



October 12, 2010

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

Re. Docket No. FDA-2010-D-0370

Dear Sir or Madam:

We appreciate the opportunity to comment on “Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010,” published by the Food and Drug Administration (FDA) for public comment.¹ This comment refers to the FDA document as “Draft Guidance for Industry” and the legislation as the “Affordable Care Act”² BA supports the goals of Congress and the FDA to “provide Americans the opportunity to exercise personal responsibility and make informed choices about their diets” and to achieve national uniformity in labeling.

A. Brewers Association Background

The Brewers Association (BA) was established in 2005 as the successor to the Brewers Association of America and the Association of Brewers. For 85 years, BA and its predecessor

¹ 75 Fed. Reg. 52426-52428 (August 25, 2010).

² Patient Protection and Affordable Care Act of 2010, “PPACA,” Pub. L. 111-148; 21 U.S.C. § 402(q)(5).

organizations have represented diverse interests including small brewers, homebrewers, and beer consumers throughout the United States. BA membership today includes 1,168 breweries, 424 associates (large brewers, contract brewers, brewers in planning, and international brewers), 325 businesses in allied trades, 219 wholesalers, 378 individual professionals, and 166 retailers. In addition to the range of businesses related to the brewing industry, BA includes 19,065 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 maintaining 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.³ 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. Unduly burdensome and complex FDA guidance and testing procedures will 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.

³ 26 U.S.C. § 5051(a)(2).

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.⁴ 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 2009 totaled approximately 11 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 brewers located in the U.S., Canada, Mexico, and a few of our nation's European trading partners.

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 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.

⁴ Brewers Association, 2008 Member Survey.

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, the federal Department of the Treasury's Alcohol & Tobacco Tax & Trade Bureau (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, and agency officials issued more than 124,000 certificates of label approval in 2009.⁵ 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.

State alcohol beverage agencies also regulate small brewers and most require brewers to obtain one or more licenses in their home state and additional 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 beers and 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.⁶ TTB treats nutritional information about alcohol as a type of veiled health or

⁵ 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.

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

therapeutic claim, both of which are severely restricted by the Federal Alcohol Administration Act and TTB regulations.⁷

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 the requirements set out in the FDA Draft Industry Guidance.⁸ 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.⁹ Absent agreement between the FDA and TTB formats, action by small brewers to comply with the Draft Industry Guidance would contradict current TTB policy guidance and create uncertainty when the pending TTB rulemaking is completed.

E. Small Brewer Sales to Chain Restaurant and Similar Retail Food Establishments

The Draft Industry Guidance broadly defines chain restaurants and “similar retail food establishments” (SRFEs) to include retail outlets well beyond the basic industry understanding of what constitutes a chain restaurant. 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 Draft Guidance for Industry, including convenience stores, quick-service restaurants, airports, stadiums, and other concessionaires, grocery store cafes, and other retail outlets. Since TTB has

⁷ 27 U.S.C. § 205, 27 CFR parts 4, 5 and 7.

⁸ The Draft Industry Guidance requires 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.

⁹ *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).

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. The additional statutory requirements set out in the Draft Industry Guidance further complicate small brewer efforts to comply with federal law.

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 associated logistical issues present a major barrier to entry for small brewers to the chain restaurant and SRFE sectors.

Another concern of small brewers is that national chains will seek nutritional information from all suppliers regardless of size or the length of time that products remain on their menus. Many small brewers produce limited volumes of certain brands that are not likely to be in the market beyond the sixty-day period that the Affordable Care Act establishes as a threshold for mandatory disclosures. The FDA should accordingly provide additional guidance on the subject of short-term specials.

Final FDA guidance should also define the term “standard menu item” in a manner that excludes locally-produced beers and other foods and beverages not available in sufficient quantities for sale at 20 or more locations. The Affordable Care Act utilizes the term “standard

menu item” that should be fairly construed to mean an item available at 20 or more locations. FDA should clearly state that chain restaurants and SRFEs do not need to collect and maintain nutritional disclosure for products that are not available at 20 or more locations.

