

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