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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (Docket No. FDA-2011-F-0172, and RIN 0910-AG57) (76 Fed. Reg. 19192 (April 6, 2011))

Dear Sir or Madam:

On behalf of the undersigned trade associations representing virtually all alcohol beverage producers, including brewers, distillers, vintners, and importers, we greatly appreciate the opportunity to share our views regarding the Food and Drug Administration's (FDA) proposal to implement the menu labeling provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).

We support FDA's proposal to exclude alcohol beverages from the Agency's menu labeling rules. The rationale underpinning FDA's decision will best serve the intent of Congress to provide consumers with nationally uniform and readily available information about the caloric content of food served at chain restaurants and similar retail food establishments covered by the menu labeling requirements.

FDA's position is well taken because:

(1) the Alcohol and Tobacco Tax and Trade Bureau of the Department of Treasury (TTB) is the primary regulatory authority on the labeling of alcohol beverages pursuant to the provisions of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. 201 et seq.)[1];

(2) TTB has a "Serving Facts" rulemaking underway that is intended to establish a clear and consistent manner for determining and expressing nutrient values for alcohol beverages; and

[1] We acknowledge that FDA exclusively regulates the labeling of alcohol beverages that are not under TTB's jurisdiction, including beers that do not meet the definition of a "malt beverage" under the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. 201 et seq.) and wine beverages containing less than 7 percent alcohol by volume. See, e.g., FDA, "Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Draft Guidance." August 2009.

(3) establishment of an FDA menu labeling requirement for alcohol beverages while a TTB rulemaking on alcohol beverage container labeling is underway could result in inconsistent information between alcohol beverage container labels and menu caloric information, creating uncertainty and confusion.

The course of action set forth in FDA's proposal, particularly FDA's recognition of TTB's expertise in alcohol beverage labeling, preserves the historical bifurcation of jurisdiction between two fellow federal agencies, and helps support the goals of the Act to provide consistent and accurate information for consumers.

I. TTB/FDA Alcohol Beverages Regulatory Framework

As FDA recognized in its proposed rule, the primary federal regulatory Agency overseeing alcohol beverage labeling is TTB. In exercising its broad and longstanding regulatory authority, TTB is very familiar with the entire range of alcohol beverage products, as well as the day-to-day practices of producers and importers across the beer, wine and spirits categories. The Bureau regulates virtually every aspect of alcohol beverage products and the industry members who produce and/or import these products. Within the broader food industry, alcohol beverage importers and domestic manufacturers are the only entities required to undergo an investigation prior to commencement of operations. TTB requires completion of employment and financial questionnaires by key personnel and investors, as well as detailed information on the location and operation of each business.

TTB's regulatory authority over labeling and formulation of alcohol beverages includes statutory pre-approval processes and testing designed for consumer protection and tax classification purposes. Each year, over 100,000 alcohol beverage label and container designs are pre-approved by TTB to ensure that "packaging, marking, branding, and labeling and size and fill of container" will not deceive consumers and that statements and other information on each product are not likely to mislead consumers.[2] Label approval must be received by a U.S. importer before a product is imported into the United States or introduced into interstate commerce by a domestic producer.[3]

TTB and the FDA operate under a longstanding Memorandum of Understanding (MOU) that has been updated various times since the 1940s. The most recent version reiterates TTB's statutory authority and the scope of existing TTB regulations and states that the Bureau of Alcohol, Tobacco and Firearms (TTB's predecessor agency), "will be responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wine, and malt beverages pursuant to the Federal Alcohol Administration Act."[4] The bifurcation of jurisdiction between TTB and FDA has well served the consuming public and the respective goals of each Agency.

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[2] 27 U.S.C. 205(e).
[3] 27 CFR Parts 4, 5 & 7.
[4] Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms, § III(A), November 20,1987.

