

DISTILLED
SPIRITS
COUNCIL
OF THE
UNITED
STATES

September 26, 2005

Mr. Francis W. Foote
Director
Regulations and Rulings Division
Tax and Trade Bureau
1310 G Street, N.W.
Washington, D.C. 20220

Re: Notice No. 41 – Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages (70 Fed. Reg. 22274 (April 29, 2005))

Dear Mr. Foote:

On behalf of the Distilled Spirits Council of the United States, Inc. (DISCUS), a national trade association representing producers and marketers of distilled spirits and importers of wines sold in the United States, we appreciate the opportunity to comment upon TTB's advance notice of proposed rulemaking regarding possible changes to the labeling and advertising requirements of beverage alcohol products regulated by the Bureau. Some of our members also are producers, importers and marketers of malt beverage brands sold in the United States.

With a full portfolio of beverage alcohol products, DISCUS members support and endorse an even-handed and equitable approach to all the products TTB regulates. This approach is in sync with other Federal agencies, including the Department of Health and Human Services, the Department of Agriculture and the Federal Trade Commission.

As regulated producers, importers and marketers of distilled spirits, wine and beer, we share the goal of TTB and the Federal Alcohol Administration (FAA) Act of providing consumers with meaningful information about the beverages they choose to purchase. It is from that shared objective that we respectfully submit our views regarding the questions posed by the instant notice.

Introduction

The Bureau's advance notice poses a host of questions regarding the labeling and advertising requirements of beverage alcohol products. As the Bureau well knows, some of these labeling and advertising issues, such as ingredient labeling, are not new and TTB's practice and policy responding to these issues have been in place for many years. These questions warrant the same answer today as they have in the past. Their respective responses are sound, sensible and fulfill the statutory objectives set forth in the FAA Act. Other matters raised in the



notice merit a fresh look and, in that regard, we encourage the Bureau to clarify that industry members should have the opportunity to provide on a voluntary basis appropriate and factual information to their consumers in a format similar to a display panel on other food and beverage containers.

TTB's initiative raises five substantive areas for consideration in the labeling and advertising of beverage alcohol products: (1) ingredient labeling; (2) allergen labeling; (3) calorie and carbohydrate statements; (4) alcohol content labeling for all beverage alcohol products; and (5) a reference to the Dietary Guidelines' advice regarding moderate drinking. The notice also requests input regarding how certain aspects of this information could be displayed on labels or in advertising via a "Serving Facts" panel, an "Alcohol Facts" panel or a "Composite Label" approach, which would include information components in common with the first two panels.

We respectfully submit that the Bureau's historical determination regarding ingredient labeling remains germane today. Given the substantial transformation of the raw materials used to produce beverage alcohol products in their respective production processes, there is little, if any, relationship between these raw materials and the contents of the finished product. Allergen labeling also is not new for beverage alcohol products as evidenced by the current requirement for sulfite labeling and, as in the past, the Memorandum of Understanding between the Food and Drug Administration (FDA) and TTB will guide the implementation of the Food Allergen Labeling and Consumer Protection Act of 2004.

For almost thirty years, the Bureau has permitted (and, in some cases, mandated; such as for caloric claims about a reduced calorie beer) calorie, carbohydrate, protein, and fat statements for malt beverage products and last year allowed distilled spirits and wine to make similar statements. The Bureau's historical determination to allow the inclusion of this information on labels and/or in advertising equally remains relevant today. Alcohol content labeling for beverage alcohol products also is a matter that has been longstanding before the Bureau. Mandatory alcohol-by-volume labeling should be required for all products as a core, essential component of consumer information.

Finally, the proposal to include on product labels the Dietary Guidelines' advice regarding moderate drinking ("U.S. Dietary Guidelines advice on moderate drinking: no more than two drinks per day for men, one drink per day for women") urged by the Center for Science in the Public Interest (CSPI) and the National Consumers League (NCL) may run afoul of the Bureau's rules and current guidance to industry regarding health claims and other health-related statements. We are interested in the Bureau's views regarding same.

A quintessential predicate for the consideration of such a proposal, however, is enacting a requirement for mandatory alcohol-by-volume labeling for all beverage alcohol products. Irrespective of the Bureau's determination regarding the CSPI and NCL proposal to reference the

Dietary Guidelines, industry members should be allowed at their discretion to include standard drink and alcohol content per serving information on their product container labels or in their advertising. Information about what constitutes a standard drink is the building block of, and inherent in, the Dietary Guidelines' advice about moderate drinking.

In displaying the relevant information, we support the approach taken by the Bureau in both of its White Papers issued last year regarding the use of a "Serving Facts" panel. The caption "Serving Facts," rather than "Alcohol Facts" proposed by the 2003 petition, is a more accurate description of the type of information that would be displayed on this panel since it would not include, for example, all the mandatory information required by the Bureau's rules. We also fully support the information components set forth by the Bureau regarding the optional "Serving Facts" panel, including the requirement to state the amount of fluid ounces of alcohol in each serving, and continue to support the optional inclusion of the standard drink statement in that panel.

In the discussion below, each of these points is amplified and appended hereto are separate responses for the discrete questions posed by the Bureau in the advance notice. Separately, we are submitting an inter-industry response on behalf of a coalition of both domestic and international organizations pertaining to allergen labeling for beverage alcohol products.

