

Comments of Center for Science in the Public Interest to the Alcohol and Tobacco Tax and Trade Bureau on the Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages

September 23, 2005

The Center for Science in the Public Interest (CSPI) is a nonprofit health education and advocacy organization that promotes public and private policies to improve the health status of Americans. In addition to its work on nutrition issues, CSPI has focused since 1981 on improving federal and state policies related to alcoholic beverages. Primary support for CSPI's work comes from more than 900,000 members who subscribe to *Nutrition Action Healthletter*, and from foundations and private contributions. CSPI does not accept funds from government or corporate sources. We welcome the opportunity to comment on issues concerning the labeling of alcoholic beverages.

In 1972, CSPI first petitioned the Tax and Trade Bureau's (TTB) predecessor agency, the Bureau of Alcohol, Tobacco, and Firearms, to require ingredient labeling of alcoholic beverages. Since that time, CSPI has advocated a variety of alcohol-labeling improvements, few of which have been implemented. Therefore, we much appreciate the opportunity to comment on the current, comprehensive labeling proposal, and hope that the time has finally come when producers will be required to provide consumers with a wide range of important, specific information about the alcoholic beverages they consume. Such action by TTB would address vital consumer and public health and safety concerns. We applaud TTB's consideration of long-overdue, consumer-friendly labeling improvements.

CSPI's position on TTB's labeling initiative can be found in its December 2003 petition, filed jointly with the National Consumers League and others, which forms one basis for the subject Request for Comments. Our comments today differ only marginally from the proposal CSPI made in that petition.

Although the following comments will address only some of TTB's specific questions regarding its labeling initiative, we believe fundamentally that TTB's efforts should be governed by certain basic principles that will ensure that labeling changes will assist consumer choice, promote public health and safety, and minimize the potential for the promotion of alcoholic beverages either as healthful beverages or as a source of essential nutrition. Simply stated, CSPI calls upon TTB to put the concerns of the public above the interests of alcohol producers, who seek labeling changes at least partly to enhance their competitive prospects and expand the market for their products.

The following principles should guide TTB's development of final rules for the labeling of alcoholic beverages:

1. Labeling rules concerning important consumer information must be mandatory, rather than voluntary.

Consumers should not have to guess about the alcohol strength, serving size, number of servings per container, calories, or ingredients of alcoholic beverages. To allow voluntary labeling rather than require it would stand TTB's ANPRM rationale – to provide more specific information to consumers – on its head. Voluntary labeling would elevate producer discretion above consumer interest or need. Consumers should be able to look at *any product* in the marketplace to learn its ingredients, alcohol strength, etc. and use the information to compare among the myriad of available products. By generating questions about unlabeled products, incomplete or ad hoc labeling may create even more confusion than currently exists among consumers. Allowing labeling rules to be voluntary would permit producers to use labels selectively for marketing purposes, rather than for the purpose of providing important specific consumer information.

Past experience with nutrition labels for foods suggests that voluntary labeling of “alcohol facts” or “serving facts” would leave substantial gaps in consumer information about alcoholic beverages. “The grocery industry predicted in 1975 that 85% of companies would use nutrition labeling ‘in the near future,’ but as of 1986, nutrition labeling appeared on foods making up only 55% of grocery store sales of FDA-regulated processed foods and only 43% of total sales of USDA-regulated processed meat and poultry products. The percentage of FDA-regulated foods that carried nutrition labeling rose moderately from 1978 to 1982 but was stagnant from 1982 to 1986. Even giants such as Nabisco and Safeway fail to provide nutrition labeling on some of their foods.”¹

Some who have commented on this ANPRM, noting that this rulemaking may take many years (if in fact it moves forward), have suggested that voluntary labeling be permitted during the rulemaking period. We agree, although we urge that temporary voluntary labeling be limited to the following information: alcohol content by volume, serving size, number of servings per container, number of calories per serving, ingredients and allergens, and a statement of the U.S. Dietary Guidelines benchmarks for safe and low-risk drinking. Labels for products that make nutritional claims (such as light beers or “low-carb” products) should also include “average analysis” information, disclosing carbohydrate content and other currently required information.

