

June 10, 2011

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

Submitted Online

RE: FDA Proposed Rules - Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

Docket No. FDA-2011-F-0172; RIN 0910-AG57

Dear Commissioner.

Marin Institute appreciates the opportunity to comment prior to the Food and Drug Administration's (FDA) issuance of rules regarding food labeling and nutrition labeling of standard restaurant menu items. The health and societal problems associated with alcohol greatly exceed those of other products. Still, alcohol is a food that significantly contributes calories to people's diets. Accordingly, the FDA should reconsider including alcohol in the proposed food labeling and nutrition labeling requirements.

Marin Institute is a nonprofit organization fighting to protect the public from the impact of the alcohol industry's negative practices. Because the consumption of alcohol carries with it significant problems, the Marin Institute is uniquely qualified to comment on the importance of regulating alcoholic beverages. Over the years, we have waited in vain for the Alcohol and Tobacco Tax and Trade Bureau (TTB) to issue labeling requirements for alcoholic beverages. Despite repeated attempts, the TTB has continually failed to follow through with this and other regulations that would improve public health. Congress has granted the FDA significant authority to address public health issues. Given the vacuum resulting from TTB inaction, the FDA should fill this void and address health concerns associated with the consumption of alcohol.

The overconsumption of calories is a major problem in the United States. Requiring restaurants and similar retail food establishments to post nutrition information is an important step in helping people to make better decisions regarding what to eat and drink. From both a public health and a legal standpoint, the proposed exemption of alcohol from these requirements is an error. As described below, alcohol should be covered because it contributes to calories just as other drinks do and would be confusing to exclude them. Moreover, because the FDA has significant authority to protect public health, in addition to concurrent jurisdiction over alcohol with the TTB, it can and must impose regulations controlling food and nutrition labeling of standard menu items on alcoholic beverages.

Health Concerns

The consumption of alcohol negatively affects the health and well being of people in the United States in many ways. The harms most commonly associated with alcohol consumption include problems such as drunk driving, violent crime, spousal and child abuse, and diseases such as liver cirrhosis and cancer. Though these problems often result from underage drinking, binge drinking, and alcoholism, moderate alcohol consumption can also contribute to health problems, especially various forms of cancer. Consumption of alcoholic beverages also contributes a significant source of calories to the American diet and can facilitate increased food consumption and poor dietary choices. Thus, alcohol can contribute to obesity, which in turn may be associated with a range of health problems including heart disease, Type 2 diabetes, hypertension, and stroke.

Ultimately the purpose of nutrition labeling for standardized menu items is to provide consumers with information about the healthfulness of the food they are consuming in restaurants. Exempting alcoholic beverages from menu labeling requirements may give the mistaken impression that alcoholic beverages are more healthful choices than other non-alcoholic beverages. Considering all the health and societal harms associated with alcohol consumption, this proves especially problematic.

Furthermore, it is difficult for consumers to calculate the number of calories contained in a specific alcoholic beverage. The caloric content of an alcoholic beverage depends on the volume of alcohol it contains. As a result, the caloric content can vary between similar types of alcoholic beverages. Mixers can also add additional calories to alcoholic beverages. Because restaurants are in a better position to know the contents and serving size of an alcoholic beverage, it should be their responsibility to inform consumers.

Finally, merely monitoring total calorie consumption will not increase overall health. Though reducing calories will help with weight loss, it is also important to monitor both the types of calories and nutrients that are being consumed. Diets high in fats and sodium contribute to many health problems including heart disease and high blood pressure.

Merely requiring additional nutrition information be made available upon request will result in fewer people being informed of the nutritional value of the drinks they are consuming. Additionally, in the context of alcohol, merely stating calories may result in people mistakenly concluding that an alcoholic beverage is more healthful than another non-alcoholic option. By requiring the prominent display of additional nutritional information can further improve health by helping consumers make informed decisions with regard to those foods and beverages that best meet their nutritional goals.

Jurisdictional Concerns

The FDA has significant authority to regulate alcoholic beverages as a result of its mandate to protect the health of people living in the U.S. In support of this purpose, the FDA is authorized, in part, to regulate food safety. Included in the definition of food are alcoholic beverages. Furthermore the FDA has specific authority to regulate wine and hard ciders that contain less than seven percent alcohol and beers made from grains other than barley and hops. Much of the other regulation of alcoholic beverages is assigned to the TTB. By contrast, the purpose of the TTB, in part, is to collect alcohol taxes and ensure that these products comply with commodity, safety and distribution requirements. It is this division of regulatory purpose that allows for the two agencies to have concurrent jurisdiction over alcohol. In effect the FDA is concerned with health issues while the TTB is concerned with trade issues. In the absence of a specific prohibition or direct conflict, it follows that each agency can regulate alcohol so long as it is in line with its mandate.

