Food & Beverage ISSUE ALLIANCE

September 30, 2019

Dr. Ned E. Sharpless, Acting Commissioner
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
CommissionerFDA@fda.hhs.gov

**Re: Request for Enforcement Discretion Related to Compliance Date for Final Rules on the Nutrition Facts Label (Docket Nos. FDA-2012-N-1210 and FDA-2004-N-0258)**

Dear Dr. Sharpless,

The undersigned trade associations write to request that the Food and Drug Administration (FDA or the agency) provide flexibility in its enforcement of the new nutrition labeling rules as the January 1, 2020 compliance date approaches. We note at the outset the food industry is wholly committed to implementing the new nutrition labeling rules and our member companies have expended significant time and resources to transition to new labels. We support the goal of the final rules to provide consumers information that will help them make informed decisions about the foods they purchase and enjoy. As we have done throughout the rulemaking process, we ask that this labeling initiative be implemented in a way that takes into consideration the time and complexity involved in making changes to product labels.

In particular, we ask the agency to provide a six-month period of enforcement discretion following the compliance date, during which time the agency would not take enforcement action against companies unable to transition their full portfolio of labels to the new format. We believe such a period of enforcement discretion is warranted in light of (1) the magnitude of the task of revising all labels, (2) the difficulty of predicting label inventory levels and the significant cost and environmental impact of disposing of existing label inventory, and (3) the fact that the existing labels would not present a risk of misleading consumers. We note the increased flexibility and exercise of enforcement discretion we are requesting is similar to FDA's approach in implementing several of the Food Safety Modernization Act (FSMA) final rules.

In the event the agency is reluctant to exercise such enforcement discretion on a broad basis, we ask FDA to recognize that enforcement discretion is warranted in specific situations where FDA becomes aware that a company did not label a product prior to the compliance date and the company can demonstrate good-faith efforts to bring their full portfolio of labels into compliance. In such situations, we ask FDA to recognize that additional time and flexibility is warranted when a company can provide a justification for why it has been unable to meet the compliance date for all affected labels.

Alternatively, we ask the agency to establish a process for companies to submit case-by-case requests for additional time, along with a justification for the request and how much additional time is

needed. We are concerned, however, that FDA may be inundated with requests and question whether the agency would have the resources needed to respond to the multitude of requests that we expect would be submitted. Many of the factors involved will be similar among companies, so reviewing such requests on a case-by-case basis would be an inefficient use of the agency's limited resources.

Assuming the agency agrees to provide the type of flexibility we are requesting, we ask that FDA provide similar flexibility for the later January 1, 2021 compliance date for manufacturers with less than $10 million in annual food sales, as we expect these companies will also face challenges in achieving 100 percent compliance by January 1, 2021.

Below we provide background information on the industry's efforts to implement the new nutrition labeling rules and the rationale for our request for flexibility.

**Background**

Our respective member companies are deeply committed to implementing the new nutrition labeling rules and have been diligently working to update labels, many of which are already available in the marketplace. Many of our member companies expect that while they will have already transitioned a significant majority of product labels to the new format, it will be difficult to meet the compliance date for 100 percent of labels in time to apply the new labels to any product labeled on or after January 1, 2020. Even where the new labels will be ready, in many cases companies maintain significant inventories of the old labels, which absent enforcement discretion would need to be sent to a landfill at great cost to the company and the environment. These difficulties are in line with the challenges we projected companies would face in implementing rules of this magnitude in a 3.5 year period.

In initial comments to FDA on the proposed rule, the food industry broadly commented that a two-year compliance period would be insufficient to implement changes of the magnitude of those proposed. Many trade associations requested a four- or five-year compliance period. When FDA finalized a two-year compliance period, the food industry again requested additional time to comply, particularly in light of the then-forthcoming U.S. Department of Agriculture labeling initiative requiring the disclosure of bioengineered foods. Many of the undersigned associations requested an additional two years to comply. The agency provided an additional year and a half, for a total of 3.5 years for compliance for large manufacturers (and an additional year for manufacturers with less than $10 million in annual food sales).

We greatly appreciate the extension provided, and for many products, this amount of time has been sufficient to achieve the required changes. For some small percentage of stock keeping units (SKUs), however, compliance by January 1, 2020 will not be possible, and there will be significant inventories of old labels that will need to be disposed of in order to apply the new label for any products labeled on or after the compliance date.