2. Information labeling rules for alcoholic beverages must be universal and consistent, and apply to all alcoholic beverages regulated by TTB.

Today, different beverage types and different types of beverages within those types have different labeling requirements. For example, light beers must list calories and a statement of average analysis on the label; but beer containers are not required to

¹ Record of the Hearings Before the Human Resources and Intergovernmental Relations Subcommittee on Government Operations, House of Representatives (1st Sess. 1989) at 450 et seq. (The Nutrition Labeling and Education Act, which made nutrition labeling mandatory, became law in 1990 and was finally implemented in 1994.)

list alcohol content. Oddly, a can of Budweiser discloses (in tiny print set vertically on the container) its alcohol content (5% alc/vol), yet a can of Miller Lite, which bears an “average analysis” declaration required by FDA, doesn’t. We get to know that light beer contains no fat, but not that regular beer is also fat-free. Strangely, “malternative” products – but only those which derive most of their alcohol from distilled spirits sources (flavoring agents) – must provide alcohol-strength information. Brewed “malternatives” need not list alcohol content. Under current regulations, only wines that contain 14% alcohol by volume or more must label their alcohol strength. Additionally, wines containing less than 7% alcohol by volume are regulated by FDA, not TTB. They bear a full nutrition facts label.

If the purpose of labeling is to provide information and give consumers the ability to make informed choices about their alcohol consumption, there is no justification for such variation, which perpetuates only ignorance and massive confusion about alcoholic beverages. TTB should require that all beverages containing alcohol be labeled in the same way, both in terms of content and label design.

3. Some proposed label information is more important and meaningful than other proposals.

Requiring *all* alcoholic beverages, whether beer, wine, distilled spirits, malternatives, or others, to be labeled for alcohol content is essential. Alcohol can be harmful when consumed in excess and even addictive for a substantial number of consumers. For that reason, labeling should provide clear information that allows consumers to measure and moderate their drinking. Providing serving size, number of servings per container, and the U.S. Dietary Guidelines definition of safe drinking limits² would help consumers understand objective, scientifically determined safe limits and, conceivably, reduce their risk of alcohol problems. Information about calories per serving would also assist consumers in better understanding how alcohol consumption fits into their diets. Such knowledge could help consumers maintain a healthy weight or reduce weight, if desirable. Ingredient disclosures would help consumers gauge the quality of products and assist in making choices among them. More importantly, listing allergens, according to FDA protocol, would help consumers avoid potentially dangerous (even life-threatening) physical reactions, and could even save lives.

In contrast, listing protein and fat content, which are essentially irrelevant for most alcoholic beverages, provides little of value and may even do harm. Consumers may come to believe that alcoholic beverages are an ordinary source of those (and other) nutrients; in particular, if “serving facts” labeling of protein and fat content were voluntary, consumers would have no way of gauging whether unlabeled products contained those nutrients. Allowing the labeling of such information could also help

² “Moderation is defined as the consumption of up to one drink per day for women and up to two drinks per day for men. Twelve fluid ounces of regular beer, 5 fluid ounces of wine or 1.5 ounces of 80-proof distilled spirits count as one drink for purposes of explaining moderation.” (Dietary Guidelines for Americans, 2005)

open the door to meaningless marketing of “no-fat” claims for alcoholic beverages, suggesting they are somehow in the category of health foods.

4. Alcoholic-beverage labeling must be clear, comprehensive, and utilitarian.

Consumers have become familiar with nutrition facts labeling of the foods they eat. That information is provided in an easy-to-find, clear and compact, standard format on most foods. In addition to listing what’s in the food, the nutrition label tells consumers how that information affects their diet. For example, in addition to listing calories, carbohydrates, fats, proteins, etc., the label advises what portion of daily dietary needs are fulfilled for key nutrients that are found in a particular amount (a designated serving size) of the food consumed. Percent daily values (DV) are presented for 2,000 calorie diets.

