Dear Dr. Ostroff and Dr. Mayne,

On behalf of the Food and Beverage Issue Alliance (FBIA) and organizations affiliated for purposes of this letter, we write you today to request that FDA provide clarity on key questions related to the agency’s review of data and other information submitted to support FDA’s listing of certain fiber ingredients as “dietary fiber.” As discussed further below, this clarity is essential to facilitate effective information sharing between the food industry and FDA on these issues, including through the petition process, and will help ensure that FDA’s review of this information is efficient, with the least burden to agency resources as is possible.

In its May 27th final rule updating the Nutrition Facts Label, FDA defined “dietary fiber,” for the first time, to mean “non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.” In this rulemaking, FDA concluded that β-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose all have beneficial physiological effects such that they are “dietary fiber” under FDA’s new definition. However, FDA declined to make a determination about the status of certain other fibers, including inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber, concluding that it was necessary to provide an opportunity to comment on the available scientific evidence regarding these substances’ physiological effects.

FDA’s new approach to defining dietary fiber marks a significant change for the entire food industry, and in particular for certain product categories that have extensively used, for decades, fibers about which FDA did not reach a conclusion in its final rule. We understand that FDA intends to publish a separate notice to seek comment specifically on these additional fibers.
and offer guidance for industry on the petition process and FDA’s intended approach. Based on FDA’s discussion of this issue in the rulemaking, we have identified a few key issues that we request FDA specifically address in these forthcoming publications. Further guidance and explanation on these issues will assist industry in providing FDA with the information it needs to evaluate these ingredients and help ensure that FDA’s process for reaching a final conclusion is as efficient and streamlined as possible, which will conserve FDA resources and also help prevent unnecessary disruptions and costs to industry.

We also respectfully request that FDA release its notice and its guidance document as soon as possible, as ingredient suppliers need to make decisions imminently about whether and how best to file citizen petitions for particular ingredients, and finished food manufacturers need to make decisions as to whether to reformulate their products quickly so that they can comply with the revised nutrition labeling rules by the July 26, 2018 deadline. At a minimum, stakeholders would deeply appreciate FDA identifying concretely its anticipated timeline for the release of the notice and guidance, again to facilitate industry decision-making. We understand that FDA has stated the guidance would be released by the end of this calendar year, but we would appreciate clarity as to whether this means in December or earlier.

In the final rule, FDA indicated that the guidance document would provide more insight regarding the information FDA recommends be provided to the agency for scientific review to demonstrate a fiber’s beneficial physiological effect and the approach FDA intends to use to evaluate the studies, including the approach for its evaluation of the strength of the scientific evidence. We have identified a few aspects of this scientific review process and FDA’s intended approach, described in more detail below, that could benefit from further clarification related specifically to the strength of evidence FDA expects, what FDA considers to be a beneficial physiological effect, and how FDA intends to review data it receives efficiently and effectively.

- **Strength of Evidence**
  - FDA indicated that the strength of the total evidence should demonstrate a specific beneficial physiological effect, and that the beneficial effect should be replicated. *What does this mean in terms of quantity of evidence? What is FDA seeking in terms of consistency of evidence? Is FDA seeking a certain threshold number of studies that demonstrate a beneficial physiological effect?*
  - FDA indicated that the scientific evidence from a clinical study to support a beneficial physiological effect should provide an amount of the fiber that is a reasonable level to be expected in a food and relevant based on typical consumption of dietary fiber. *What is a “reasonable level” to be expected in a food? Is it based on some percentage of the daily value for dietary fiber?*
  - FDA concluded that the publicly available scientific data for certain fibers were not sufficient to allow FDA to determine that those fibers provide a beneficial physiological effect. *Will FDA's notice provide additional clarification about its assessment of these dietary fibers and their respective strength of evidence?*

- **Beneficial Physiological Effect**
  - FDA identified a number of physiological effects that it considers to be beneficial, including attenuation of blood glucose and cholesterol levels, increased satiety, improved laxation, and increased absorption of minerals, and also those that FDA does not consider to be beneficial, such as fermentation. Per the preamble, FDA has acknowledged that it is open to additional beneficial physiological effects
as science continues to evolve. Has the Agency identified any additional physiological endpoints through their on-going scientific evaluations of dietary fibers?

- FDA did not discuss in the rulemaking the types of endpoints that it would expect to demonstrate a beneficial physiological effect. Must a clinical trial have studied, as endpoints, the precise beneficial physiological effects identified by FDA? What endpoints would FDA consider to support an effect of increased satiety, improved bowel function, or increased absorption of minerals?

