



July 5, 2011

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

**Re: Docket No. FDA-2011-F-0172**

Dear Sir or Madam:

On behalf of its members, the Brewers Association (BA) appreciates the opportunity to comment on proposed rule published by the Food and Drug Administration on April 6, 2011, entitled “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.”<sup>1</sup> This comment supplements the comments the Brewers Association submitted in with other alcohol beverage supplier trade associations to address specific concerns of America’s small and craft brewers. The Brewers Association agrees with FDA’s decision to exclude alcohol beverages from menu labeling at this time. FDA has at least two options for future action: coordinate rule making with the Alcohol and Tobacco Tax and Trade Bureau (TTB) once TTB has concluded its pending serving facts rule making, or excluding alcohol beverages permanently.

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<sup>1</sup> 76 Fed. Reg. 19192.

These comments reiterate some points made in the Brewers Association comments filed on October 12, 2010 in response to FDA's draft guidance document, to the extent that the same issues remain relevant in the current rulemaking, particularly the potential for conflict between the FDA menu labeling regulations and labeling regulations promulgated by the TTB.

#### **A. Brewers Association Background**

The BA was established in 2005 as the successor to the Brewers Association of America and the Association of Brewers. For 86 years, BA and its predecessor organizations have represented diverse interests including small brewers, homebrewers, and beer consumers throughout the United States. BA membership today includes 1,218 breweries, 625 associates (large brewers, contract brewers, brewers in planning, and international brewers), 343 businesses in allied trades, 275 wholesalers, 486 individual professionals, and 184 retailers. In addition to the range of businesses related to the brewing industry, BA includes 22,291 beer consumers and homebrewers who belong to an affiliated organization, the American Homebrewers Association.

#### **B. Congress and the States Have Actively Fostered the Development of Small Brewers**

Federal and state alcohol beverage control policies encourage and promote small brewers as a means of maintaining a local brewing industry presence and a greater diversity of products and choices for beer consumers. In 1976, Congress enacted a differential brewer excise tax rate in recognition of the different business models of small brewers.<sup>2</sup> Several states also have laws granting a reduced excise tax rate for small brewers along with special regulatory measures that reflect the differences in scale and business models. Recognition by Congress and state lawmakers of those differences is important in developing industry guidance for menu labeling.

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<sup>2</sup> 26 U.S.C. § 5051(a)(2).

Unduly burdensome and complex FDA guidance and testing procedures would have a disproportionate effect on small brewers, many of whom will have to contract out product testing to comply with the new requirements. FDA action that would adversely affect local brewery sales and profitability would undermine the legislative goal of promoting small brewers.

### **C. Role of Small Brewers in National and Regional Economies**

Small brewers are an important segment of the U.S. beer industry and the nation's manufacturing base. Small brewers provide jobs to approximately 100,000 Americans.<sup>3</sup> Most small brewers in the U.S. distribute their products on a local or regional basis, although several have expanded to serve all 50 states and niche export markets. Small brewer production in 2010 totaled approximately 13 million barrels, which constitute 5 percent of the entire U.S. beer market. This sector is markedly different from the major international brewers, which produce over 90 percent of the beer consumed in the U.S. at approximately 30 large breweries located in the U.S., Canada, Mexico, and a few European nations. There are currently 1,719 small brewers in the U.S.

In addition to scale, the number of brands and styles of beer produced by U.S. small brewers varies dramatically from their larger counterparts. Small brewers produce an estimated 11,000 different brands. Over the course of a year, a typical U.S. small brewer will produce one or two "flagship brands," several smaller-volume year-round offerings, and a number of seasonal and "one-off" brands.

Successful small brewers have used several business models. A few have established networks of beer distributors in several states or throughout the U.S. Some are small bottling

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<sup>3</sup> Brewers Association, 2008 Member Survey.

operations that distribute their beer in a metropolitan area or a cluster of adjacent states. Many more are brewpubs, small breweries with restaurants at the same location. Brewpubs are particularly popular in urban areas and major tourist destinations, which ensure a critical mass of beer enthusiasts who seek out varied beer styles and enjoy pairing food and unique beers. Brewpubs have played an important role in economic development and tourism promotion in dozens of U.S. cities.