I. Ingredient Labeling

Regarding ingredient labeling, the Bureau has investigated and reviewed the matter of mandatory ingredient labeling on prior occasions. For example, during the 1970s and 1980s, the Bureau studied and explored this matter in depth and ultimately determined that ingredient labeling should not be required. The Bureau based its conclusion, in large part, on its finding that ingredient labeling not only would be of little value, but also would be misleading to the consumer because "[t]he substantial transformation involved in the production process means that there is only a strained relationship between the initial ingredients which go into the production process and the ultimate contents of the product to be consumed." (48 Fed. Reg. 45549 at 45555 (October 6, 1983).)

The Bureau's determination was upheld by the U. S. Court of Appeals for the District of Columbia wherein the Court found that the evidence "support[s] the agency's conclusion that, in many cases, both basic ingredients and additives will be substantially transformed by distillation and fermentation;" therefore, "the ingredients information...would have been of little value to consumers generally or to people with allergies, and the label information might even have been misleading since it would not accurately describe the contents of the finished product." (Center for Science in the Public Interest v. Department of Treasury, 797 F. 2d 995 at 1000, 1001 (D.C. Cir. 1986).)

Twenty years later (July 2003), the Government also concluded in the context of USDA's National Organic Program regulations (<http://www.ttb.gov/alfd/alfdorganic.htm>) that ingredient labeling would be inappropriate for beverage alcohol products and eliminated any requirement for an ingredient statement on beverage alcohol products.

We submit that the Bureau's longstanding conclusion that an ingredient statement would not provide useful information as to the actual contents of beverage alcohol products remains equally valid today. Consequently, the proposal to require ingredient labeling should be rejected since it will not provide meaningful information to consumers and, in fact, would be misleading.

II. Allergen Labeling

Regarding allergen labeling, this matter also is not new for the Bureau. The Bureau has required sulfite labeling for allergenic purposes since 1987 where sulfur dioxide or a sulfiting agent is detected at a level of ten or more parts per million, measured as total sulfur dioxide. Pursuant to the Food Allergen Labeling and Consumer Protection Act of 2004, food products, including beverage alcohol products, that contain an ingredient that bears or contains a major food allergen (milk, egg, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) must include this information on their labels unless the food ingredient does not cause an allergic response that poses a risk to human health or does not contain allergenic protein.

As for other food products and pursuant to the MOU between FDA and the Bureau, FDA will be making decisions regarding what food products will or will not require allergen labeling. In that regard, we understand that FDA is in the process of promulgating guidance in establishing thresholds for these major food allergens in terms of the application of the Act's labeling requirement. We applaud that undertaking and also encourage due regard to the actions taken by the European Union regarding what products do or do not require labeling under the EU Allergen Directive (2003/89/EC).

Many beverage alcohol products are outside the scope of the Food Allergen Labeling and Consumer Protection Act since they do not contain protein. For example, irrespective of the "ingredients" used in producing a wide array of distilled spirits, protein is not carried over into the distillate after the completion of the distillation process. Other beverage alcohol products also will fall outside the Act either because their food ingredients do not cause an allergic response posing a human health risk or do not contain allergenic protein. For these other beverage alcohol products, we urge the Bureau to follow the approach taken by the EU that excludes categories of products that are produced and/or processed in a similar manner, *i.e.*, the exclusions from the allergen labeling requirement are linked to the specific methods of manufacture and/or uses identified in the documentation supporting the exclusions.

Finally, for those products that will require labeling, we urge the Bureau to follow the approach currently utilized in Parts 4, 5 and 7 regarding sulfite labeling. We also urge the Bureau to take into account the approach adopted by the EU whereby a labeling indication is not

necessary when the allergen already is included under its specific name on the label of a product or in the name under which the beverage is sold. These approaches have served and will continue to serve all interests well-- the Bureau, the consuming public and industry members both here and abroad.

We submit that this broad framework and the more detailed consideration set forth in the inter-industry submission will meet and satisfy the Congressional directive to the Bureau set forth in the Act's conference report: "The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products."

We trust that, working in tandem, TTB and FDA will implement the Food Allergen Act in a manner that meets its objectives. In that regard, the Food Allergy & Anaphylaxis Network (FAAN) has stressed during the recent FDA stakeholder meetings that any labeling for food allergens must take into account whether or not that food will produce an allergic reaction and that labeling for all allergen levels may lead to further restricted diets, increased frustration and risk-taking, and undermining the integrity of labeling statements. Consumers need to trust that the allergen labeling information is reliable and not be subjected to precautionary statements where the statement will be ignored based upon, for example, prior experience consuming the food product in question.

III. Carbohydrate and Calorie Statements

We support the guidance provided by TTB in Ruling 2004-1 regarding the optional use of calorie, carbohydrate, protein, and fat statements in the advertising and/or labeling of beverage alcohol products and applaud the Bureau for extending the use of these statements for distilled spirits and wine products by this Ruling.

Since at least 1976, the Bureau has allowed (or, in some cases, mandated, such as for caloric claims about a reduced calorie beer) carbohydrate, caloric, protein, and fat references on malt beverage labels as part of a "Statement of Average Analysis." Except for those products where claims are made about these components, the provision of this information has remained optional for an industry member choosing to provide information about the carbohydrate and caloric content of his/her product. We urge the Bureau to continue its longstanding approach to allow these statements on a voluntary basis by an industry member choosing to provide such information in the labeling and/or advertising of his/her product.

