

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,