

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.