim on a malt beverage label.

(B) TTB will approve the use of a specific health claim on a malt beverage label only if the claim 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 levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of malt beverage or alcohol consumption is presumed misleading unless it—

(A) 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 malt beverage or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement the following disclaimer: "This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;" or

(2) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

* * * * *

9. Section 7.54 is amended by revising paragraph (e) to read as follows:

§ 7.54 Prohibited statements.

* * * * *

(e) *Health-related statements.* (1) *Definitions.* When used in this

paragraph (e), terms are defined as follows:

(i) *Health-related statement* means any statement related to health and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, malt beverages, or any substance found within the malt beverage, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, malt beverages, or any substance found within the malt 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 the malt beverage, as well as statements and claims of nutritional value (e.g., statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

(ii) *Specific health claim* is a type of health-related statement that, expressly or by implication, characterizes the relationship of the malt beverage, alcohol, or any substance found within the malt beverage, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between malt beverages, alcohol, or any substance found within the malt beverage, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of malt beverage or alcohol consumption.

(2) *Rules for advertising.* (i) *Health-related statements.* In general, advertisements may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-

related statement. Such disclaimer or other qualifying statement must appear as prominent as the health-related statement.

(ii) *Specific health claims.* A specific health claim will not be considered misleading if 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 levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim and in a manner as prominent as the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of malt beverage or alcohol consumption is presumed misleading unless it—

(A) 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 malt beverage or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement, and in a manner as prominent as the health-related directional statement, the following disclaimer: "This statement should not encourage you to drink or increase your alcohol consumption for health reasons;" or

(2) Includes as part of the health-related directional statement, and in a manner as prominent as the health-related directional statement, some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

* * * * *

Signed: February 13, 2003.

Arthur J. Libertucci,
Administrator.

February 25, 2003,

Timothy E. Skud,
Deputy Assistant Secretary, (Regulatory, Tariff and Trade Enforcement).

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