**Rationale for Request**

1. **Revising all labels to comply with the new nutrition labeling requirements is a task of significant magnitude.**

Updating virtually all labels that bear a Nutrition Facts Panel involves considerable time, planning, resources, and complexity to be done correctly. Many companies' product portfolios are ever increasing in size in an effort to provide consumers with choices. The label revision process

involves new label design, making plates, and obtaining a place in queue with the printing company. Many partners are involved, including software vendors, ingredient suppliers, graphic designers, and printing companies. Each plays an important role in the process, often working with multiple companies at the same time. Graphic designers and printing companies in particular have limited capacity to handle the hundreds of thousands of stock keeping units (SKUs) in a short and concentrated period of time. These capacity constraints create several bottlenecks that increase the time required to complete the label changes. Additionally, these factors are compounded in private label manufacturing agreements, where a company may not have the ability to dictate the timing of label changes

While some labels are relatively straightforward to update, in many cases the label changes are highly complex and even involve product reformulation. The new nutrition labeling rules are the first major update to the Nutrition Facts Panel in over 20 years and result in significant changes to the label. For the first time, the label will need to include a declaration of added sugars, which companies have never previously calculated. There is significant complexity involved in assessing the added sugars content of certain ingredients, such as juice concentrates and fermentation products, and companies are still in the process of implementing the agency's much-needed guidance on the added sugars calculation. Additionally, the new regulation changed the definition of "dietary fiber" and does not "count" certain added fibers as dietary fiber unless the fiber has been shown to have a beneficial physiological effect on human health. Several fiber ingredients, including acacia gum, are still in the process of being evaluated by FDA to determine if they can count toward the dietary fiber declaration.

We greatly appreciate FDA's efforts to provide timely guidance on the numerous technical issues raised by new rules. However, we note several guidance documents were finalized in 2019 (including one document on the declaration of folic acid and other nutrients issued in August 2019), which has left limited time for companies to review and incorporate the guidance into labeling practices. 1/ There are also several guidance documents that remain in draft form, including guidance documents on serving sizes and RACCs, as well as allulose.

Beyond the many technical complexities of the rule, there are a number of changes to the rules that require reformulation if a company is to maintain eligibility for longstanding claims, such as changes to the daily values for nutrients that result in a change to the amount of a nutrient needed to qualify for a claim. Adding a product reformulation adds years to the amount of time needed to update the labels.

In light of the magnitude of the task at-hand, we believe additional flexibility is warranted as the compliance date approaches.

2. **It is difficult to predict label inventory levels with precision; disposing of existing label inventory would result in significant cost and environmental impact.**

---

1/ *See, e.g.,* FDA Draft Guidance for Industry: The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels (Apr. 2019); FDA Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products (June 2019) (we note it was particularly helpful that FDA announced enforcement discretion until July 1, 2021 for products affected by this guidance); FDA Guidance for Industry: Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on Nutrition Supplement Facts Labels (Aug. 2019).

Our associations greatly appreciated the FDA's clarification that the compliance date would apply to the date a product is "labeled" – rather than the date the food is available on store shelves or some other date. 2/ This clarification allowed companies to better plan for the approaching compliance date. It also appropriately reflects that manufacturers typically do not have control over or visibility into the date a food is available for sale in commerce, whereas manufacturers do have insight into the date a product is labeled.

There is still, however, great imprecision involved in trying to predict label inventory levels in order to use up as much existing label inventory prior to the January 1, 2020 compliance date. In many cases, procurement teams will not have the ability to accurately predict how many months the existing label inventories are likely to last. For this reason, many companies will have existing label inventory that will go unused by January 1, 2020 absent some type of enforcement discretion from the agency. Disposing of these labels in landfills will involve sizable cost and impact to the environment. Some of our member companies have estimated that they will need to dispose of existing label inventory in the range of $1 million or more that will go unused prior to the January 1, 2020 compliance date, unless enforcement discretion is available to use these labels for a short period following the compliance date.

**3. The continued use of existing labels for a short period of time following the compliance date would not present a risk of misleading consumers.**

The flexibility we are requesting would not result in the use of false or misleading labels. Rather, our request for enforcement discretion would involve the continued use for a short period of time of labels that comply with the nutrition labeling rules in effect for the last 20+ years. Consumers have already experienced a multiple-year transition period during which products with both new and old label formats are available on the market. Adding up to six months to this period for a limited number of labels would not add to consumer confusion. Generally, the use of the old format is apparent because the type size and format is different than required for the new format, so consumers will be able to tell whether a label has been updated. For the vast majority of products, the new label formats will be available and consumers will have access to nutrition information in the updated format.

