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July 5, 2011

The Honorable Margaret A. Hamburg, M.D.
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire, Avenue
Building 1, Room 2217
Silver Spring, MD 20993

RE: Docket Nos. FDA-2011-F-0172 and RIN 0910-AG57 (Proposed Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments) (76 Federal Register 19192 (April 6, 2011))

Dear Commissioner Hamburg:

The establishment of a uniform federal standard for nutrition disclosure is a top priority for the National Restaurant Association (Association) and our diverse membership consisting of chain restaurants, independent operators, franchisors and franchisees. It is critically important to our membership that the final rule implementing nutrition disclosure reflects the intent of Congress and the shared goal of the Association, as well as the approximately 70 public and private organizations and consumer advocate groups that supported the passage of the nutrition disclosure law.

The Association is the leading business association for the restaurant industry, which comprises a diverse 960,000 restaurant and foodservice outlets and a workforce of nearly 13 million employees. The Association's extensive membership uniquely positions us to provide feedback on the proposed rule on nutrition disclosure as our membership includes not only the leading chain restaurants but also restaurants that are independently owned and operated. It is important that FDA shape the final regulation to account for the sheer depth and breadth of restaurant concepts that reflect the great diversity of consumers that our industry serves. The Association has provided substantial information illustrating this diversity in prior comments. The Association has appreciated the open dialogue that Food and Drug Administration (FDA) has fostered among all stakeholders. Ensuring that final execution eases implementation for chains and incentivizes participation for all of our members, including those eligible for the voluntary program, is a top priority for the Association and is critical if the goals of the unprecedented new law are to be realized.

We greatly appreciate the opportunity to provide comments on the proposed rule. These comments supplement the comments submitted jointly on behalf of the chain restaurant industry. As you will see, without significant revisions to the proposed rule, the goal of establishing a uniform federal standard for nutrition disclosure will be jeopardized and non-chain restaurant operators will not have an incentive to participate in the voluntary federal program. This result minimizes the impact of the new federal law and potentially exacerbates the patchwork of nutrition disclosure laws the new federal

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requirement was specifically intended to eliminate. We anticipate that many restaurants that operate fewer than 20 units will be eager to participate in the voluntary program, but only if it is practical and not too costly. The consistency and wide availability of a national law that is accessible to small restaurants will directly benefit consumers who will have accurate and useful nutrition information on a consistent basis when they dine out.

Faced with a patchwork of state and local menu labeling requirements, the Association along with several of our chain members sought a federal approach to the labeling of restaurant and restaurant-type food. After several years of discussion, the Association, by a vote of its Executive Committee of the Board, was pleased to support the efforts of Senators Harkin, Carper and Murkowski along with Congressman Matheson, Upton and DeLauro that resulted in the passage of the new law. The historic legislation represented a true win-win – for consumers and industry.

Our support for the new law was predicated on the inclusion of several provisions including a reasonable basis standard for nutrition disclosure, an interpretation of similar retail food establishment that includes coverage of entities serving restaurant and restaurant-type food, flexible implementation in providing nutrition information, and a reasonable timeline for compliance. In addition, strong and immediate federal preemption over non identical state and local requirements was necessary to create a uniform standard. We greatly appreciate the FDA comments indicating that preemption took effect immediately and efforts to communicate that to state and local officials. We urge FDA to carefully consider the comments relating to practical and broad implementation by restaurants of all sizes and configurations and to publish final regulations as soon as possible. Implementation that advances the plain language of the statutory language used by Congress, and the underlying goals shared by all stakeholders, will establish a uniform, national mandate and voluntary program that will furnish calorie and other nutrient information on a consistent basis no matter where restaurant and restaurant type foods are enjoyed.

