

COMPLIANCE MATTERS

93-1

This issue of ***Compliance Matters*** is the first in a series of publications which the Office of Compliance Operations will issue in order to inform members of the alcoholic beverage industry of policies or procedures which might affect them. Compliance Matters will include the publication of items of national and regional significance.

Compliance Matters (93-1) provides a list of various types of imported and domestic alcoholic beverages which require a laboratory analysis by ATF's National Laboratory Center (NLC) in Rockville, MD, prior to the submission of an application for a Certificate of Label Approval (COLA). Samples must be accompanied by a method of manufacture and a list of every ingredient used in the manufacture of the alcoholic beverage. This information must be submitted on the foreign producer's letterhead and must be signed by an officer of the company. The sample and the accompanying paperwork must be submitted to the NLC, Beverage Alcohol Section, 1401 Research Boulevard, Rockville, MD 20850 (FAX 301-413-9463).

Upon completion of the analysis, a Pre-Import letter, which provides the proper class and type designation for the product, will be issued to the importer or to the Importer's designated representative. A copy of the Pre-Import letter must accompany the submission of the COLA application. Samples of domestic products requiring laboratory analysis should also be sent to the NLC together with a letter indicating the reason for the submission.

Compliance Matters (93-1) also provides a list of those domestically produced wines, distilled spirits and malt beverage products which require an approved formula or statement of process prior to submission of a COLA.

Products which require laboratory analysis prior to label submission.

IMPORTED PRODUCTS

WINES (containing 7% or more alcohol by volume)

Agricultural	Honey wine (Mead), Rhubarb, etc.
Effervescent	Flavored Sparkling or Flavored Carbonated Wine.
Other than standard	Wine specialties, flavored wine, wine cocktails, aperitifs (with the exception of Italian vermouth), coolers and blends of wines from different fruits.
Nonbeverage wine	To determine potability.
Plum wine (Asian)	To determine if product is wine or flavored sake.

DISTILLED SPIRITS

Vodka	All Vodka.
Brandy*	All Brandies with the exception of Cognac, Armagnac, and Calvados.
Whisky	All Whiskys with the exception of Scotch, Irish, and Canadian.
Flavored Distilled Spirits Products	Cordials, Liqueurs and Flavored Gins, Brandies, Whiskys, and Vodkas.
Distilled Spirits Specialties	Flavored distilled spirits, cocktails, and coolers.
Diluted Distilled Spirits	Diluted Vodkas, Gins, Brandies, and Whiskys.
Aguardiente	To determine proper class and type designation.
Shochu, Michiu	To determine proper class and type designation.
All South African Distilled Spirits Products	

* Until September 30, 1993 all applications for Certificates of Label Approval (COLA) for French Brandies (except Cognac, Armagnac and Calvados) may be submitted for approval, provided that a sample, together with a list of ingredients and method of manufacture, has been submitted to the NLC in Rockville, MD., and the assigned laboratory number has been placed in item 11 of the application. The labels, if acceptable, will be approved with a 6-month termination date pending an approved laboratory analysis. Applications for these brandies which are submitted after September 30, 1993, will require a completed laboratory analysis prior to submission for label approval.

MALT BEVERAGES

Alcohol free Malt Beverages.

Flavored Malt Beverages such as Coolers, Lambics, Shandies, etc.

Malt ciders and any other malt beverage marketed under a name other than Beer, Ale, Porter, Stout, Lager, or Malt Liquor.

DOMESTIC PRODUCTS

Grappa	Methanol.
Nonbeverage wine	If denatured with other than 1.5g of salt per 100ml.
Fruit Brandy (pear, peach, etc.)	For methanol content.
White Brandy	To determine lovibond (color), age and character.

Domestic Products which require approved formulas or statements of process prior to label submission.

WINE

Agricultural	Honey wine (Mead), Rhubarb, etc.
Effervescent	Flavored Sparkling or Flavored Carbonated Wine.
Other than standard	Wine specialties, flavored wine, wine cocktails, aperitifs (includes vermouth), coolers and blends of wines from different fruits.
High Fermentation Wine, Heavy Bodied Blending Wine and Spanish Type Sherry.	
Nonbeverage wine	All nonbeverage wine.

DISTILLED SPIRITS

Vodka	Charcoal filtered and/or critic acid and/or sugar addition and/or redistillation.
Gin	Compound or redistilled.
Brandy	White Brandy or Brandy with added blending materials.
Whisky	Blended Whisky, Spirit Whisky, and Whisky with added blending materials.
Rum	With added blending materials.
Flavored Distilled Spirits Products	Cordials, Liqueurs, and Flavored Gins, Brandies, Whiskys, and Vodkas.
Distilled Spirits Specialties	Including cocktails and coolers.
Diluted Distilled Spirits	Diluted vodkas, Gins, Brandies, and Whiskys.