According to the Bureau's Rulings, representations about the calorie or carbohydrate content of a product must be accompanied by a "Statement of Average Analysis" that lists the serving size in fluid ounces and the quantity of each of the following contained in a single serving size: (1) calories; (2) carbohydrates (in grams); (3) protein (in grams); and (4) fat (in

grams). In providing this optional labeling and advertising information, we also urge the Bureau to adopt the approach outlined in its two White Papers issued last year and allow the use of the "Serving Facts" panel proposed in those White Papers, as well as described in the instant notice, in lieu of the use of a "Statement of Average Analysis."

The voluntary "Serving Facts" panel includes the serving size in fluid ounces, the number of servings per container and the quantity in each serving of the following information: (1) calories; (2) carbohydrates (in grams); (3) protein (in grams); (4) fat (in grams); and (5) alcohol expressed in fluid ounces. The voluntary "Serving Facts" panel also could include an optional standard drink statement: "A standard drink contains 0.6 fl. oz. of alcohol. A serving of this beverage is (x number) standard drink(s)."

A requirement to state the amount of alcohol in each serving will provide consumers with pertinent information about the relationship between the serving sizes set forth in Ruling 2004-1 and the amount of alcohol in those servings. It is a requirement that is endorsed by the CSPI and NCL in their 2003 petition to the Bureau. Moreover, it is a requirement that was endorsed by the majority of comments filed in response to TTB's 2004 White Papers (based upon the documents produced pursuant to our FOIA requests) that included submissions by public health officials, industry members and advocacy groups.

We also support the optional inclusion of a standard drink statement in the voluntary "Serving Facts" panel. Government experts and public health organizations have recognized the importance of standard drink information and have defined a standard drink in the manner the Bureau has done in its original draft "Serving Facts" White Paper. For example, the U.S. Department of Education's Higher Education Center for Alcohol and Other Drug Abuse and Violence Prevention uses the same information in the standard drink definition as has every edition of the Dietary Guidelines for America issued by the Departments of Health and Human Services and Agriculture since 1985 (excerpts attached).

Similarly, the National Institute on Alcohol Abuse and Alcoholism, the National Consumers League, the Automobile Association of America, the National Highway Traffic Safety Administration, the American College of Emergency Physicians, the National Council on Alcoholism and Drug Dependence, the American Medical Women's Association, Mothers Against Drunk Driving, the National Alcohol Beverage Control Association, State Motor Vehicle Departments, and health professionals across the country define a standard drink as reflected in the Bureau's 2004 White Paper (excerpts attached).

To ensure a consistent and easily understood approach to issues surrounding various carbohydrate, calorie, protein, and fat claims, we urge that TTB work in tandem with FDA regarding specific standards for the use of terms, such as "low calorie," "reduced calorie," "lower calorie," "calorie-free," and "light" or "lite" on beverage alcohol products. In the context of the application of these terms vis-à-vis the carbohydrate and caloric content of a product, it only makes sense for all food products, including beverage alcohol products, to follow the same standards.

IV. Alcohol Content Labeling

It has been over a decade since the Supreme Court struck as unconstitutional the FAA Act's provision prohibiting the placement of alcohol content statements on malt beverage labels. (Rubin v. Coors Brewing Co., 514 U.S. 476 (1995).) The Bureau has had in place an interim rule and a proposed rule for the labeling of malt beverages with a statement of alcohol content since 1993 after the U.S. District Court ruled that the Act's prohibition was unconstitutional.

We submit that the Bureau should require alcohol content labeling for all malt beverages. Such action not only would be in accord with other beverage alcohol products, but also would be consistent with TTB's recent mandate that any malt beverage containing any alcohol derived from added flavors or other added nonbeverage ingredients (other than hops extract) include its alcohol content as mandatory information on the brand label.

It makes sense that the labels of all malt beverages, not just those malt beverages that contain added flavors or added nonbeverage ingredients (other than hops extract), should state their alcohol content. The Bureau's new mandatory requirement for certain malt beverages does not "supersede" State laws any more than a mandatory alcohol content labeling requirement for all malt beverages. Further, wine 14% and under alcohol by volume currently is not required to have an alcohol content statement. As a practical matter, however, the overwhelming majority of such wines do include such a statement and we urge the Bureau to make that statement mandatory as well.

Questions that have been raised by a few industry members about standard drink information and the inclusion of the amount of alcohol per serving in an optional "Serving Facts" panel seem to be misplaced given the fact that not all beverage alcohol products currently are required to provide information about their total alcohol content by volume.

It is true that there is variability in the alcohol content of the wide array of distilled spirits, wines and beers available in the marketplace. In that regard, most regular beers contain 5% alcohol by volume (ABV), many distilled spirits contain 40% ABV and many wines contain 12% ABV. The trend over the last several years, for example, has been for distilled spirits to have an alcohol content of less than 40% ABV and, conversely, the trend has been for beer brands new to the market to have an alcohol content greater than 5% ABV. Given this variability and irrespective of this variability, critically important information for a consumer is the amount of alcohol in the beverage alcohol product they choose to purchase. We urge the Bureau to promulgate a mandatory alcohol content labeling requirement for all beers and wines.

V. Dietary Guidelines' Advice Regarding Moderate Drinking

We fully appreciate the substantive points made by CSPI and NCL in their 2003 petition to the Bureau urging the inclusion of a label statement reflecting the Dietary Guidelines'

definition of moderate drinking: “consumption of up to one drink per day for women and up to two drinks per day for men” (the quoted text is from the 2005 Guidelines whereas the 2003 petition referenced the 2000 Guidelines). In support of this proposed label information, the petitioners cite the following:

Excessive consumption of alcohol produces a range of serious adverse health effects, including liver disease, acute pancreatitis, cardiomyopathy, reproductive disorders, diabetes, nutritional disorders, and some cancers. At the same time, *moderate* alcohol consumption may have a protective effect against coronary heart disease for some consumers. Those consumers who wish to take advantage of the health benefits of moderate alcohol consumption while avoiding the harm of excessive consumption should have clear information about the amount of alcohol per serving and the number of drinks per container so that they can measure their intake and ensure that they remain within the daily intake limits recommended by the *Dietary Guidelines*.