Although alcohol labeling might not require such detailed information, the concept of applying comprehensive information to individual needs (or limits in the case of alcohol) is transferable. For example, providing serving size, number of servings per container, and the U.S. Dietary Guidelines definition of moderate drinking (as proposed in CSPI’s 2003 petition) would help consumers regulate their drinking and avoid potential alcohol-related harm, such as driving after too much drinking.

Labeling requirements should focus on those items that are most important in educating consumers about the alcohol they consume, without potentially misleading them about the products. For that reason, labeling information should include calories per serving, alcohol by volume, serving size, number of servings per container, U.S. Dietary Guidelines advice on moderate drinking, and ingredients (especially known allergens). Nutritional information (“serving facts”) should generally be limited to listing carbohydrates and calories. Listing fats and proteins should be permitted only if they meet a certain meaningful, minimum threshold amount. Otherwise, label zeroes could trigger marketing claims by a producer that wants to tout the low fat or low carbohydrate content of its products. It could also suggest non-existent distinctions from unlabeled products, about which consumers would still be in the dark. CSPI also has a concern that listing nutrient information – proteins, fats, carbohydrates – might suggest to consumers that the product is akin to food and represents an ordinary source of nutrition.

The layout and container location of an alcohol-facts label also will affect its usefulness to consumers. TTB should follow FDA’s lead in developing a standard format and design – in a standard location on a container – for alcohol facts labels. The appearance of an alcohol-facts label provides a unique opportunity to present consumers with helpful, easy to access information about the alcoholic beverages they buy and consume. TTB should mandate informational panels that are visible, readable, understandable, and non-promotional (see CSPI and NCL petition). Like many basic mandatory labeling requirements already on the TTB books, the informational panel must generally appear parallel to the base of the container, be in a box, be readily legible, appear on a contrasting background (black on white), and be separate and apart from other information on the label. Similarly, TTB should revise its requirements for warning

label design to ensure that they're also prominently noticeable, legible, consistent in size and location on containers, and understandable.

5. TTB allergen labeling requirements should emulate FDA policies.

Labels should disclose the presence of any major allergen intentionally added to the beverage unless the major allergen is a highly refined oil or the TTB and FDA determine that the amount of the major allergen in the beverage does not pose a public health risk. Producers that claim an exemption from labeling potentially allergenic ingredients could petition TTB, but would bear the burden of proving that the allergen is undetectable in the beverage and does not present a risk to users with such allergies.

The House of Representatives committee report on the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2003 clearly states that the committee expects TTB to determine how to apply the Act's allergen labeling requirements to alcoholic beverages, and expects TTB to work with FDA to promulgate those regulations. And with good reason: FALCPA found that approximately 2 percent of adults and 5 percent of infants and young children suffer from food allergies and that each year roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food. Congress also found that eight major foods – milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans – account for 90 percent of food allergies. (see *infra*, for a more extensive analysis of allergen labeling issues)

6. The consumer benefits of labeling can be significant and the costs of requiring informational panels is trivial

Providing information about calories, alcohol content, serving size, number of servings per container, and ingredients (including allergens) of alcoholic beverages could yield distinct benefits for consumers. Alcohol provides a significant portion of calories (3% to 5%) in the American diet (for heavier drinkers, it contributes even more generously) and many drinkers and other consumers watch their calorie intake in order to help maintain a healthy weight. Particularly today, when drinking is widely portrayed as an adjunct (if not a prerequisite) to a healthy lifestyle, and popular, newer, ready-to-drink concoctions often contain more than 200 calories per serving, calorie information takes on added importance. Obesity and excessive weight represent substantial threats to individual and public health. The medical and other costs related to those problems are staggering, and continue to grow, along with the human suffering. Calorie labeling could provide a constant, low-cost reminder that alcohol consumption adds generally empty, discretionary calories to the diet. Along with other educational and policy approaches, such labeling could help raise awareness and potentially provide information that consumers can use to modify their drinking behavior.

