

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