(CSPI/NCL Petition at 5, footnote omitted.)

Distillers always have encouraged those adults who choose to drink to do so responsibly and in moderation. People should not choose to drink alcohol for health reasons. Abuse of alcohol can cause serious health and other problems. Even drinking in moderation may pose health risks to some people. We always have urged those who have questions regarding potential risks and benefits of alcohol consumption, as well as all other health, diet and lifestyle choices, to talk to their health care professional.

In considering whether to adopt the proposed reference to the Dietary Guidelines' advice regarding moderate drinking proposed by CSPI and NCL, we presume that the Bureau will take into account its rules regarding health claims and other health-related statements set forth in TTB T.D.-1 (68 Fed. Reg. 10076 (March 3, 2003)), as well as the guidance provided to industry regarding health-related statements in TTB Ruling 2004-1. In that regard, the Bureau's 2003 final rule provides that “directional statements will not be allowed in the labeling or advertising of alcohol beverages unless accompanied by a disclaimer.” (Id. at 10097.) We would appreciate learning the Bureau's views regarding whether the CSPI/NCL proposal would constitute a “directional statement” under TTB's current rules and/or otherwise fall within these rules in terms of its permissibility on a beverage alcohol label.

VI. “Serving Facts” Panel

Regarding the proposed voluntary label panels and information components that would

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be contained in such a panel, we urge that the Bureau provide for the use of a "Serving Facts" panel in lieu of the use of a "Statement of Average Analysis" for the voluntary provision of information about the carbohydrate, caloric, protein, and fat content of a beverage alcohol product.

The information components of such a panel should include the serving size in fluid ounces based upon TTB Ruling 2004-1, the number of servings per container and for each serving the following information: calories; fat (in grams); carbohydrates (in grams); protein (in grams); and the alcohol content expressed in fluid ounces. We also urge that any industry member choosing to provide this information be allowed to include in the panel on an optional basis a standard drink statement consistent with the Dietary Guidelines for Americans issued by the Departments of Health and Human Services and Agriculture.

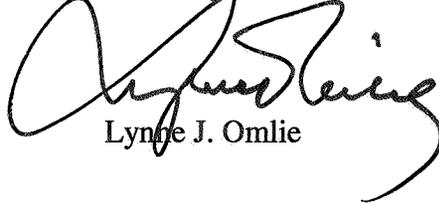
We submit that the caption "Alcohol Facts" in the panel proposed by CSPI and NCL does not best reflect the information components that would be set forth in such a panel. To that end, the caption "Serving Facts" is more appropriate to describe components in a serving of a beverage alcohol product. Regarding the information components proposed by CSPI and NCL, we submit that an ingredient labeling requirement for beverage alcohol products would not serve the interests of consumers or satisfy the objectives of the FAA Act for the reasons previously articulated by the Bureau and that any allergen labeling requirement follow the precedent set forth in the Bureau's current sulfite labeling rules.

In sum, we support the voluntary use of a "Serving Facts" panel that sets forth required and essential information regarding the alcohol, carbohydrate, caloric, fat, and protein content of a beverage alcohol product if an industry member chooses to provide that information on a label or in advertising. We also support the option of including a standard drink statement in that voluntary panel.

Conclusion

On behalf of DISCUS members, we appreciate the opportunity to comment upon the Bureau's advance notice. As always, we stand ready to assist TTB in whatever way possible. If you have any questions concerning our comment and/or otherwise, please do not hesitate to call.

Sincerely,



Lynne J. Omlie

LJO:smt

Enclosures

**TTB Notice No. 41
Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages**

General Questions	DISCUS Position
<p>1 Should TTB seek to require mandatory nutrition labeling (that is, calories, fat, carbohydrates, and protein) for alcohol beverage products, or should nutrition information be permitted only on a voluntary basis?</p>	<p>We respectfully submit that the provision of this information should be on a voluntary basis. The Bureau's longstanding position to allow an industry member the option of voluntarily providing this information has served all interested parties and stakeholders well, and there is no reason to depart from the Bureau's historical practice and policy.</p>
<p>2 Should TTB seek to require mandatory ingredient labeling (that is, a list of all ingredients used to make the product, including processing aids) for alcohol beverage products, or should ingredient labeling be permitted only on a voluntary basis?</p>	<p>We respectfully submit that the Bureau's longstanding position that ingredient labeling should not be required remains valid today. The Bureau, after exhaustive study and review, concluded more than 20 years ago that ingredient labeling would not provide useful information to consumers due to the substantial chemical changes that occur during the fermentation and distillation processes. This position also has withstood judicial scrutiny and has been upheld by the court. The transformation of the raw materials used to produce distilled spirits, for example, in the distillation process renders an "ingredient" statement both useless and inaccurate. For example, the corn used to produce whiskey is no longer present in the finished product. For most distilled spirits, the "ingredients" are alcohol and water, which already are noted by the ABV statement.</p>
<p>3 What areas need further research and evaluation before TTB can reach decisions on whether and how changes can be made?</p>	<p>Many, if not most, of the labeling and advertising matters raised in the Bureau's advance notice are not issues that require further research and evaluation. Rather, it is most critically important that these issues are approached in an even-handed manner; cognizant of the marketplace but not driven by competitive positioning of industry members in that marketplace; and with due regard concerning whether, in fact, labeling information, such as an alcohol content line in an optional Serving Facts panel, would violate Section 105 of the FAA Act in terms of deceiving or misleading consumers. We submit that providing such truthful and accurate information on a voluntary Serving Facts panel is supported by the FAA Act and its implementing regulations.</p>
<p>4 Are there modifications TTB can make to current requirements regarding alcohol beverage labels to help consumers better understand and benefit from the information on the label?</p>	<p>Those industry members that choose to include a carbohydrate and calorie statement, should be allowed to voluntarily provide such information and, in addition, to provide information about the alcohol content in the serving sizes specified by TTB Ruling 2004-1, as well as the option of setting forth a standard drink statement. These entries in a Serving Facts panel or in a Statement of Average Analysis would provide consumers with pertinent and useful information. Provision of such information is supported by the current regulatory scheme.</p>