Similarly, those who drink are at risk of driving impaired or consuming unsafe and unhealthy excess quantities of alcohol. Some consumers may have severe reactions to the ingredients in alcoholic beverages. "Alcohol Facts" labeling will help consumers

better gauge their alcohol consumption and may protect them from some of the many costly risks – and private and public costs – associated with drinking. Secondly, improved product information will help consumers make better choices among alcoholic beverages and alcoholic-beverage types, based on quality concerns relating to the ingredients. Improved safety, health, and consumer consequences, though difficult to quantify, could mean lives saved, obesity averted, and other alcohol problems dodged, as well as a more robust, quality-oriented marketplace. Those savings and benefits, over time, could amount to billions of dollars.

In contrast, the extra costs of changing labels, which could be amortized over the full life of a label (often several years), would be trivial, likely amounting, on average, to a small fraction of a penny per label. In past assessments done by the FDA regarding nutrition and trans-fat labeling, that agency found that the cost of new labels per “stock keeping unit” (a specific product sold in a particular size) was insignificant, given the large number of packages of each. FDA estimated the cost to range from \$1,100 to \$2,600 per sku.³ Applying that to a winery selling 5 wines would yield a total cost of \$5,500 to \$13,000. Applying that to a brand: for example, in 2003 La Terre wine (a Canandaigua Wine product and the 120th largest wine brand in the U.S.), according to Adams Wine Handbook 2004, produced 320,000 9-liter cases (3,840,000 750 ml bottles). Each of those bottles would incur a cost of \$0.000677 – less than 7/100ths of a penny – if the cost were \$2,600 per sku.

To protect truly small producers, TTB could exempt them temporarily from the new labeling requirement. For example, small producers could be required to add an alcohol-facts label either when they next revise their labels or within three years following a labeling requirement, whichever comes sooner. Labels on alcoholic beverages in small containers could be required to provide abbreviated information.

7. TTB should require the disclosure of nutritive information and comparisons to a company’s “regular” products in labeling and advertising that include specific nutritive claims (e.g., light, low-calorie, reduced-calorie, low-carbohydrate, reduced-carbohydrate).

Alcohol producers have exploited today’s increasingly health-conscious marketplace by developing and promoting low-calorie and low-carbohydrate products as more healthful alternatives to other beverages. Many advertisements (not to mention product names or designations) tout those special qualities, but in the absence of specific standards for those claims, the proclaimed product attributes have little meaning and can easily mislead consumers. In order to avoid misleading consumers about the character of an alcoholic beverage, and provide consistency in the marketplace, TTB should finalize regulations defining such terms as “low- and reduced-carbohydrates.” It should apply FDA requirements for low-calorie unless it considers those limits to be inappropriate.⁴ In addition, producers should be required to include statements in their advertising that

³ 68 Fed. Reg. 41477 July 11, 2003

⁴ FDA has defined “low-calorie” as 120 calories or less per 100 grams or 40 calories or less per 50 grams, if small reference amount.

identify those standards (“contains 7 grams or less of carbohydrates”; “contains 25% fewer calories than our regular beer”) and offer a statement of “average analysis,” as currently required (in addition to an “alcohol facts” panel). TTB should carefully monitor whether claims made in such advertising qualify as prohibited health claims.

8. If TTB explores the adoption of international labeling standards for alcoholic beverages sold in the United States, all attempts must be made to ensure “upward global harmonization.”

Because so many alcoholic-beverage products are imported today, and the harmonization of labeling and advertising standards is inevitable in a growing global economy, TTB should work with foreign governments and international authorities to establish as much consistency in labeling requirements as possible. Such an endeavor must be guided by several key principles, including: 1) a focus on adopting standards that represent best practices (“upward harmonization”) that at least ensure that U.S. labeling standards are not diluted; 2) a transparent process of deliberation that includes consumer participation, public comment, and stakeholder consultations; 3) a priority for public health and safety, consumer, and quality and purity concerns above pure trade issues; and 4) consumer recourse to challenge inadequate standards.