At present, the FDA has proposed rules requiring certain restaurants to post nutritional information regarding standardized menu items. The FDA proposes excluding alcoholic beverages from the final rules because it has concluded that the TTB has sole authority to regulate the labeling of alcoholic beverages. This conclusion ignores the purpose of the enabling statute. Congress specifically outlined certain exemptions in the Patient Protection and Affordable Care Act for menu labeling, but alcohol was not one of them. Congress wants consumers to know the number of calories contained in food sold at restaurants. Because the FDA recognizes alcoholic beverages as "food" it must be concluded that the regulations require the posting of nutritional information for alcoholic beverages at restaurants covered by the statute.

The FDA can disregard any potential conflict with the TTB. The FDA cites the holding in the case *Brown-Forman Distillers Corp. v. Mathews*² to support the supposition that it cannot regulate the labeling of alcoholic beverage. Though the U.S. District Court ruled that the exclusive jurisdiction to regulate the labeling of alcoholic beverages resides in the TTB,³ the case dealt with alcoholic beverage *labels*, not restaurant *menus*. Moreover, nearly 35 years have passed since the ruling, and Congress has now imparted the FDA with the authority to require menu labeling, not TTB. Moreover, because TTB only has authority over product labeling, without FDA inclusion of alcoholic beverages under the proposed rule, we will not have any federal action on this issue, which cannot be Congress' intent.

Additionally, the ruling in *Brown-Forman*⁴ asserts, in part, that the FDA ceded any authority to regulate the labeling of alcoholic beverages because it failed to do so in the preceding decades. In fact, since this ruling the TTB has continued to fail at establishing any rules regarding nutritional labels on alcoholic beverages. Following the logic used in *Brown-Forman*, a court may now rule against the TTB and its inaction. It is therefore an error for the FDA to forgo acting on the basis that the TTB has not acted. The FDA states that it will exclude menu labeling requirements on alcoholic beverages because the TTB is going to issue alcohol labeling rules in the near future. In fact it has been nearly four years since the TTB published its proposed rules.

It will likely be some time before the TTB takes an action that promotes public health, as history has shown. For example, in 2010 the FDA and Federal Trade Commission (FTC) were the first federal agencies to take action against a sub-group of alcoholic beverages known as caffeinated alcoholic beverages. The combination of alcohol and caffeine represented a dangerous mix that appealed to underage and inexperienced drinkers. Letters sent to the four manufacturers of these products by the FDA and FTC required these companies to remove these products from the market. Despite continued efforts by public health groups for years before the FDA and FTC action, the TTB remained largely silent on the issue of caffeine in alcohol. The FDA played a lead role in preventing more harm from these dangerous products despite the TTB's concurrent jurisdiction. Indeed, it was the TTB that approved these products for sale in the first place.

Though conflicts may exist between the TTB and the FDA over the labeling of alcohol, the FDA does have explicit authority to regulate some labeling (i.e. additives and certain beverage subtypes). It therefore does not follow that the FDA should apply the proposed regulations in an unequal manner to those products it can regulate.

The FDA is also willing to impose nutritional disclosure requirements on products regulated by another US agency. The FDA states on its website that with the exception of certain game meat, that the US Department of Agriculture (USDA) regulates meat and poultry. Despite a potential conflict the current FDA proposal imposes the nutritional disclosure requirements on meat, poultry, and processed egg products.

As for concerns regarding small alcohol producers, the FDA can remove the burden of needing to test the nutritional of content by creating an exemption for small producers. The FDA is concerned that because the TTB does not already require alcoholic beverages to be labeled with nutritional information the disclosure requirements will represent a great burden for small brewers. Because large companies produce most beer and other alcoholic beverages, exempting those products produced by small producers will have a limited effect on the effectiveness of the proposed regulations while negating concerns about burdening regulation.

Conclusion

The FDA has sufficient authority to regulate alcohol. As a result, the FDA can include alcoholic beverages in the definition of "food" for purposes of the food and nutrition labeling standards for restaurant menus. Inaction on the part the FDA may contribute to consumer confusion, undermining the very purpose of menu labeling law and potentially contributing to further health problems associated with the consumption of alcohol.

Respectfully submitted,

Michele Simon, JD, MPH Research and Policy Director Marin Institute

REFERENCES

¹ See http://aje.oxfordjournals.org/content/161/4/368.full and http://www.adajournal.org/article/S0002-8223%2809%2902096-3/abstract

² 435 F.Supp. 5 (1976).

³ At the time of the holding the TTB was the Bureau of Alcohol, Tobacco and Firearms (BATF).

⁴ 435 F.Supp. 5 (1976).

⁵ http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDADoesntRegulate/default.htm