MALT BEVERAGES REQUIRING STATEMENTS OF PROCESS

Alcohol free and nonalcoholic malt beverages.
Flavored malt beverages such as Coolers, Lambincs, Shandies, etc.
All Sakes and Cereal Beverages.
Malt ciders and any other malt beverage marketed under a name other than Beer, Ale, Porter, Stout, Lages or Malt Liquor.

INDUSTRY COMPLIANCE DIVISION

NOTE: The Alcohol User Fee Bill was dropped from the Budget Reconciliation Bill recently passed by the Congress.

LABELING SECTION

The TURNAROUND TIME targeted for label applications is nine (9) calendar days, the equivalent of 6-7 workdays. We continually strive to complete the review and processing of applications for certificates of label approval in nine days or less. Our nine-day goal applies to all label applications—regardless of the submission method; regular mail, express mail, and our front desk service. While nine days is our goal, and the majority of applications are processed in nine days or less, there are unavoidable instances (detailed research required, legal review required, etc.) where we will exceed the nine days. However, our ultimate goal is to review and process level applications as efficiently as possible. We are aware that emergency situations will occur. If an emergency arises, you may request EXPEDITE service through the Chief, Labeling Section. No expedite requires will be considered without documentation as to the need for expedited handling.

MARKET COMPLIANCE BRANCH

Compliance Matters 93-1 is part of a package which includes two Industry Circulars:

- Industry Circular Number: IC-93-6 dated 7/12/93 "**TRADE PRACTICE ENFORCEMENT**"
- Industry Circular Number: IC-93-8 dated 8/2/93 "**HEALTH CLAIMS IN THE LABELING AND ADVERTISING OF ALCOHOLIC BEVERAGES**"

REVENUE PROGRAMS DIVISION

WINE & BEER BRANCH

STANDARD OF IDENTITY FOR MALT LIQUOR

ATF published Notice No. 771 in the Federal Register April 19, 1993, (58 FR 21126). ATF announced it is considering amending regulations issued under the Federal Alcohol Administration Act (FAA Act) to provide a standard of identity for malt liquor. Currently, regulations under the FAA Act do not set forth a standard of identity for malt liquor, or for any other malt beverage product.

- **ALCOHOLIC CONTENT LABELING FOR MALT BEVERAGES**

ATF published Notice No. 772 in the Federal Register April 19, 1993, (58 FR 21233), this notice solicits comments on an interim rule permitting the optional statement on a malt beverage label of alcoholic content. Specifically, the notice requested comments regarding the form of the statement, type and so forth.

If you have questions concerning any information contained in this publication or if you wish to suggest

topics for future issues you may write to:

Bureau of Alcohol, Tobacco and Firearms
Compliance Matters
Industry Compliance Division
650 Massachusetts Avenue, NW
Washington, DC 20226

INDUSTRY

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Washington, DC 20226

Number: IC-93-6 Date: 7/12/93

IC-93-6 Date: (Also Included)

CIRCULAR

TRADE PRACTICE ENFORCEMENT

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

PURPOSE: The purpose of this circular is to advise members of the regulated industries of the position of the Bureau of Alcohol, Tobacco and Firearms (ATF) concerning the establishment of "exclusion in whole or in part" in exclusive outlet, tied house, and commercial bribery investigations under the Federal Alcohol Administration Act ("FAA Act"). 27 U.S.C. § 205(a), (b), and (c) Guidance to the industry is necessary in this area due to the decision in Fedway Associates, Inc., et al. v. United States Treasury Department, Bureau of Alcohol, Tobacco and Firearms, 976 F.2d 1416 (D.C. Cir. 1992). The provisions on consignment sales, labeling and advertising are not affected by the decision since those provisions do not involve the element of exclusion. 27 U.S.C. § 205(d), (e), and (f).

BACKGROUND: After an extensive investigation, ATF charged Fedway Associated, Inc. (Fedway), an importer and wholesaler of alcoholic beverages, with furnishing televisions, microwaves, CD players and VCR's, among other things, to retailers to induce the retailers to purchase Finlandia vodka and Captain Morgan rum to the exclusion of alcoholic beverages offered for sale by Fedway's competitors, all in violation of the tied house and commercial bribery provisions. Following an administrative proceeding and administrative appeal to the Director, Fedway sought judicial review of the suspension of its basic permits. The United States Court of Appeals for the District of Columbia Circuit rules in favor of Fedway.