Complexity of the Restaurant Industry

The 960,000 unit restaurant industry is large and quite diverse. Chain restaurants may be company owned, franchised, or a combination of the two. Depending on the parent company, individual franchises may have more or less autonomy in determining what is on the menu and how it is served. Menu items may change daily, as ingredients of standard items change depending on the cost and product availability. Independently owned and operated restaurants are even more diverse in their service. As previously stated, restaurateurs support providing nutrition information but require adequate flexibility to successfully implement both the mandatory and voluntary provisions of the law. Flexibility is especially important for small, independent operators who are considering whether to participate in the voluntary program.

As noted in the proposed rule, there are certain costs associated with implementation of menu labeling- costs related to nutritional analysis, menu board and menu design, and employee training. Although such costs are primarily an issue for chains with 20 or more units given the mandatory requirement they must meet, it is also of particular concern to smaller operations that are considering participation in the voluntary program. FDA has long taken special account of the impact of its regulations on small businesses. Nutrition information is of no less value regardless of whether it is one of several locations, or part of a national chain. Congress wisely determined that nutrition labeling should not be imposed on small restaurant operators, but their participation on voluntary basis is a

critical feature of the new law. We encourage FDA to take the cost and feasibility of small restaurant participation into account so as to ensure maximum impact as FDA revisits the issues raised in the rulemaking and publishes a final rule.

Reasonable Basis Standard

To help address the need for flexibility, while accomplishing the goal of a uniform standard, Congress put a “Reasonable Basis” provision into the law that allows restaurants to use a variety of methods to determine nutrition information. As explained more fully in the joint industry comment, this standard was first adopted by FDA. As memorialized by Congress, requiring that a restaurant demonstrate to FDA’s satisfaction that a restaurant operator has a reasonable basis for the nutrient value presented to consumers provides an enforceable, effective compliance standard.

As you are aware, FDA has recognized the challenge with variability with restaurant food in regulation for nearly 20 years when it created separate compliance standards for restaurants and packaged food. Indeed, FDA understands that there is inherent variability in restaurant prepared foods. For example, you are never going to get the precise same amount of ice cream in a scoop, the same number of fries in a carton, much less the exact same amount of pasta and sauce in a dish of spaghetti. When presented with a choice between codifying the restaurant food or the packaged food compliance standard, Congress understandably picked the restaurant food standard for nutrition disclosure by the restaurant industry. In fact, it codified the current restaurant standard in the law as follows:

“(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.”

The Association strongly opposes FDA’s tentative decision in the proposed rule to disregard the statutory language and 20 years of FDA practice and instead enforce restaurant food disclosure accuracy and compliance to the same standard required of prepackaged processed foods produced in food processing facilities. In addition, as outlined in the attached letter from Senator Harkin and Congresswoman DeLauro, FDA would be in contradiction of the intent of Congress. According to Senator Harkin and Congresswoman DeLauro “So long as the stricter 80/120 rule is used to enforce the new regulation, the “reasonable basis” standard set forth elsewhere in the regulation is simply irrelevant. Section 4205 of the Affordable Care Act plainly intends a different result.” We agree. FDA cannot impose the so-called 80/120 rule to restaurants in any fashion and still take the position that it has implemented the new law’s “reasonable basis” standard.

As further illustrated in our joint comments, without this change in the compliance standard, restaurant chains would effectively be unable to attain the type of exact certainty that is possible with prepackaged foods. For the reasons detailed in our joint comment, such an outcome could not be supported as a matter of law or sound public policy. Legal precedent provides clear and unquestioned direction to FDA- an agency cannot substitute its own judgment for that of Congress when a law compels a given result in plain language that clearly expresses the intent of Congress. That is certainly the case here. Moreover, as a matter of public policy, FDA would greatly undermine the goals it seeks to advance

if it constructs an unobtainable compliance standard. Such an outcome, finally, could not be defended as the outgrowth of reasoned decision-making.