Additionally, we request that FDA identify in the notice the studies and other scientific literature, by citation, that the agency evaluated when determining its initial list of dietary fibers. Doing so would help the industry identify which papers were evaluated and have a better understanding of the conclusions drawn, especially in relation to the substances for which FDA has not yet finalized their determination.

Further, we note that the amount of time that it can take for FDA to respond to petitions submitted through the process that FDA intends to use to evaluate the scientific evidence of specific ingredients can be considerable. FDA referenced, in its final rule, its regulations related to citizen petitions that require FDA to respond to a petitioner within 180 days to approve the petition, deny the petition, or provide a tentative response. However, as you are aware, the time it can take FDA to reach a final decision is in the vast majority of circumstances far longer than 180 days and there are no binding requirements for the agency to render a final decision within a certain period of time. For example, on June 1, 2016, FDA denied a citizen petition on sodium that had been pending with the agency since 2005. We are concerned that a lengthy time period for reviewing the science for fiber petitions could have chilling effects on healthy product innovation. Therefore, we would appreciate understanding FDA’s plans for staffing and properly resourcing the team that will be responsible for reviewing these petitions in a timely manner, and how long it expects to take to render final decisions.

Similarly, FDA emphasized in the final rule the value it sees in listing in the rule itself the specific fibers that meet the definition of dietary fiber, so that manufacturers will know that, when they use those fibers as an ingredient in their product, they must include the fibers in the declaration of dietary fiber, and consumers will have a consistent basis on which the declared values for dietary fiber are derived and can use that information in making healthy dietary choices and for comparing products. We are concerned, however, that listing these fibers only through rulemaking will be time intensive and consume FDA resources unnecessarily.

Moreover, a delay in formally listing as dietary fiber those ingredients shown to have a beneficial physiological effect could have adverse public health consequences. Manufacturers may reformulate to eliminate these ingredients if they cannot be listed as dietary fiber by the time they must relabel their products to comply with the deadline for the updated Nutrition Facts Label. Consumers would then have even fewer options for consumption of dietary fiber, an under-consumed nutrient of public health concern.

FDA should consider a more flexible approach to conveying this information that would still provide clarity to manufacturers, regulators, and consumers, but would also be more efficient than rulemaking. Specifically, we strongly encourage FDA to post, on a designated part of its website, any decisions the agency reaches about the status of a fiber ingredient it has been evaluating, and to immediately allow any additional fiber ingredients that FDA concludes are “dietary fiber” to be used as such. FDA could make uniform updates to the regulation
periodically (e.g., every five years) but in the interim should exercise enforcement discretion until the regulation is updated. This is an incredibly time sensitive issue and we recognize that FDA has committed to make a determination about the pending fiber ingredients as quickly as possible. Our suggested approach would facilitate the speed and effectiveness of FDA’s review.

Finally, we note that, in the rulemaking, FDA declined a request to allow industry to continue using and labeling fibers already on the market for the pendency of FDA’s review process, because the agency was not aware of how many fibers are currently used as an ingredient in food that it had not already evaluated and had no information to suggest that it would receive numerous petitions or that, if we were to receive petitions, review would extend beyond the compliance dates. Many of the fibers about which FDA declined to make a determination are widely used by various sectors of the food industry, and we anticipate that FDA will receive numerous submissions in support of the continued use of these fibers. One such ingredient – acacia (gum arabic) – is expressly listed in FDA’s regulations for its function as a dietary fiber (21 CFR 172.780(c)), and manufacturers will wish to continue using this ingredient in accordance with this regulation. We understand that the uncertainty about the status of these fibers in the interim is incredibly disruptive and could hinder the ability of manufacturers to come into compliance with other new labeling requirements.

Given this, we encourage FDA to request comment in its forthcoming Federal Register Notice specifically on the current scope of use of ingredients as dietary fiber but about which FDA declined to make a determination. In particular, we are asking FDA for enforcement discretion allowing time for industry to be able to finalize viable solutions that meet FDA’s new definition for dietary fiber and avoid disruption in the marketplace. We think this information could help FDA better understand the broad scope of products affected by the agency’s current position on dietary fiber and the potential value in allowing industry to continue using and labeling fibers already on the market for the pendency of FDA’s review process. Such comments would also be of assistance as the agency plans strategically for reviewing and responding to forthcoming petitions, so that it can ensure it has the necessary staffing and resources.

We greatly appreciate the agency’s further consideration of these crucial issues, and look forward to working collaboratively with FDA throughout this process to facilitate effective petitions and efficient review.

Sincerely,

American Bakers Association
American Frozen Food Institute
Calorie Control Council
Council for Responsible Nutrition
Grocery Manufacturers Association
Independent Bakers Association
International Dairy Foods Association
International Food additive Council
North American Millers Association
SNAC International
The Association for Dressings & Sauces
The Sugar Association