**4. The requested flexibility is similar to FDA's approach in implementing a number of the final rules under FSMA.**

Finally, the flexibility we are requesting is consistent with FDA's approach to FSMA implementation. Generally, FDA has adopted an "educate before and while we regulate" approach. The agency has engaged in extensive education, outreach, and technical assistance while bringing the regulations online, with the goal of fostering industry compliance, on the basis that the regulations are new territory for both industry and FDA. Additionally, for each of the three final rules discussed below, FDA announced that it would not inspect until a later date following the compliance date.

---

2/ FDA Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals (Nov. 2018), at question 1, *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-nutrition-and-supplement-facts-labels-questions-and-answers-related-compliance.

- For the Preventive Controls for Animal Food regulation, FDA delayed the start of routine regulatory inspections to ensure compliance with the Preventive Controls requirements for large facilities "to allow them time to develop, implement, and then fine tune their food safety pans." 3/ Similarly, while facilities that are small businesses were required to comply with the preventive controls requirements by September 2018, FDA announced that it did not intend to conduct routine regulatory inspections to ensure compliance with those specific requirements until the fall of 2019.

- For the Intentional Adulteration regulation, FDA announced that routine inspections to verify compliance with the rule will begin in March 2020, although the first compliance date arrived in July 2019. 4/

- For the Produce Safety regulation, the first major compliance date was January 26, 2018, when larger farms were required to comply with the rule. However, FDA announced that routine inspections would not begin until the spring of 2019 "to give both farmers and state regulators more guidance, training, technical assistance, and planning to ensure that they have the tools they need." Because FDA delayed the start of routine inspections under the Produce Safety Rule, FDA also did not start FSVP inspections for produce importers until 2019. 5/

Each of the FSMA rules discussed above involves a novel area of regulation for both the industry and the agency. The nutrition labeling rules similarly involve novel issues related to new nutrients to declare, new recordkeeping requirements, and complex calculations for nutrients. We therefore believe FDA should explore potential ways to incorporate flexibility as the compliance date approaches, just as the agency did in the above situations.

**Request**

We ask the agency to provide flexibility in its enforcement of the new nutrition labeling rules, in order of most to less-preferred, and providing similar enforcement discretion for both the 2020 and 2021 compliance date:

1. Provide a six-month period of enforcement discretion following the January 1, 2020 compliance date, during which time the agency will not take enforcement action against companies unable to transition their full portfolio of labels to the new format.
2. Provide enforcement discretion in specific situations where the agency discovers a company did not label the product by the compliance date and the company can demonstrate good-

---

3/ *See* https://www.fda.gov/food/conversations-experts-food-topics/what-expect-next-compliance-dates-fsma-preventive-controls-animal-foods-rule.

4/ *See* https://www.fda.gov/food/conversations-experts-food-topics/protecting-food-supply-intentional-adulteration-such-acts-terrorism ("FDA has heard from stakeholders that due to the novel nature of this rule and its requirements more time is needed to develop fully compliant food defense plans. We are working hard to provide resources, including the final portion of the draft guidance, which may be helpful to industry. To allow industry time with the forthcoming materials, tools, and trainings, and because the IA rule represents new regulatory territory for all of us, the start of routine IA rule inspections will begin in March 2020").

5/ *See* https://www.fda.gov/food/conversations-experts-food-topics/what-expect-now-larger-farms-must-comply-fsma-produce-safety-rule.

faith efforts to bring their full portfolio of labels into compliance by the January 1, 2020 compliance date.

Alternatively, FDA could establish a process by which companies may submit case-by-case requests for additional time to comply. As discussed above, there are a number of downsides to this approach, particularly the constraints on the agency's limited resources, and we therefore believe one of the first two options is preferable.

* * *

We thank you in advance for your consideration of this request.

Sincerely,

American Bakers Association
American Frozen Food Institute
American Herbal Products Association
Corn Refiners Association
Council for Responsible Nutrition
Food Marketing Institute
Independent Bakers Association
International Dairy Foods Association
National Automatic Merchandising Association
National Confectioners Association
National Grocers Association
Peanut and Tree Nut Processors Association
SNAC International

cc: Frank Yiannas, Deputy Commissioner for Food Policy and Response
Anna Abram, Deputy Commissioner for Policy, Planning Legislation and Analysis
Caitlin Boon, Associate Deputy Commissioner for Food Policy and Response
Stacy Cline Amin, J.D., Chief Counsel
Dr. Susan T. Mayne, Director, Center for Food Safety and Applied Nutrition
Dr. Douglas Balentine, Director, CFSAN, Office of Nutrition and Food Labeling