General Questions	DISCUS Position
<p>5 Should TTB harmonize its alcohol beverage labeling regulatory requirements with those of other major producing nations, such as the Member States of the European Union, Australia, and Canada, and with regulatory schemes of other Federal agencies, such as the Food and Drug Administration (FDA)? If so, how would that be best done?</p>	<p>If and when a majority of other countries ever reach commonality on labeling issues and the U.S. appears to be the outlier, harmonization would be beneficial. In particular cases, such as allergen labeling that should be based upon available scientific research, decisions adopted by other countries based upon sound science should be given due regard and consideration in making TTB decisions.</p>
<p>6 Are consumers likely to derive benefits from more specific information on alcohol beverage labels, and, if so, are those benefits sufficient to warrant the economic costs associated with such revisions?</p>	<p>If information (unless required by law such as allergen labeling) is allowed on a voluntary basis, the consumer and the marketplace will determine the value and benefits of any associated costs.</p>
<p>7 What should be the agency's priorities in deciding which changes to make on alcohol beverage labels, that is, which changes are most important and which are least important?</p>	<p>The allergen labeling requirements are mandated by law and should be the primary priority in terms of promulgating new regulations. The provision of voluntary information, such as carbohydrate and calorie statements pursuant to TTB Ruling 2004-1, also should be permitted forthwith in a format such as the Serving Facts panel proposed by the Bureau last year.</p>
<p>8 Should any new labeling requirements apply equally to advertisements?</p>	<p>No. The Bureau's rules regarding labeling and advertising differ as they should. First, an industry member should have the option of choosing to provide information about the carbohydrate and caloric content of his/her product on the container label and/or in advertising. Second, the provisions of the Food Allergen Labeling and Consumer Protection Act apply only to the labeling of food products.</p>

Carbohydrate and Calorie Claims	DISCUS Position
<p>1 Should TTB promulgate regulations that define “low carbohydrate” for alcohol beverage products as containing no more than 7 grams of carbohydrates per standard serving size, as specified in Ruling 2004-1? Why or why not?</p>	<p>We respectfully submit that TTB and FDA should have the same approach to and standards for what would be considered “low carbohydrate.” The use of the same definitions will provide consumers with consistent information. Moreover, until FDA finalizes its position, TTB should abide by its position as set forth in TTB Ruling 2004-1.</p>
<p>2 Should TTB continue to prohibit use of the terms “effective carbohydrates” and “net carbohydrates” on labels and in advertisements? Why or why not?</p>	<p>We respectfully submit that TTB and FDA should have the same approach to and standards for these terms. The use of the same definitions as to what constitutes a carbohydrate for labeling and/or advertising purposes will provide consumers with consistent information.</p>
<p>3 Should TTB wait for the conclusion of FDA’s regulatory decision-making process for the use of the term “low carbohydrate” for food and beverage products FDA regulates before issuing regulations on a low carbohydrate standard for alcohol beverage products?</p>	<p>We respectfully submit that the provisions of TTB Ruling 2004-1 regarding the use of the term “low carbohydrate” should be applicable until FDA concludes its decision-making process and, at that juncture, the Bureau should issue regulations on this topic mirroring FDA’s approach.</p>
<p>4 How should TTB define the terms “low calorie” and “reduced calorie” for alcohol beverage products? Should we propose standards for these claims consistent with FDA’s standards? Should we develop our own alternate set of standards and, if so, what should they be?</p>	<p>We respectfully submit that TTB and FDA should have the same approach to and standards for these terms. The use of the same definitions will provide consumers with consistent information.</p>
<p>5 Should TTB establish regulations for the use of the terms “light” and “lite” on alcohol beverage labels? If so, should we propose standards for these claims consistent with FDA’s standards? How would these standards apply to products for which the term “light” is part of the standard of identity (such as light whisky” or “light wine”)?</p>	<p>We respectfully submit that TTB and FDA should have the same approach to and standards for these terms for purposes of carbohydrate and calorie statements. The use of the same definitions will provide consumers with consistent information. With respect to standards of identity, however, the use of the word “light” in some contexts serves a different purpose and has a different meaning. Consequently, a FDA and TTB definition of the term “light” or “lite” in comparing the caloric content of a product would not necessarily be germane to the Bureau’s standards of identity. TTB’s recognition of the categories known as “light whiskey” and “light wine,” for example, have co-existed with low calorie/low carb products for many years and should be allowed to continue to do so.</p>