9. Alternatives to labeling are inadequate and would be ineffectual

Providing alcohol and “serving” facts on Internet websites or at a telephone number indicated on the product label would be an appropriate *additional* – but not substitute – means of offering consumers important information about alcohol products. Few, if any consumers actually take the time to go on-line or make a call when directed by label information, rendering this an extremely inefficient means of reaching most consumers. In addition, such information would not be readily available when consumers need it most: at the point of purchase or consumption. Certainly, there are few opportunities to access a web site or an 800 number while shopping for alcoholic beverages or even consuming them in on-premise locations. Label referral information imposes an extra barrier to learning information that would be most useful and important at the point of purchase. People with allergies might be highly motivated to seek out those sources of information, but other consumers, for whom alcohol facts – alcohol content, serving size, number of servings per container, calories, etc. – might also have considerable value, are unlikely to be. “Alcohol facts” help guide consumer choices of what to drink, but also (hopefully) inform the decision about how much to drink. That information has broad public health and safety implications for all drinkers (and others with whom drinkers come in contact), and should be as accessible as possible.

Additional Comments and Responses to Specific Queries

One change in CSPI’s position (since filing the petition for “alcohol facts” in 2003) concerns potential requirements for label disclosures of alcohol content (expressed in ounces) and the definition of *standard* serving sizes for alcoholic beverages across beverage types. In retrospect, in order to avoid over-crowding a label with duplicative,

confusing, and/or extraneous information, we recommend limiting an “Alcohol Facts” label to the following: serving size, number of servings per container, alcohol content expressed as a percentage of volume, the US Dietary Guidelines “definition” of moderate and responsible alcohol consumption, calories, and ingredients. Although a single drink of an alcoholic beverage may contain approximately 0.6 ounces of alcohol, CSPI believes that it is unnecessary – and perhaps confusing – to put such information on a label. Consumers do not think in those terms, but rather understand that drinks are served generally in standard, common sizes that vary according to the product.

Therefore, labeling should clearly communicate the serving size of a drink using common, everyday terms for measure. Standard serving definitions (12 ounces for a standard beer, 5 ounces for a glass of wine, or 1.5 ounces for a shot of 80-proof spirits) have been adopted by the Departments of Health and Human Services and Agriculture in the U.S. Dietary Guidelines, as well by the Centers for Disease Control. Products that contain more or less alcohol than the standard volume definition of a drink would adjust the serving size and number of servings per container accordingly. Thus, a malt liquor containing 8% alcohol by volume would report a smaller serving size than a regular beer (perhaps 8 ounces vs. 12 ounces) and a larger number of servings per container. The number of servings per container would be reported in increments of 0.25 drinks. For example, a 40-ounce bottle of an 8% alcohol by volume malt liquor might contain 5 servings. As proposed in our 2003 petition, the number of servings per container would be reflected in an icon (beer mug, wine glass, shot glass) to attract consumer attention.

Providing “standard drink” information, though useful in some more general education contexts, might not be helpful on labels of particular products. For example, many over-sized containers, such as 16-ounce beers, are ordinarily sold – and meant to be consumed -- as a single serving. Those containers would disclose that they contained 1.25 servings; however, the calorie (and any nutrient) declaration – consistent with FDA requirements – would indicate the number of calories (carbs, fat, protein) in an entire container that has as much as 1.5 servings of alcohol.

Section I. General Questions

I. 4. Are there modifications TTB can make to current requirements regarding alcoholic beverage labels to help consumers better understand and benefit from the information on the label?

TTB should revise its requirements for the design and placement of the mandatory health warning statement. As with other required label information, warning messages should be parallel to the bottom of the container, in a conspicuous place on the container, on a contrasting background, and readily visible to the consumer. The lettering should be in easier to read upper- and lower-case characters that are legible; and the warning should be surrounded by a ruled box, much like proposals for “alcohol facts” labels.