DISCUSSION: The core issue in Fedway involved ATF's interpretation of the statutory phrase "exclusion in whole or in part." ATF argued that Fedway violated the FAA Act when it engaged in a promotion that resulted in the retailers purchasing less of a competitor's products, in whole or in part, as a result of the promotion. The court, however, held that Congress used exclusion "to indicate placement of retailer independence at risk by means of a "tie" or "link" between the wholesales and the retailer or by any other means of wholesaler control."

While Fedway court declined to articulate a specific standard or criteria pursuant to which ATF could establish exclusion under the FAA Act, there are several factors or guidelines developed in the decision which the court felt were evidence of an unlawful tie or link. Additionally, the Fedway court

acknowledged the judicial precedents that have recognized certain practices as plainly threatening retailer independence. Finally, the Fedway court stressed the utility of rulemaking to define practices which result in exclusion under the FAA Act.

As a result of the Fedway decision, ATF will initiate rulemaking to identify the practices which constitute exclusion under the FAA Act. The rulemaking will develop the factors which ATF will use in determining whether a particular practice has resulted in exclusion of a competitor's products.

ATF anticipates the notice of proposed rulemaking will involve a three-tier or category approach to the question of exclusion. First, the proposed rule will identify certain practices or conduct which will be presumed to result in exclusion under the FAA Act. This category will most likely include the practices and conduct which the Federal Court have recognized as resulting in a violation of the unfair trade practice provisions. These include: Levers v. Anderson, 153 F.2d 1008 (10th Cir. 1946) (relating to a wholesaler using indirectly majority stock ownership of a retailer to control the retailer's purchases of alcoholic beverages), Distilled Brands, Inc. v. Dunigan, 222 F.2d 867 (2d Cir. 1955) (relating to a tie-in sale where the wholesaler conditions the purchase of one distilled spirits products on the retailer purchasing another distilled spirits product at the same time), Black v. Magnolia Liquor Co. 355 U.S. 524 (1957) (relating to a tie-in sale similar to that in Distilled Brands, Inc.), and Stein Distributing Co. v. Department of the Treasury, Bureau of Alcohol, Tobacco and Firearms, 779 F.2d 1407 (9th Cir. 1986) (relating to a wholesaler control over the retailer about the placing of all the alcoholic beverage products on the premises and providing labor to reset the products on the premises).

After identifying the practices or conduct which are presumed to result in exclusion under the FAA Act, the rulemaking will identify certain types of trade practices that would be permissible regardless of their effect on the trade buyer. In essence, this would create a safe harbor area. Such an approach could be accomplished through the specific authorization in the regulations of certain promotional practices that could be utilized by industry members without fear of violating the FAA Act. It would be similar to the approach in the existing exceptions in 27 C.F.R. Part 6, but with a greater emphasis on the principles set forth in the Fedway decision in the development of such safe harbors.

The rulemaking would also establish standards or factors which would be used to determine if conduct exceeding the specific practices sanctioned in the safe harbor area would result in exclusion under the FAA Act. That is, exclusion would not occur simply by the mere fact that an industry member engaged in a practice outside the safe harbor area. Assuming such practice was not one already identified as exclusionary, ATF would evaluate the industry practice in light of such factors to determine if the practice resulted in exclusion. This tier or category of the rulemaking would include the factors which were identified in the Fedway decision. In making a determination of whether the retailer's independence is at risk by a tier or link, the Fedway court discussed factors such as the duration of the practice or promotion, the non-discriminatory feature of a practice where the promotion is available to all retailers, and the degree to which a practice involves an industry member in the day-to-day operations of a retailer. For example, a promotion running for a long period of time can threaten a retailer's independence, whereas a one-time or short-term promotional offering may not.

Although rulemaking will be initiated, ATF emphasizes that there is no enforcement holiday as a result of the Fedway decision. ATF will continue to undertake investigations, institute administrative actions against basic permits, and accept offers in compromise in situations where there is evidence of a link or tie to any other control over a retailer which threatens its independence. In making these determinations, ATF will be guided by the factors identified in the Fedway decision.

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.

Stephen E. Higgins

INDUSTRY

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Washington, DC 20226

Number: IC-93-8 Date: 8/2/93

CIRCULAR

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. The ABLA 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 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 21 C.F.R. § 101.14(c)).

DISCUSSION: ATF recognizes that there are differences between ATF's statutory mandate to prevent misleading statement 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 produce, 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 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 or 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.

Stephen E. Higgins

This was last updated on August 25, 1998