

March 14, 2017

The Honorable Thomas E. Price, MD
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price,

On behalf of the food and beverage industry, we are writing to express our concern with the current compliance deadline of July 2018 for the Nutrition Facts and Serving Size (NFL) rules and to request extending the deadline to May 2021. We wish to be very clear, our member companies support providing consumers with clear information to help them make healthy choices and we are committed to implementing these rules.

We believe however, this can be accomplished with far less complexity and cost. As demonstrated in FDA's own Regulatory Impact Analysis (RIA)¹ for these rules, additional time will avoid billions of dollars in wasteful spending on duplicative relabeling schemes, allow coordination with planned label updates, provide the FDA time to issue guidance that is critical for implementing key provisions of the rule, and create a timeline that will allow USDA to complete its work on a separate rule mandated by PL 114-216, which requires mandatory disclosure of ingredients produced with biotechnology.

During the notice and comment process for the NFL, our respective organizations individually requested up to five years to comply in order to minimize the regulatory burden associated with the massive task of relabeling the entire food supply. Inexplicably, FDA provided only two years, setting the compliance deadline at July 26, 2018 for all but the smallest companies. FDA's Regulatory Impact Analysis found that the cost associated with a two-year compliance deadline could be as high as \$4.6 billion and that could be reduced by nearly \$2 billion with a calculated cost of a four-year compliance deadline as high as \$2.8 billion. Unfortunately, FDA, under the previous Administration, chose the option that is 39% more expensive.

The current compliance deadline does not sufficiently account for the time, resources, and complexity involved in label changes of this magnitude. While a two-year compliance timeline may have been sufficient for the original nutrition facts panel rules issued in the 1990s, the food and beverage world is much more complicated today. According to Nielsen data, 400,000 new products have been introduced since the early 1990's, which substantially affects the ability of manufacturers to change labels within the same timeframe allotted more than 20 years ago.

Additionally, to change essentially every single food package in the U.S. requires testing and analyzing products, entering ingredient information into databases, new label and packaging designs, new printing plates, and queuing up in line with printing companies. The process requires coordination among

¹FDA Regulatory Impact Analysis for Final Rules on Food Labeling – Docket No.'s FDA-2012-N-1210 and FDA-2004-N-0258.

software vendors, ingredient suppliers, compliance/quality assurance teams, graphic designers, printing companies and others on a scale of magnitude that has never before been executed.

This untenable situation is exacerbated by the fact that as of today, with only 16 months left in the implementation period, FDA has yet to issue final guidance on how to define and properly calculate two common food ingredients: dietary fiber and added sugar.

Moreover, immediately after the July 26, 2018 compliance date for the NFL, USDA is mandated to finish the biotechnology disclosure rule on July 29, 2018. This means that only three days after over 715,000 covered food and beverage products are required to be in compliance with FDA's NFL rules, industry must again begin the expensive and time-consuming process to redesign labels and related materials and relabel their products to come into compliance with the biotechnology disclosure rule.

FDA is aware of the massive burden multiple labeling deadlines place on the industry. In its own RIA of the two NFL rules (Nutrition Facts and Serving Size), FDA notes the importance of coordinating the compliance date for those two rules, so that packaging would only need to be changed once, resulting in a 20% savings. While this RIA did not contemplate the pending biotechnology disclosure rule, as it is pending at USDA, nor the costs associated with FDA's current delay in finalizing crucial guidance, the same logic applies. The most cost effective approach would be to minimize the number of times packaging must be redesigned, reprinted and relabeled.

An extension of the current NFL compliance date to May, 2021 is urgently needed in order to ease regulatory burden on the economy. We welcome the opportunity to provide additional information on the food industry hurdles and what it takes to efficiently achieve compliance for all labels.

Thank you for your consideration.

Sincerely,



Robb Mackie
President & Chief Executive Officer
American Bakers Association



Alison Bodor
President & Chief Executive Officer
American Frozen Food Institute



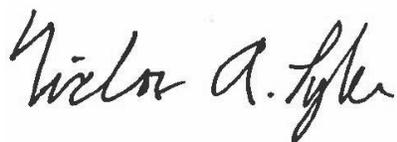
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Jeannie Milewski
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CC: The Honorable Stephen Ostroff, MD
Acting Commissioner
Food and Drug Administration