F. Sources of Nutritional Information and Testing Requirements

As indicated in the Draft Guidance for Industry:

Section 4205 states that a restaurant or SRFE shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in Title 21 Code of Federal Regulations, section 101.10.¹⁰

In the course of responding to TTB rulemaking notices over the last several years, BA’s membership and staff investigated existing federal sources of nutritional information on alcohol beverages. Two widely-recognized sources exist, (i) the Federal Dietary Guidelines for Americans published jointly by the Department of Health and Human Services and (ii) the Department of Agriculture and the annual publication titled U.S. Department of Agriculture, Nutrient Database for Standard Reference.

The Nutrient Database is well-suited as a reference for calorie and nutritional disclosures. It provides a recognized and well-established source and testing protocol that small brewers can utilize to provide accurate estimates of calories, nutrient content, serving sizes, and other information required for compliance with FDA Industry Guidance. Data for each product also is presented in a manner consistent with the Nutrition Labeling and Education Act (NLEA) requirements for display of nutrient information.

¹⁰ Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010, *available at* <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm223266.htm> (proposed August 24, 2010); 21 U.S.C. § 403(q)(5)(H)(iv).

The existing “alcoholic beverage” category of the Nutrient Database already includes light beer, regular beer, and several specific brands. Beers produced by small brewers have greater variation in alcohol content and ingredients than the existing USDA “regular beer” category, but general classifications can be established that will provide industry members and consumers with accurate calorie and nutritional information. BA stands ready to work with the USDA to develop easily measured criteria, such as an original gravity measurement, that would provide a consistent benchmark for brewers and accurate information for consumers. The Nutrient Database can be updated to accurately reflect product differences in the same manner that it has been regularly updated to provide nutrient information for the wine category, where considerable variation also exists. For beer, as for other products, the Nutrient Database provides information for one ounce and for a typical serving. Retailers could either use the established serving size or adjust it by calculating the calorie and nutrient data as appropriate to match the actual serving on a menu and in the more detailed written disclosures.

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

In response to TTB Notice No. 73, BA commented on proposed reference or serving sizes, which are particularly important for alcohol beverages as they determine calories and a consumer’s alcohol consumption. 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.

H. Tolerances for Calorie and Nutrient Content Disclosures

Beer is an agricultural product that may have relatively minor, but discernable batch-to-batch variation due to variations in natural ingredients, manufacturing processes, and human factors. Many of the smallest brewers do not have automated systems that allow them to precisely match the exact mash temperature in every batch, which may create minor differences in calories from one batch to another. FDA accordingly should establish a tolerance for beers. For example a beer that is marked on menus as having 175 calories per 12-ounce serving could be between 150 and 200 calories. This option would avoid costly batch-to-batch testing. Establishing consistent tolerances with TTB would allow greater flexibility for small brewers.

Existing TTB labeling requirements for disclosure of alcohol content, caloric, carbohydrate, fat and protein on beverage labels are set out in *TTB Procedure 2004-1*.¹¹ The tolerances in that guidance present costly challenges with the batch-to-batch variation inherent in the brewing process (and winemaking process). The tolerance for alcohol content is 0.3% above or below the stated alcohol content. The tolerance for caloric content is +5 to -10 the stated caloric content. The carbohydrate and fat content are acceptable “within a reasonable range below the labeled or advertised amount...but must not be more than 20 % above the labeled or advertised amount.”¹² The protein content is acceptable “within a reasonable range above the labeled or advertised amount...but must not be more than 20 % below the labeled or advertised

¹¹ TTB Procedure 2004-1, July 12, 2004.

¹² *Id.*

amount.”¹³ The use of a tolerance that has the phrase “reasonable range” provides insufficient guidance for industry because what is reasonable to one person may not be reasonable to another. Subjective standards should be replaced by clear objective standards. The tolerances in *TTB Procedure* 2004-1 were adopted without the benefit of public input, but had the BA been able to comment, an explanation of the batch-to-batch variation in the brewing might have led to the adoption of a different standard. Variables such as malt specifications or water pH might prevent a brewer from achieving identical lab results for each batch of the same brand. If a product is outside the tolerances for any of these items, the brewer would need to apply for a new label or blend the beer to obtain the exact same lab results. In either case unique character and freshness could be compromised. The BA accordingly believes that the tolerance ranges should be more liberal for disclosure of alcohol, caloric, fat, carbohydrate and protein content.

The Brewers Association recommends the following tolerances:

- 0.5% ABV above or below the labeled amount for alcohol content.
- 5 percent over or 10 percent under the labeled caloric content.
- 10 percent below or 25 percent above the labeled carbohydrate and fat contents or 1 gram below or above the stated fat content, whichever is greater.
- 25 percent below or 10 percent above the labeled protein content or 1 gram below or above the stated protein content, whichever is greater.