<p>Alcohol Facts Petition of National Consumers League (Dec. 2003) to require all labels to include the following in a standardized format:</p>	<p>DISCUS Position</p>
<ul style="list-style-type: none"> • The beverage's alcohol content • serving size • alcohol in fluid ounces per serving • calories per serving • ingredients (including additives) • number of standard drinks per container • US Dietary Guidelines' advice on moderate drinking for both men and women 	<p style="background-color: #cccccc;">[Redacted]</p>
<p>Should alcohol beverage containers bear an Alcohol Facts label similar to the one presented in the CSPI petition? Why or why not?</p>	<p>We respectfully submit that a voluntary "Serving Facts" panel with information components discussed by the Bureau in both of its 2004 White Papers is a preferable and more informative approach. The information components of such a panel should include the serving size in fluid ounces based upon TTB Ruling 2004-1, the number of servings per container and for each serving the following information: calories; fat (in grams); carbohydrates (in grams); protein (in grams); and the alcohol content expressed in fluid ounces. We also urge that any industry member choosing to provide this information could include in the panel a standard drink statement consistent with the <u>Dietary Guidelines for Americans</u> issued by the Departments of Health and Human Services and Agriculture. Further, the caption "Serving Facts," rather than "Alcohol Facts" proposed by the 2003 petition, is a more accurate description of the type of information that would be displayed on this panel since it would not include, for example, all the mandatory information required by the Bureau's rules. Moreover, the facts are logically more relevant to a <u>serving</u> of the beverage alcohol product, rather than to the product as a whole. Regarding the other information components proposed by CSPI and NCL, we submit that an ingredient labeling requirement for beverage alcohol products would not serve the interests of consumers or satisfy the objectives of the FAA Act for the reasons previously articulated by the Bureau and that any allergen labeling requirement should follow the precedent set forth in the Bureau's current sulfite labeling rules. The proposal to include the <u>Dietary Guidelines'</u> advice regarding moderate drinking may run afoul of the Bureau's rules and current guidance to industry regarding health claims and other health-related statements. We look forward to learning the Bureau's position regarding this proposal as this process unfolds.</p>

<p>Alcohol Facts Petition of National Consumers League (Dec. 2003) to require all labels to include the following in a standardized format:</p>	<p>DISCUS Position</p>
<p>1. Should such a label include an ingredient list as suggested in the CSP1 petition?</p>	<p>No. We respectfully submit that the Bureau's longstanding conclusion that an ingredient statement would not provide useful information as to the actual contents of beverage alcohol products remains equally valid today. Consequently, the proposal to require ingredient labeling should be rejected since it will not provide meaningful information to consumers and, in fact, would be misleading.</p>
<p>2. Should the label be voluntary or mandatory?</p>	<p>The provision of information regarding the carbohydrate and caloric content of a product should remain voluntary. We fully support and endorse, however, a mandatory alcohol content labeling requirement for all beverage alcohol products.</p>
<p>3. If mandatory, should there be any exemptions from the alcohol facts and ingredient labels, such as for small businesses or for small containers?</p>	<p>We submit that there should be no exemptions from a mandatory alcohol content labeling requirement. Distillers both large and small have had a mandatory alcohol content labeling requirement for all of their container sizes for seventy years. Consumers should be provided with this vital information on all containers of beverage alcohol products.</p>
<p>4. Should current alcohol content statement labeling requirements be expanded to cover wines with an alcohol content of 14 percent alcohol by volume or less and malt beverages?</p>	<p>Yes. Alcohol content labeling should be required for all products as the core, essential component of consumer information. It should be stated as percentage alcohol by volume across all beverage alcohol classes, types and categories.</p>
<p>5. What would be the costs associated with mandatory alcohol facts and ingredient labeling to the industry and, ultimately, the consumer?</p>	<p>Please see the responses set forth above.</p>
<p>6. How might consumers benefit from such a label?</p>	<p>Consumers obviously will benefit from an alcohol content labeling requirement applicable to all malt beverages and all wines with an alcohol content of 14% ABV or less. Knowing the alcohol content of a product a consumer chooses to purchase is a critical fact in drinking responsibly.</p>
<p>7. As a consumer, how much extra would you be willing to pay for alcohol facts and ingredient labeling information?</p>	<p>DISCUS members are producers and importers.</p>
<p>8. Are there alternatives to mandatory alcohol facts and ingredient labeling for alcohol beverages? For example, if a label lists a Web site or telephone number where a consumer could obtain such information about the product, would this be sufficient?</p>	<p>There are a variety of different avenues to provide consumers information about a product, including websites and 1-800 numbers; however, alcohol content labeling should be mandatory for beverage alcohol products, including all malt beverages and all wines with an alcohol content of 14% ABV or less for which there are no current requirements.</p>

Allergen Labeling in response to Federal Allergen Labeling & Consumer Protection Act of 2004 (FALCP)	DISCUS Position
<p>Should TTB require allergen labeling on alcohol beverage containers to be part of or adjacent to a larger list of all ingredients found in the product, similar to the requirements of the Food Allergen Labeling and Consumer Protection Act of 2004? Why or why not?</p>	<p>No. First, there should be no requirement for ingredient labeling or an ingredient statement. Given the substantial transformation of the raw materials used to produce beverage alcohol products in their respective production processes, there is little, if any, relationship between these raw materials and the contents of the finished product. Second, for those products that will require allergen labeling pursuant to the Food Allergen Labeling and Consumer Protection Act, we urge the Bureau to follow the approach currently utilized in Parts 4, 5 and 7 regarding sulfite labeling. We also urge the Bureau to take into account the approach adopted by the EU whereby a labeling indication is not necessary when the allergen already is included under its specific name on the label of a product or in the name under which the beverage is sold. These approaches have served and will continue to serve all interests well -- the Bureau, the consuming public and industry members both here and abroad.</p>
<p>If the product name appearing on the label of an alcohol beverage container indicates that an allergen is present in the product, is it helpful to the consumer to have the allergen labeled again in a standardized allergen statement elsewhere on the container? To illustrate: If a product is called "Wheat Beer," should it also have a label elsewhere on the container that reads: "Allergens: wheat"? Why or why not?</p>	<p>No. A second label indication would be confusing and redundant with no offsetting benefit to the consumer. This approach is consistent with the EU determinations regarding allergen labeling requirements whereby a labeling indication is not necessary when the name of the allergen already is included in the name under which the beverage is sold.</p>

