



INDUSTRY CIRCULAR

DEPARTMENT OF
THE TREASURY

Bureau of Alcohol, Tobacco and Firearms
Washington, D. C. 20226

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HEALTH CLAIMS IN THE LABELING AND ADVERTISING OF ALCOHOLIC BEVERAGES

Distilled Spirits Plants, Wineries, Brewers, Wholesalers and Importers of Alcoholic Beverages, and Others Concerned:

PURPOSE. The purpose of this circular is to announce the position of the Bureau of Alcohol, Tobacco and Firearms (ATF) with respect to health claims made in the labeling and advertising of alcoholic beverages. This circular also announces ATF's intention to engage in rulemaking on this subject, so as to develop more concrete guidelines with respect to health claims in the labeling and advertising of alcoholic beverages.

BACKGROUND. ATF has received many inquiries regarding the inclusion on wine labels and in wine advertising of statements which make therapeutic or curative claims or which otherwise attribute positive effects to the consumption of wine.

Under the FAA Act, 27 U.S.C. §205(e) and (f), ATF is authorized to issue regulations on the packaging, labeling, and advertising of alcoholic beverages as will prohibit deception of the consumer, and will prohibit, irrespective of falsity, such statements relating to analyses, guarantees, and scientific or irrelevant matters as are likely to mislead the consumer. Under these regulations, labels and advertisements are prohibited from containing any statement, design, representation, pictorial representation, or device representing that the use of distilled spirits, wine, or malt beverages has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression.

Lacking substantial evidence to the contrary, ATF and its predecessor agencies have historically taken a very strict view of the regulatory prohibition on curative or therapeutic claims about alcoholic beverages. This view is based on the fact that distilled spirits, wine, and malt beverages are, in reality, alcoholic beverages and not generally recognized as medicines.

ATF views statements which make claims regarding health benefits associated with alcoholic beverage consumption as making therapeutic or curative claims. ATF believes that any claim which sets forth only a partial picture, representation, or truth is as likely to mislead the consumer as those that are actually false. A statement which attributes positive health benefits to the moderate consumption of alcoholic beverages, even if backed up by medical evidence, may have an overall misleading effect if such statement is not properly qualified, does not give all sides of the issue, and does not outline the categories of individuals for whom any such positive effect would be outweighed by numerous negative health effects.

Furthermore, ATF believes that its traditional policy regarding health claims on labels has been reinforced by the 1988 enactment of the Alcoholic Beverage Labeling Act (ABLA), 27 U.S.C. §213 ~~et seq~~ et seq. A B L A 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 alcoholic 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 alcoholic beverages. In order to effectuate this goal, Congress prescribed specific language which must appear on the labels of alcoholic beverage products. It is ATF's position that to the extent that the overall message of any health **claim** is inconsistent with the message of the health warning statement, then it may result in label information which is misleading and confusing to the consumer, and which would thus be prohibited under the FAA Act.

ATF does recognize that there is currently a growing body of scientific research and other data that seems to provide evidence that lower levels of drinking decrease the risk of death from coronary artery disease. However, as a result of the most recent advice from the Department of Health and Human Services, ATF has also been advised that there are numerous negative health tradeoffs that must be considered in the formulation of any policy surrounding the dissemination of such information.

Several questions are presented by these recent studies. The first is whether the studies represent isolated findings, or **whether** there is significant agreement within the scientific and medical communities with respect to these findings. If there is such agreement, the next issue is whether such a health benefit claim would be misleading unless it was further qualified by information regarding the adverse effects of alcohol consumption. Finally, the question has been raised as to whether any type of health claim should ever be allowed in the labeling and advertising of alcoholic beverages, due to the inherent dangers associated with these products.

Due to the complex scientific nature of these claims, ATF arranged for discussions with the Food and Drug Administration (FDA) to develop a consultative approach for evaluating the use of these health claims in the labeling and advertising of alcoholic beverages. ATF may, with the consent of the department or agency affected, utilize the services of any department or other agency of the United States Government to the extent necessary to carry out its powers and duties under the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. § 202(f).

While ATF has jurisdiction over the labeling of alcoholic beverages, the Bureau has consistently utilized the scientific and public health expertise of FDA in approving ingredients in alcoholic beverages, requiring label disclosure of certain substances, and in identifying adulterated alcoholic beverages which are deemed mislabeled. In light of the expanding universe of medical evidence dealing with the moderate consumption of alcoholic beverages, and in an **effort** to continue to draw upon the expertise of other agencies, ATF believes it is **useful** to consult with FDA when ATF is evaluating such health benefit claims.