I. 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?

The least important changes are those initiated by alcohol producers to facilitate the marketing of their products as health foods and diet aids. Industry advertising practices that trumpet the low-calorie and low-carbohydrate properties of certain drinks steer perilously close to making prohibited health claims, and misrepresent the fundamental nature of alcoholic beverages as foods, rather than highly regulated, potentially addictive intoxicants. Therefore, we believe that industry proposals for "serving facts" that provide predominantly nutrition information should get low priority, if any.

Section V. A. Carbohydrate and Calorie Claims

V. A. 1. and V. A. 3. Should TTB promulgate regulations that define "low carbohydrate" for alcoholic beverage products as containing no more than 7 grams of carbohydrates per standard serving size, as specified in Ruling 2004-1?

Generally, TTB should avoid allowing or requiring labeling information that helps characterize alcoholic beverages as a food and/or a source of nutrition. However, if TTB does address carbohydrate issues, then it should issue guidance consistent with its current policy and conform its standards with FDA rules – when they are implemented.⁵ Nonetheless, TTB should prohibit the use of such information in a promotional manner that suggests that the product is a healthy alternative to other beverages or may be part of an effective weight-loss diet. Special vigilance should apply to advertising that makes such claims (directly or indirectly).

"Reduced carbohydrate" claims should warrant additional requirements. First, such label and advertising claims should be permissible only when the product has at least 25% fewer carbohydrates per serving than the producer's standard product in that category. The label should disclose the amount of carbohydrates and bear a statement comparing the product to its "full-carbohydrate" version (such as, "contains 25% fewer carbs than our regular brand").

V. A. 2. Should TTB continue to prohibit use of the terms "effective carbohydrates" and "net carbohydrates" on labels and in advertising?

Those terms are virtually meaningless to consumers and can only help to confuse and mislead them about the character of the beverage. TTB should continue to prohibit such terms.

V. A. 4. How should TTB define the terms "low-calorie" and "reduced calorie" for alcohol beverage products?

⁵ FDA is currently planning a rulemaking proceeding on carbohydrate claims.

TTB should follow FDA guidance on these issues.⁶ Generally, with 7 calories per gram, alcohol is a calorie-dense component in beverages widely consumed by Americans. It is difficult to conceive of them as “low calorie” in any sense. With regard to reduced-calorie claims, the calorie reduction should meet FDA standards for food (25% fewer calories than the “regular” product). Any declaration of “lower in calories,” “reduced-calorie,” etc. should be accompanied by a statement of calories per serving (or the amount of calories in the container, if the container size is ordinarily considered a single serving – up to 1.5 times the size), and a comparison of the “reduced-calorie” beverage with the regular. (i.e. 55 calories, ___% fewer calories than beverage X).

V. B. 1.– 9. “Alcohol Facts” Label and Ingredient Labeling

These questions relate to CSPI’s proposal for ingredient labeling and an “alcohol facts” label. Answers may be found in our December 2003 petition and in the general principles noted above.

V. C. Allergen Labeling

A. The Federal Alcohol Administration Act and the Federal Food, Drug, and Cosmetic Act have complementary purposes of protecting the consumer.

In 1935 Congress passed the Federal Alcohol Administration Act (“FAAA”), which, in subsections 105(e) and (f), prohibits the sale of distilled spirits, wine at least 7 percent alcohol by volume or malt beverages if the product’s label or advertising is deceptive or misleading. (27 U.S.C. 205(e), (f)) Three years later Congress passed the Federal Food, Drug, and Cosmetic Act (“FFDCA”), which, in subsection 403(a)(1), prohibits the sale of food if its label is false or misleading in any particular (21 U.S.C. 343(a)(1)).

In August 2004 President Bush signed the Food Allergen Labeling and Consumer Protection Act of 2003 (“FALCPA”), Title II of P. L. 108-282. In section 202 of FALCPA Congress found that approximately 2 percent of adults and 5 percent of infants and young children suffer from food allergies and that each year roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food. Congress also found that eight major foods – milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans – account for 90 percent of food allergies.