Congress has expressly encouraged TTB and FDA to work together in implementation of two recently enacted statutes governing areas where FDA and TTB jurisdiction overlap, the Food Allergen Labeling and Consumer Protection Act of 2004[5] and the Food Safety Modernization Act of 2010.[6] Cooperation in rulemaking between TTB and FDA is beneficial because it helps minimize uncertainty and confusion in the marketplace for consumers, industry and the federal agencies. Coordination between TTB and FDA in rulemaking is also not unusual. Two recent examples of TTB coordination of rulemaking with FDA include:

a) Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages, mandatory labeling standards for major food allergens used in the production of alcohol beverages subject to the labeling requirements of the Federal Alcohol Administration Act and the Federal Food, Drug and Cosmetic Act contained in the Food Allergen Labeling and Consumer Protection Act of 2004.[7]

b) Disclosure of Cochineal Extract and Carmine in the Labeling of Wines, Distilled Spirits, and Malt Beverages, revisions to TTB regulations to require the disclosure of the presence of cochineal extract and carmine on the labels of any alcohol beverage product (addressed separately in a final rule issued by the Food and Drug Administration).[8]

As recognized by FDA, given detailed prior Acts of Congress and the history of alcohol beverage policy in the United States, TTB has a clear, multifaceted and ongoing administrative and regulatory mission with respect to labeling and public disclosure of information about alcohol beverages. The discharge of this mission has served well the retail customers of our industry and our consumers who choose to drink alcohol beverage products.

We respectfully submit that the goals of the Affordable Care Act will best be effectuated by the continuation of the long history of cooperation and coordination between TTB and FDA.

II. Interim Steps for Menu Labeling of Alcohol Beverages

TTB has invested several years of careful effort, analysis and Agency resources in the "Serving Facts" rulemaking, and it has done so within the broader context of other labeling challenges, some of which are unique to alcohol beverages and to TTB's statutory authority. Likewise, industry members participated in the administrative activity including, but not limited to the following:

a) Caloric and Carbohydrate Representations in the Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages, Agency guidance on making truthful and specific statements about calorie and carbohydrate content in the labeling and advertising of wine, distilled spirits, and malt beverages, addressing false or

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[5] P.L. 108-282, August 2, 2004.
[6] P.L. 111-353, January 4, 2011.
[7] 71 F.R. 42329, July 26, 2006.
[8] 75 F.R. 67669, November 3, 2010.

misleading claims or representations about calorie or carbohydrate content in the labeling and advertising, and prohibiting statements that imply that the consumption of low carbohydrate alcohol beverages is a part of a specific weight reduction plan.[9]

b) Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages, a notice of proposed rulemaking regarding "Serving Facts," which would amend current alcohol content disclosure requirements and, for the first time, require nutrient information (calories, fat, carbohydrates, and protein) on all alcohol beverage labels.[10]

c) Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages, an advance notice of proposed rulemaking to solicit public comment on general approaches to disclosure of nutrient information and alcohol content.[11]

Just as FDA experienced considerable challenges grappling with the Nutrition Labeling and Education Act (NLEA) labeling mandates, TTB has studied various methodologies and approaches to calculating caloric and nutrient content in a manner that is workable for thousands of alcohol beverage brands sold in the United States. No final rule has been published at this time; therefore, no certainty exists about the manner in which nutrition values for alcohol beverage labeling and advertising will be determined and communicated to millions of consumers. For long-term consistency and to avoid potential conflict, the TTB "Serving Facts" rulemaking should be completed before the FDA takes further action.

FDA correctly pointed out in the NPRM that a menu labeling requirement for alcohol beverages at this point creates uncertainty for both regulators and industry. The absence of Congressional hearings prior to enactment of the menu labeling law prevented both agencies and industry representatives from advocating a straightforward means to address potential conflicts between specific alcohol beverage labeling requirements and labeling requirements that are generally enforced by the FDA for other food and beverage products, such as NLEA.

Simply put, the current alcohol beverage regulatory framework does not establish a clear and consistent manner for determining or expressing nutrition values for alcohol beverages. That situation should change in the foreseeable future as TTB completes the pending "Serving Facts" rulemaking.

Conclusion

Again, the undersigned organizations appreciate FDA's recognition of the dilemma posed for alcohol beverage products and for proposing a common-sense approach that will ultimately serve the public interest, as well as efficiency and economy in government by avoiding inconsistent calorie and nutrition information on TTB-approved product labels and FDA-sanctioned menu labeling. In excluding alcohol beverages from the menu labeling rule at this

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[9] *TTB Ruling* 2004–1, April 7, 2004.
[10] 72 F.R. 41860, July 31, 2007.
[11] 70 F.R. 22275, April 29, 2005.

early stage in the process, FDA implicitly recognizes the schedule for administrative action in the Affordable Care Act cannot be perfectly coordinated with ongoing administrative actions, such as TTB's pending "Serving Facts" rulemaking.

In sum, it is incumbent on TTB and FDA to continue working collaboratively in the future. Our associations and the industry members we represent stand ready to cooperate in those important efforts.

Sincerely,

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