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Allergen Labeling in response to Federal Allergen Labeling & Consumer Protection Act of 2004 (FALCP)	DISCUS Position
<p>3</p> <p>TTB's current regulations allow certain allergens such as milk, albumen (egg), isinglass (a protein from fish bladders), and soy flour to be used as fining, processing, and filtering agents in the production of alcohol beverages. While fining, processing, and filtering agents are not primary ingredients in an alcohol beverage product, low levels of an agent may remain in the final product after production. When an allergen is used as a fining, processing, or filtering agent to produce an alcohol beverage, should TTB require that the product be labeled "Processed with [a specific allergen]" or "May contain [a specific allergen]"? Why or why not?</p>	<p>When an allergen is used as a fining, processing or filtering agent to produce a beverage alcohol product, the finished product will require allergen labeling pursuant to the Food Allergen Labeling and Consumer Protection Act if the allergenic protein remains in the finished product unless that ingredient does not cause an allergic response that poses a risk to human health. For all food products, including beverage alcohol products, and pursuant to the MOU between FDA and the Bureau, FDA will be making decisions regarding what food products will or will not require allergen labeling. In that regard, we understand that FDA is in the process of promulgating guidance in establishing thresholds for these major food allergens in terms of the application of the Act's labeling requirement. We applaud that undertaking and also encourage due regard to the actions taken by the European Union regarding what products do or do not require labeling under the EU Allergen Directive (2003/89/EC).</p> <p>Many beverage alcohol products are outside the scope of the Food Allergen Labeling and Consumer Protection Act since they do not contain protein. Other beverage alcohol products also will fall outside the Act either because their food ingredients do not cause an allergic response posing a human health risk or do not contain allergenic protein. For these other beverage alcohol products, we urge FDA and the Bureau to follow the approach taken by the EU that excludes categories of products that are produced and/or processed in a similar manner, <u>i.e.</u>, the exclusions from the allergen labeling requirement are linked to the specific methods of manufacture and/or uses identified in the documentation supporting the exclusions.</p>
<p>4</p> <p>Should allergenic fining, processing, and filtering agents be labeled in the exact same fashion as all other allergen ingredients? Why or why not?</p>	<p>Please see the responses set forth above.</p>
<p>5</p> <p>Testing methods for detecting allergens in food and beverage products typically can only detect an allergen if it is present at or above a certain minimum value. In light of that fact, would it be helpful to consumers for TTB to require an allergenic fining, processing, or filtering agent to be labeled regardless of whether a detection test shows that the allergen is or is not present in the final product? Why or why not?</p>	<p>Please see the responses set forth above. In addition, it is never possible to prove a negative. Modern test methods have evolved to test at extremely low levels and should be sufficient to scientifically establish that no allergenic protein exists. A labeling requirement regardless of whether a detection test shows that an allergen is not present would be misleading to the consumer and would remove a multitude of food selection choices for the consumer based upon misleading information.</p>

Allergen Labeling in response to Federal Allergen Labeling & Consumer Protection Act of 2004 (FALCP)	DISCUS Position
6 What is the lowest amount of an offending food allergen (or minimum threshold level) in an alcohol beverage product necessary to provide a mild, yet perceptible adverse allergic reaction in consumers with the most sensitive food allergies?	Please see the responses set forth above.
7 Is it possible to define a minimum threshold level for each major food allergen? If so, what are the minimum threshold levels for each major food allergen?	Please see the responses set forth above. In addition, TTB should follow the lead of FDA and the scientific community in terms of exemptions from allergen labeling requirements.
8 If FDA and/or the scientific community establish conclusively a minimum threshold level for a particular allergen, should TTB exempt from any allergen labeling requirements products containing the allergen proteins, but at a level below the established minimum threshold level? Why or why not?	Please see the responses set forth above. In addition, TTB should follow the lead of FDA and the scientific community in terms of exemptions from allergen labeling requirements.
9 What would be the costs associated with mandatory allergen labeling to the industry and, ultimately, the consumer?	Mandatory allergen labeling requirements pursuant to the Food Allergen Labeling and Consumer Protection Act were signed into law by the President in August 2004.
10 How might consumers benefit from allergen labeling?	Consumers will benefit from meaningful allergen labeling statements that provide information that an individual with allergies can rely upon in making food choices. Scientifically-based allergen labeling, which properly identifies those products containing allergenic protein capable of causing an adverse reaction, can provide beneficial information to consumers with allergies. Labeling that is not based upon scientific fact, and is misleading or confusing, will limit consumer choices unnecessarily and would not be beneficial.