#### **D. Existing Labeling Regulation Applicable to the U.S. Beer Industry**

All commercial brewing operations in the U.S. are subject to significant government regulation. In addition to the FDA, TTB, the Federal Trade Commission, and other agencies oversee details of the brewing process, labeling, advertising, trade practices, and other business activities. Federal law enacted immediately after the repeal of Prohibition requires TTB to approve each alcohol beverage label. TTB issued more than 124,000 certificates of label approval in 2009.<sup>4</sup> For almost eight decades, TTB and its predecessor agencies have been the primary regulator of labeling and advertising for small brewers and other alcohol beverage producers. The one judicial decision that examined the relationship between TTB and FDA authority over alcohol beverage labeling found in part that the specificity the Federal Alcohol Administration Act labeling provisions and mandates unique to alcohol beverages indicated that Congress intended to grant primary jurisdiction to TTB.<sup>5</sup>

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<sup>4</sup> 27 U.S.C. § 205(e), 27 CFR parts 4, 5 and 7; Alcohol and Tobacco Tax and Trade Bureau Annual Report, Fiscal Year 2009, p.5.

<sup>5</sup> *Brown Forman v. Matthews*, 435 F.Supp. 5 (W.D. Ky. 1976).

State alcohol beverage agencies also regulate small brewers. Brewers must obtain one or more licenses in their home state as well as licenses, permits, brand registrations, or other filings in each additional state where they sell beer.

In spite of extensive labeling requirements applicable to small brewers, calorie content and nutrient information currently are mandated only for light beer and are permitted on a voluntary basis for other malt beverages. In 1993, the Yakima Brewing and Malting Company was ordered by TTB's predecessor agency, the Bureau of Alcohol, Tobacco and Firearms, to remove an accurate Nutritional Labeling and Education Act (NLEA) label printed on its packaging.<sup>6</sup> TTB treats nutritional information about alcohol as a type of veiled health or therapeutic claim, both of which are severely restricted by the Federal Alcohol Administration Act and TTB regulations.<sup>7</sup>

Labels currently approved by TTB with a statement of average analysis constitute a very small portion of the total volume and a small number of the brands that BA members produce. The format of the TTB statement of average analysis is not consistent with FDA's proposed regulations.<sup>8</sup> TTB has engaged in a comprehensive rulemaking process with the objective of promulgating new regulations that would require labels to display calorie content and at least some of the information required by the Nutritional Labeling and Education Act for foods other than alcohol beverages.<sup>9</sup> Absent agreement between the FDA and TTB formats, action by small

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<sup>6</sup> See, "BATF extends deadline for public comment on nutrition labeling for malt beverages," *Modern Brewery Age*, November 8, 1993.

<sup>7</sup> 27 U.S.C. § 205, 27 CFR parts 4, 5 and 7.

<sup>8</sup> The proposed regulations require disclosure of calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, fiber, and total protein. TTB's current format for the statement of average analysis mandates that only calories, carbohydrates, protein, and fat be disclosed.

<sup>9</sup> See generally, *Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages*, 70 Fed Reg. 22274 (April 29, 2005) and *Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages*, 72 Fed. Reg. 41860 (July 31, 2007).

brewers to comply with FDA menu labeling rules could contradict current TTB policy guidance and create uncertainty when the pending TTB rulemaking is completed.

#### **E. Practical Issues Concerning Small Brewer Sales to Chain Restaurant and Similar Retail Food Establishments**

BA members' products are sold in cans or bottles and are on display at many places that meet the definition of chain restaurants and SRFEs in the proposed menu labeling regulations. Since TTB has not yet issued final rules on the display of calorie and nutrient information on alcohol beverage labels, the packaged beer sold in SRFEs for the foreseeable future will not display that information.

BA members face the prospect of obtaining new labels for thousands of brands once TTB issues its final regulations on the display of calories and other nutritional information. Critical information on the changes that TTB contemplates is not yet available, including serving sizes and the basic mandatory disclosures that TTB will require in its new label format.

Chain restaurants already present a challenging market for small brewers operating in regional markets. Small brewers must seek limited opportunities available for the sale of locally produced beers at most chains, which often feature only national brands. The costs associated with multiple label changes and related logistical issues present a major barrier to entry for small brewers to sell their products in the chain restaurant and SRFE sectors.

These practical issues provide further support for FDA's decision to exclude alcohol beverages from the menu labeling requirements at this point in time.

#### **G. Serving Sizes Are Very Important for Beer and Other Malt Beverages**

In response to TTB Notice No. 73 and to the 2010 FDA request for comments on its industry guidance, BA advocated specific reference or serving sizes, which are particularly

important for alcohol beverages as they determine calories and a consumer's alcohol consumption. To the extent that FDA consults further with TTB on issues related to menu labeling, we believe the position on serving sizes articulated by BA is a sound approach. BA advocated a 12-ounce serving for beers under 10 percent alcohol by volume (ABV) and 5 ounces for beers over 10 percent ABV. Beers below 10 percent ABV usually are poured or consumed directly from a 12-ounce bottle or can at home or for consumption at on-premise retail establishments. The BA-proposed reference serving size of 5 ounces for beers above 10 % ABV is comparable to the serving size for wine in the USDA Nutrient Database, although retailers and consumers often use six-ounce servings. FDA should establish graduated serving sizes for beers and other malt beverages with higher alcohol content and should recognize that consumers often share a bottle of beer with higher alcohol content.

