Congress of the United States
House of Representatives
Washington, DC 20515

August 15, 2014

The Honorable Shaun Donovan
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Donovan:

We write regarding FDA's proposed rule on menu labeling, which is titled "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" and was published in the *Federal Register* on April 6, 2011 (76 FR 19192). As you may know, we were the chief sponsors of menu labeling legislation and negotiated the deal with the public health groups and industry that resulted in section 4205 being included in the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). The proposed rule is intended to implement section 4205, which requires restaurants and other similar retail food establishments that are part of a chain with 20 or more locations to provide calorie and other nutrition information for standard menu items, including food on display and self-service food.

The purpose of this letter is to clarify Congressional intent with respect to two of the provisions at issue in the rulemaking. FDA's proposal differs in at least two material respects from the intent of the Affordable Care Act, and the proposed rule itself actually invites comment on several alternative interpretations, suggesting there may be some confusion. In light of these circumstances, we write to help dispel any potential uncertainty as the OMB considers FDA draft final rule.

1. <u>Definition of "Restaurant or Similar Retail Food Establishment"</u>:

FDA's rule proposes to define "restaurant or similar retail food establishment" in a way that excludes food outlets and concessions stands at movie theaters, amusement parks, bowling alleys, miniature golf courses, and other entertainment venues. As drafted, the menu labeling requirements would apply only to businesses the present themselves publicly as restaurants or to those – like grocery stores – that use 50% or more of their gross floor space for the preparation, purchase, service, consumption, or storage of food.

This proposed definition is narrower than that intended by Congress in section 4205 of the Affordable Care Act. In fact, Congress intended the scope of the disclosure law to extend to movie theaters, bowling alleys, bookstore cafes, and other like establishments, which is the very reason Congress used the phrase "and similar retail establishments" in the statute to extend the

reach of the law beyond restaurants. The aim 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. As drafted, the definition in the proposed rule excludes many retail food establishments that Congress intended to cover in providing consumers with more information about the nutritional content of the food they buy and consume.

2. Reasonable Basis:

Another significant issue in the proposed rule is the method by which food establishments are expected to determine the nutritional content of their foods. The standards set forth in proposed 21 CFR 101.11(c) suggest that FDA may have misunderstood Congress's reference in the Affordable Care Act to the current language in 21 CFR 101.10.

Proposed 21 CFR 110.11(c)(1) says that restaurants and similar retail food establishments must have a "reasonable basis" for their nutrient disclosures such as cookbooks, laboratory analyses, or nutrient databases. This is consistent with section 4205 of the Affordable Care Act, which says explicitly that "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."

Nevertheless, proposed 21 CFR 110(c)(2) says that, for purposes of enforcing the new labeling requirements, FDA will adopt the so-called "80/120" rule that currently applies to commercially manufactured and packaged foods under 21 CFR 101.9(g).

Use of the stricter 80/120 rule to enforce the new regulations essentially invalidates any establishment's ability to rely on the "reasonable basis" rule in proposed 110.11(a). This outcome is at odds with the intent of the Affordable Care Act, which was clearly to allow the food establishments covered by the new law to base their nutrient disclosures on reasonable bases. When Congress referenced section 21 CFR 101.10 in the law, it did so with the clear understanding that, by virtue of 21 CFR 101.9(j), the "80/120" rule applied only to commercially manufactured and labeled foods while the "reasonable basis" rule separately applied to restaurants. That understanding was reinforced by FDA in Q&A #25 in the agency's 2008 Guidance Document, titled "A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods."

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.

Thank you for your consideration of these concerns. We look forward seeing a final rule that better reflects the Congressional intent outlined above. For purposes of the administrative record, please submit a copy of this letter to docket number FDA-2011-F-0172.

If you have any questions about the letter, please contact Kelly Horton on Congresswoman DeLauro's staff at 202-225-3661 or Andi Fristedt on Senator Harkin's staff at 202-224-7675.

Sincerely,

Rosa L. DeLauro
Member of Congress

Tom Harkin
United States Senator

cc: Dr. Margaret Hamburg, FDA Commissioner