ATF has determined that a more formal regulatory structure for approving health claims on labels is desirable. FDA evaluates health claims on food labels pursuant to its authority under the Federal Food, Drug, and Cosmetic Act. This law was recently amended by the Nutrition Labeling and Education Act (**NLEA**), Pub. L. No. 101-535 (1990). As amended, 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 the FDA. See 21 U.S.C. § 343(r)(1)(B). The regulations recently issued by FDA provide that FDA will only approve a health claim when it determines, “based on the totality of publicly available 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.” 58 Fed. Reg. 2478, 2533 (1993) (to be codified at 21 C.F.R. §101.14(c)).

DISCUSSION. ATF recognizes that there are differences between ATF's statutory mandate to prevent misleading statements on labels and in advertising of alcoholic beverages under the FAA Act, and the more specific authority given to FDA in regulating health claims on food labels pursuant to the NLEA. However, in many respects, the issues presented are similar. The overriding issue is whether such health claims are false or misleading. In view of the provisions of the FAA Act dealing with misleading statements and the health warning provisions of the ABLA, ATF has the statutory authority to promulgate regulations mandating criteria for the approval of health claims on alcoholic beverage labels similar to the criteria and procedures the FDA has adopted for approving health claims on food labels. Such an approach would produce greater consistency in the positions of ATF and FDA, and would provide more structured guidance to the industry with respect to this controversial subject. ATF also believes it would be useful to incorporate the scientific and public health expertise of FDA in issuing these regulations.

Thus, ATF has decided that the issue of health claims made in the labeling and advertising of alcoholic beverages should be aired for public comment. This issue has become very controversial over the last few years, and ATF believes it would be beneficial to solicit comments on this issue from the medical and scientific communities, the alcoholic beverage industry, and consumers. In particular, ATF will solicit comments on whether ATF regulations should incorporate substantive standards for evaluating health claims similar to those contained in the new FDA regulations.

Pending the initiation of rulemaking proceedings, ATF will continue to evaluate health claims made in the labeling and advertising of alcoholic beverages on a case-by-case basis. In its evaluation of specific health claims, ATF will seek advice from experts outside the Bureau regarding the truthfulness of such claims.

While advertisements are not required to have ATF pre-approval, industry members are reminded that they may obtain advance clearance of proposed advertising materials from ATF if they wish to do so. It should be noted that the FAA Act not only prohibits false or misleading advertising, it also prohibits statements in advertising which are inconsistent with any statement on the labeling of the products advertised. 27 U.S.C. § 205(f)(5). It is ATF's position that advertising which does not present a balanced picture of the health risks associated with alcohol consumption is not only misleading, but it is also inconsistent with the health warning statement required to appear on every alcoholic beverage label.

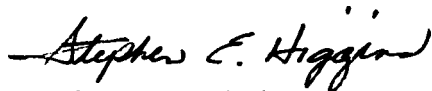
ATF has received inquiries from several industry members asking whether it would be in violation of the regulations to disseminate advertising materials which included the full text of the April 1992 edition of Alcohol Alert, which is published by the National Institute On Alcohol Abuse and Alcoholism (NIAAA) of the Public Health Service. This edition consists of an article and commentary on the subject of "moderate drinking" which present a comprehensive overview of the risks and benefits associated with the moderate consumption of alcoholic beverages. After consulting with NIAAA on this matter, ATF has determined that the dissemination of the full text of this publication in an advertisement would not be in violation of current ATF regulations. If such advertisements also contain editorializing, advertising slogans, or exhortations to consume the product, ATF will evaluate such additional text to determine whether or not the advertisement presents a balanced picture of the risks associated with alcohol consumption. In addition, the use of buttons, shelf talkers, table tents, and similar items which excerpt any portion of the NIAAA publication, which contain health slogans or other inferential statements drawn from this publication, or which are based upon any other publication or article citing the health benefits of alcohol consumption, will be closely scrutinized to determine if they present a balanced picture of the risks associated with alcohol consumption. ATF believes that the likelihood that the promotional items listed above will contain balanced statements is very low.

ATF's views do not necessarily represent the views of other Federal agencies with jurisdiction over this area, such as the Federal Trade Commission and FDA. For example, FDA has advised ATF that curative, therapeutic, or disease-prevention claims for an alcoholic beverage might place the product in the category of a drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §321(g)(1)(B). Furthermore, industry members should also be

cautioned that any approval from ATF of an advertisement containing a health claim is only valid pending the issuance of future regulations on this subject.

Although the regulations do not currently mandate specific procedures for the approval of health claims on alcoholic beverage labels, ATF would remind industry members that such health claims 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 would be outweighed by numerous negative health effects. ATF considers it extremely unlikely that such a balanced claim would fit on a normal alcoholic beverage label.

INQUIRIES: Questions concerning this circular should refer to its number and be addressed to the Chief, Market Compliance Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226.


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