#### **I. Costs and Other Business Considerations**

In analyzing the burden of the proposed regulations, BA restates its position that the cost of compliance and laboratory testing for small brewers is significant. BA conducted a thorough member survey during the comment period on TTB Notice No. 73 and documented the significant costs related to laboratory testing and staff time preparing for laboratory testing. TTB asked industry members to “estimate the time it would require annually (in hours) to test your beer to determine calorie, carbohydrate, fat and protein content (whether you do in-house testing or by contracting it out).” *See* Appendix A. BA members quantified the average hours per year companies spent by size as measured in barrels of beer sold annually:

- Under 1,000 bbls: 56.7 hours per year.
- 1,000-9,999 bbls: 129 hours per year.
- 10,000-20,000 bbls: 85.8 hours per year.

- 20,001-100,000 bbls: 269.9 hours per year.
- Over 100,000 bbls: 930.3 hours per year.

This data shows that a larger company is more likely to have an in-house laboratory, which adds to the staff time. The smallest companies still need a significant amount of time to communicate with a laboratory and to prepare and arrange for shipping the samples. Many brewers under 1,000 barrels are one-person operations, and the cost of laboratory testing plus the staff time also shows that testing requirements should be flexible and kept to a minimum.

The technical brewing projects coordinator for the BA estimates the per-sample laboratory testing cost of \$350 for brewers to provide the required information to restaurants. This cost will likely reduce the number of products from the smaller brewers available in chain restaurants, and would reduce the ability of chain restaurants to offer locally produced products that will be available to competing non-chain restaurants. That scenario negatively affects both the chain restaurant and local small brewers. We believe that the costs presented justify alternatives to testing every batch of beer produced, such as use of the Nutrient Database discussed above.

#### **J. Next Level Marketing Survey—Consumers Preferences Concerning Calorie Counts on Drink Menus**

In March 2011, Mike Ginley from Next Level Marketing made a presentation titled, "What Today's On-Premise Consumers Want" at the annual VIBE Conference in Las Vegas, Nevada. The presentation included a February 2011 survey of 502 on-premise national chain adult consumers (21+) who had ordered beer, wine, or spirits at a restaurant chain in the previous 30 days. The summary of the survey stated, "Most consumers do not want to see calorie counts on drink menus and say if they did, they would not worry about them and just order what they



want.” If most consumers do not want calorie counts on drink menus, and their inclusion is difficult and expensive for restaurants and alcohol beverage suppliers, a good case is made for permanent exclusion of alcohol beverages from the menu labeling requirements.

#### **K. Summary**

To address the multiple policy challenges facing FDA and TTB officials, retailers, and small brewers, BA proposes the following:

1. FDA should maintain the exclusion for alcohol beverages in the final menu labeling rules. The agency rationale is sound given the already-complicated regulatory landscape for alcohol beverages.
2. BA urges FDA and TTB to consult to ensure that the requirements of the two nutritional disclosure policies are consistent prior to implementation of either policy. The alternative would be a lengthy period of uncertainty, placing small brewers at risk of inadvertent violations or repeated changes in their label designs to accommodate the two statutory requirements.
3. Numerous changes and uncertainty undermine the purpose of the statute and could discredit industry and government efforts to inform consumers, many of whom appear skeptical of the benefits of menu labeling for alcohol beverages.
4. The recommendations set out above will help mitigate the costs small brewers will necessarily incur to sell their products to chain restaurants and SRFEs.

Again, the BA and its membership appreciate the opportunity to comment on the Proposed Menu Labeling Rules and stand ready to assist the FDA and other agencies in implementation of Section 4205 of the Affordable Care Act.

Respectfully submitted,



Charlie Papazian  
President

## Appendix A

### Brewers Association Comment

#### Staff Time Spent on Laboratory Sample Preparation, Shipping and/or Testing to Comply

#### With TTB Notice No. 73 Proposed Rules

*Q9 Estimate the time it would require annually (in hours) to test your beer to determine calorie, carbohydrate, fat, and protein content (whether you do testing in-house or by contracting it out):*