Section 203 of FALCPA amends the FFDCA to require that beginning in January 2006 foods containing a major allergen so indicate in one of two ways: (1) putting at the end of the ingredient list “Contains ____” followed by the name of the major allergen or (2) putting the name of the major allergen in parenthesis after the common or usual name in the ingredient list (Section 403(w) of the FFDCA, 21 U.S.C. 343(w)). While subsection 403(i) of the FFDCA in general allows spices, flavorings, and colors to be aggregated rather than listed as separate ingredients, section 203 of FALCPA, subsection

⁶ 21 CFR § 101.60 (b)

403(w)(4) of the FFDCFA, says that allergen labeling is required for flavorings and colorings. Moreover, while FDA's general ingredient regulations exempt incidental additives – including processing aids – from being listed, 21 CFR 101.100(a)(3), section 203 of FALCPA requires that incidental additives be disclosed if they are a major allergen.

Subsection 201(f) of the FFDCFA defines “food” to include “articles used for food or drink for man...”(21 U.S.C. 321(f)) The House of Representatives committee report on FALCPA, H.R. Rept. 108-608 (2004) says (at 3):

The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco and Trade Bureau (TTB) of the Department of the 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 of 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 strongly support TTB's moving to implement the Committee's expectation.

B. In order to protect the public health, TTB's allergen labeling requirements should emulate the requirements of FALCPA and the FDA's policies implementing FALCPA.

1. The label on alcoholic beverages should disclose the presence of any major allergen intentionally added to the beverage unless either the major allergen is a highly refined oil or the TTB and the FDA determine that the amount of the major allergen in the beverage does not pose a public health risk.

Beginning in January 2006 persons who are allergic to a major allergen will see on packaged foods regulated by the Food and Drug Administration (“FDA”) both: (i) a standardized allergen labeling format and (ii) for the first time, disclosure on the label of any flavoring, coloring, or incidental additive that is a major allergen. The failure to require the same allergen labeling on alcoholic beverages regulated by TTB may mislead a consumer who is allergic into believing that drinking a particular alcoholic beverage poses no health risk even though the alcoholic beverage actually contains a major allergen.

Congress recognized that a food ingredient derived from a major allergen may contain so little protein that it is no longer a health risk. Section 203(c) of FALCPA exempts from the definition of a major protein “any highly refined oil derived from a [major allergen]...and any ingredient derived from such highly refined oil.” 21 U.S.C. 321(qq)(2)(A). While the statute does not define the term “highly refined oil,” the Senate committee report says “‘Highly refined oils’ are intended to signify refined, bleached, deodorized (RBD) oils.” S. Rept. 108-226 at 7. The House committee report says

“peanut oil is a highly refined oil and does not cause food allergies.” H.R. Rept. 108-608 at 16.

Congress, however, rejected an automatic exemption for major allergens – other than highly refined oils – that may be present in very small amounts. The Senate committee report notes that in general “incidental additives, which are food substances that are used in insignificant amounts and that do have any technical or functional effect in the food, need not be identified in the food label.” S. Rept. 108-226 (2004) at 3. However, as discussed above, FALCPA requires disclosure of incidental additives that are a major allergen. The Senate committee report also says (at 7) “while the committee recognizes that thresholds for the major eight allergens have not yet been established by the scientific community, if they are established, ingredients containing allergenic proteins below the established threshold would be eligible” to be excluded from the mandatory allergen label disclosure. The House committee report says (at 17) “While the Committee recognizes that thresholds for the eight major allergens have not yet been established by the scientific community, if they are established, ingredients containing allergenic proteins below the established threshold would be eligible” to be exempt from disclosure (The FDA’s Food Advisory Committee met on July 13-15, 2005 to consider a draft FDA report on establishing thresholds for major food allergens.).