I. Costs and Other Business Considerations

In FDA’s final guidance and during future development of agency regulations, the cost of laboratory testing for small brewers is a major consideration. As explained above, consistency

¹³ *Id.*

between the FDA menu labeling and nutritional disclosure and TTB serving facts requirements would provide consistent and helpful information to consumers. The narrow batch-to-batch tolerances also would require additional laboratory testing to provide restaurants the required information.

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 and suggested in the Draft Industry Guidance.

J. Timing for Compliance

The Draft Guidance for Industry indicates an understanding on the part of FDA that industry members will need some period of time to develop and implement compliance plans. Nevertheless, FDA has indicated that the basic calorie and nutritional disclosure provisions of the Affordable Care Act are self-executing and effective upon enactment of the statute.

The FDA approach poses a significant risk of inconsistent implementation and a resulting breakdown of trust between industry and the FDA. Thousands of retail outlets are affected by the Draft Guidance for Industry and hundreds of decision-makers are attempting to fashion compliance plans in good faith, but without final industry guidance or formal regulations. FDA allotted no time for consumer testing or other measures to determine the best means of communicating calorie and nutritional information to millions of consumers who patronize chain restaurants and SRFEs. The FDA's experience in implementing the NLEA underscores the likelihood that periodic refinements will be made in agency guidance and in formal regulations to enhance consumer understanding. The BA respectfully requests that the FDA carefully revise its Draft Guidance for Industry based on comments received and set a realistic future date for implementation of the statute using final guidance. That approach would permit FDA officials to undertake a thorough analysis of the comments received in response to the Draft Industry

Guidance as well as comments in response to the July 7, 2010 FDA notice seeking comment on various substantive details that must be addressed to successfully implement the calorie and nutritional disclosures.

For small brewers and other alcohol beverage producers, the situation is further complicated by the pending TTB rulemaking discussed above. The BA respectfully urges the FDA to revise its final guidance to indicate that application of the Affordable Care Act to alcohol beverages will occur when FDA and TTB officials agree on a consistent implementation methodology. Because the federal Administrative Procedure Act bars TTB officials from disclosing details of a pending rulemaking, the BA and all other affected industry members are uncertain of the timing or substance of TTB's final regulations governing disclosure of calories and nutrient information. Basic concepts of good government and fairness to a heavily-regulated industry should guide the FDA in this situation.

K. Summary

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

1. FDA should postpone application of Section 4205 of the Affordable Care Act to alcohol beverages until the effective date of TTB's final regulations governing label disclosures. In the interim, 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. Numerous changes and uncertainty undermine the purpose of the statute and could discredit industry and government efforts to inform consumers.
2. The FDA should authorize industry's utilization of the USDA Nutrient Database as a credible source of data for calorie and nutrient disclosures. The USDA Database already contains valuable information for retailers. With additional information and industry cooperation, it can be an efficient and easily-accessible tool for all food and beverage producers and retailers covered by Section 4205 of the Affordable Care Act.

3. Once FDA and TTB develop a consistent policy in accord with the two agencies' authorizing statutes, FDA should develop a menu labeling protocol and nutrition disclosure guidance that recognize and support the ability of small brewers to access the market through chain restaurants by providing a flexible implementation schedule.
4. FDA should clearly articulate how seasonal or other short-term brands qualify for the exemption from calorie menu labeling and other mandatory nutritional disclosures at chain restaurant.
5. FDA should clearly state that products sold at fewer than 20 outlets of a chain are not regular menu items within the meaning of the Affordable Care Act.
6. FDA should establish realistic tolerances given the batch-to-batch variations found in small brewer products.
7. All of the recommendations above will help mitigate the costs small brewers will necessarily incur if chain restaurants and SRFEs sell their products.
8. The FDA should reconsider its time line and its position that some provisions of Section 4205 are self-executing to avoid inconsistent implementation by retailers, suppliers, and producers. Inconsistent implementation undermines the goal of achieving uniformity in menu labeling and developing accurate nutritional information across the diverse food and beverage industry.

Again, the BA and its membership appreciate the opportunity to comment on the Draft Industry Guidance 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):