In addition, smaller restaurant chains and independents will not participate in the voluntary program. An important objective of the “reasonable basis” standard is to recognize the inherent variability of hand-prepared restaurant foods and to acknowledge that restaurants cannot reasonably afford extensive and repeated nutrition labeling analyses. Small restaurants are particularly disadvantaged under a standard that effectively treats restaurants like sophisticated food processors that produce identical packaged foods on high speed production lines. The “reasonable basis” standard, as directed by Congress, is vital to encouraging the broad participation of restaurants under the voluntary program. Some small operators may struggle to provide information outside of the federal program in an effort to respond to consumer interest. This will re-create a patchwork of nutrition information – something that is not in the best interest of operators or our customers.

Similar Food Retail Establishments

Congress clearly wrote the nutrition disclosure law to include establishments that sell food in a similar manner as restaurants, yet the proposed rule is written to exclude many of the establishments Congress intended to include. According to Senator Harkin and Congresswoman DeLauro, “The aim [of the legislation] was not to confine the scope of the law solely to restaurants or other establishments that were engaged primarily in the sale of food, but to apply the law broadly to restaurants as well as other retail food establishments that sell food to consumers, regardless of the percentage of floor space devoted to food and regardless of whether the food sales constitute a large or small portion of the establishments’ total business.”

FDA’s interpretation set forth in the proposed rule, which excludes some competitors to restaurant operators, will deter smaller restaurant chains and independents from participating in the voluntary program. In addition, many state and local officials will likely look to enact menu labeling requirements for these excluded entities. This will once again create a patchwork of nutrition disclosure laws that runs contrary to the federal intent and introduces additional complexity for the consumer. We, like many stakeholders, see a significant benefit of the new law to include the wide scale availability of calorie and other nutrient information virtually every place consumers enjoy away from home foods.

Flexibility with Nutrition Disclosure

As written, the law requires nutrition information to be provided in a clear and conspicuous manner. The diversity and complexity of the restaurant industry make providing nutrition information to consumers far more complicated than it may seem on the surface. As a result, great flexibility is needed in order for operators to present information in a format and manner that works for their operation and customer. Without options, smaller restaurant operators may choose to stay outside the scope of the federal requirement.

Timeline for Compliance

Restaurant operators are preparing to comply with the new nutrition labeling requirement. The Association is also playing an important role in helping our members meet the upcoming compliance challenges. We have partnered with three companies, at a discount for our members, to help them

develop nutrition information. While the industry is making preparations today, the real work of menu and menu board creation cannot occur until the final rule is released. In working with our members, we know that the six month compliance standard proposed by FDA is unachievable for even some of our largest members.

The Association is requesting that operators have one year to comply with the new federal requirement. This will ensure that the restaurant is able to present the information in a usable and consistent manner and that the staff is well trained to respond to consumer inquiry. It is important that FDA clearly articulate a realistic deadline at the time the final rule is published to ensure an orderly transition. Requiring an unrealistic implementation date that is subsequently changed merely creates unnecessary and costly confusion, dislocation and added costs to what will already be a very challenging process. The restaurant industry has demonstrated its commitment to the new law and only asks that FDA ensure that the goals are realized in an orderly, cost-effective and realistic fashion.

Conclusion

The Association strongly supports the new nutrition disclosure law. We believe that nutrition labeling will provide consumers with the information they need to make informed decisions based on their particular dietary needs. Because we so strongly believe in the wisdom of Congress in enacting the nutrition labeling law, the Association is concerned that without critical changes to the proposed rule, the great promise of the law for consumers will be unmet. As appropriate, I would be pleased to meet with FDA officials, or provide any other information we might have, to assist FDA in completing the rulemaking. I, personally, and on behalf of the Association and its members, look forward to a final rule that matches the intent of Congress, encourages operators to sign up for the voluntary program, and achieves the uniform federal standard envisioned by the many supporters of this law. Thank you for your consideration of these comments and we pledge our continued support to ensure a full and timely implementation of the final rule once published.

Sincerely,



Dawn Sweeney
President and CEO
National Restaurant Association