TTB should adopt the two ways provided in FALCPA by which a manufacturer can present the scientific evidence that justifies a labeling exclusion for a major allergen that occurs as an ingredient in very small amounts. Section 203 of FALCPA says that a person may petition the FDA for an allergen labeling exemption for a food ingredient by providing the scientific evidence demonstrating that the food ingredient does not cause an allergic response that poses a risk to public health; the FDA is directed to make the petition public within 14 days and, after considering public comments, to grant or deny the petition within 180 days. Section 203 of FALCPA also permits a person to file with the FDA a notification that the FDA has already determined, under its food additive approval process, that the ingredient does not cause an allergic response that poses a risk to human health; this notification is also to be made public, and the FDA is given 90 days to decide whether there is sufficient scientific evidence to determine that the food ingredient either does not contain allergenic protein or does not cause an allergic response that poses a risk to human health.

In the case of alcoholic beverages, such a petition or notification for exempting fining, processing, and filtering agents – such as milk, albumen (egg), soy flour, and isinglass (derived from fish bladders) – should be submitted to both TTB and the FDA. The scientific evidence on the public health risks of, say, a very small amount of milk should be the same whether it is in an alcoholic beverage or a packaged food. If the scientific evidence does not warrant an exemption, then consumers would expect fining, processing, and filtering agents to be labeled in the same way as any other major allergenic ingredient.

2. When a major allergen is accidentally present in a particular alcoholic beverage the TTB should emulate the FDA's policy on whether the label should indicate the beverage may contain an allergen.

Congress recognized that an allergenic ingredient may accidentally be found in a particular food. The Senate committee report explains (at 3-4):

Food allergens sometimes inadvertently find their way into a food because of a firm's production practices; such as rework addition or product carryover due to use of common equipment or production scheduling. Such practices present an unintentional opportunity for a product that contains an allergen to come into cross-contact with a product that does not contain that particular allergen as an ingredient or as a component of an ingredient. In some instances it may not be possible to eliminate the possibility of cross-contact following good manufacturing practices. In such instances, it may be appropriate for food manufacturers to use advisory labeling (such as 'may contain') to indicate the possible presence of food allergens in a food product.

Section 204 of FALCPA directs the FDA to report to Congress by February 2006 on: (i) the ways in which foods are unintentionally contaminated with major allergens, (ii) whether good manufacturing practices can be used to reduce or eliminate cross contact, and (iii) "how consumers with food allergies would prefer that information about the risk of cross-contact be communicated on food labels."

TTB's proposed regulation on when "may contain" may be used should be based on what the FDA learns about consumers' preferences so that both foods and alcoholic beverages will be governed by the same standard.

V.D. Voluntary "Serving Facts" Labeling

As indicated above, CSPI supports mandatory labeling of "alcohol facts." We believe that voluntary labeling will not provide the comprehensive information that consumers need and deserve (and that the FAAA indeed requires) to inform them about the ingredients and quality of the alcoholic beverages they ingest. Because only some products would be labeled, consumers could be even more confused than they are now, when almost all product labels are devoid of important disclosures related to alcohol content, serving size, calories, ingredients, and servings per container. CSPI opposes the proposed voluntary "serving facts" label for another reason: the proposal before the TTB seeks to include nutrition information that, for the most part, is totally irrelevant for alcoholic beverages. Alcoholic beverages, although they contain calories, carbohydrates, and occasionally small amounts of other nutrients, should not be considered as ordinary food products. Alcohol labels should not suggest that the products are sources of nutrients, nor should they suggest they contain nutrients that are generally absent in those beverages, such as proteins and fats. "Serving facts," whether true or not, should not be permitted to provide a platform for diet, nutrition, or health claims, such as "fat-free," or

“low-fat,” that misrepresent alcoholic beverages as healthful options to other alcoholic beverages.

V. E. Composite Label Approach

Should TTB opt to create a “composite” label, drawing from the proposed “alcohol facts” and “serving facts” labels, CSPI believes that such label should nonetheless be mandatory, that it be designed for maximum utility in the consumer market, and that it focus more on alcohol than nutrition information. That information should allow consumers to gauge their alcohol consumption and judge whether it is in a safe “range” for optimal health and safety. Label declarations that tout the nutritive components of alcoholic beverages would obscure well-documented findings – and the consistent judgment of the Dietary Guidelines – that alcohol provides calories, but few essential nutrients.

Respectfully submitted,

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