Voluntary "Serving Facts" Labeling (industry member inquiries since Dec. 2003)	DISCUS Position
<p>1 Should alcohol beverage containers bear a Serving Facts label similar to the one presented in this section? Why or why not?</p>	<p>Yes. An industry member should have the option to provide on a voluntary basis information about the carbohydrate, caloric, protein, and fat content of his/her product in a Serving Facts panel in lieu of the manner in which the information is reflected in a Statement of Average Analysis.</p>
<p>2 Should such a label include a definition of a "standard drink" and if so, how should a "standard drink" be defined?</p>	<p>We support the inclusion on an optional basis of a standard drink statement in the voluntary carbohydrate/calorie panel. Government experts and public health organizations have recognized the importance of standard drink information and have defined a standard drink in the manner the Bureau has done in its original draft "Serving Facts" White Paper. For example, the U.S. Department of Education's Higher Education Center for Alcohol and Other Drug Abuse and Violence Prevention uses the same information in the standard drink definition as has every edition of the <u>Dietary Guidelines for America</u> issued by the Departments of Health and Human Services and Agriculture since 1985. Similarly, the National Institute on Alcohol Abuse and Alcoholism, the National Consumers League, the Automobile Association of America, the National Highway Traffic Safety Administration, the American College of Emergency Physicians, the National Council on Alcoholism and Drug Dependence, the American Medical Women's Association, Mothers Against Drunk Driving, the National Alcohol Beverage Control Association, State Motor Vehicle Departments, and health professionals across the country define a standard drink as reflected in the Bureau's 2004 White Paper. In that regard, a standard drink is 1.5 oz. of 80 proof distilled spirits, 12 oz. of regular beer or 5 oz. of wine and each contains 0.6 fl. oz. of alcohol.</p>
<p>3 Should such a label include graphic icons similar to, but not necessarily limited to, the one presented in this section? Why or why not?</p>	<p>An industry member should be permitted and, in fact, has the right to provide truthful, accurate information and/or depictions about its products. We support the optional and voluntary use of the standard drink graphic as set forth in the Bureau's original White Paper and in the instant advance notice. This depiction could be included in the "Serving Facts" label panel or elsewhere on the product container.</p>
<p>4 Should the label be voluntary or mandatory?</p>	<p>The "Serving Facts" panel should be voluntary and used at the option of an industry member.</p>
<p>5 If mandatory, should there be any exemptions from the serving facts label, such as for small businesses or for small containers?</p>	<p>Please see the responses set forth above. In addition, we reiterate that this type of labeling should be voluntary.</p>

Voluntary "Serving Facts" Labeling (industry member inquiries since Dec. 2003)	DISCUS Position
6 If not mandatory for all alcohol beverage products, should the Serving Facts label be required at least on alcohol beverages that make certain calorie or carbohydrate claims?	Yes. Such an approach would be consistent with the Bureau's Rulings and industry guidance over the last thirty years.
7 What would be the costs associated with mandatory serving facts labeling to the industry and, ultimately, the consumer?	The "Serving Facts" panel should be voluntary and used at the option of an industry member.
8 How might consumers benefit from such a label?	The consumer and the marketplace will determine the value and benefits of any associated costs.
9 As a consumer, how much extra would you be willing to pay for serving facts labeling information?	DISCUS members are producers and importers.
10 Are there alternatives to mandatory serving facts labeling for alcohol beverages? For example, if a label lists a Web site or telephone number where a consumer could obtain such information about the product, would this be sufficient?	There are a variety of different avenues to provide consumers information about a product, including websites, 1-800 numbers, and, of course, the option of a voluntary "Serving Facts" panel.
11 Should TTB allow a further breakdown of nutrients (for example, trans fat, sugars, fiber)?	TTB should follow FDA's approach to these matters as is appropriate for beverage alcohol products.

Voluntary "Serving Facts" Labeling (Industry member inquiries since Dec. 2003)	DISCUS Position
<p>Does the use of "standard drink" and "serving size" on the same label create confusion? Does any confusion arise if a label specifies ounces of alcohol in conjunction with serving size and percent alcohol?</p>	<p>No. First, the <u>Dietary Guidelines for Americans</u>, which is the foundation for nutrition policy in the United States and issued by the Departments of Health and Human Services and Agriculture every five years, historically has defined a standard drink as 12 ounces of regular beer, 5 ounces of wine, and 1.5 ounces of 80 proof distilled spirits. Certainly, there has been no confusion by these lead Federal Agencies in defining a standard drink for purposes of providing recommendations to Americans about their diet choices and responsible consumption.</p> <p>Millions of copies of these <u>Guidelines</u> have been distributed throughout the country over the past decades. The <u>Dietary Guidelines for Americans</u> is just one example among hundreds that have used together a "standard drink" and a "serving size." The fact that this information is in a Federal document and not on a label is not a relevant consideration in terms of whether such information is permissible under the Bureau's rules.</p> <p>Second, many government agencies and consumer advocacy groups, such as the National Consumers League, have specified the ounces of alcohol in conjunction with a serving size and the percentage of alcohol. For close to a decade, NCL has distributed and has made available via its website its fact sheet entitled: "Alcohol: How It All Adds Up" that combines ounces of alcohol, serving sizes and percentages of alcohol in terms of a standard drink.</p> <p>Health professionals also convey information about alcohol in terms of ounces of alcohol, serving size and the percentage of alcohol. Using the benchmark that a standard drink contains 0.6 fl ounces of alcohol, these professionals address the fact that the alcohol content in different types of beverage alcohol drinks may vary. NIAAA, the lead Federal Agency on alcohol issues, uses an identical approach in its publications.</p>