American Bakers Association
The Voice of the Baking Industry Since 1897

By Electronic Submission

February 13, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30), Docket No. FDA-2016-D-3401.

Dear Sir or Madam:

The American Bakers Association (ABA) is pleased to submit these comments in response to FDA's request for comments the Draft Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30) (Draft Guidance).[1]

ABA is the Washington D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 700 baking facilities and baking company suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families. The baking industry generates more than $102 billion in direct annual economic activity and employs over 706,000 highly-skilled people. ABA appreciates this opportunity to submit these comments on the Draft Guidance, Scientific Evaluation of the Evidence on the Beneficial Psychological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30) ("Draft Guidance").

More than any other sector in the food industry, ABA believes that bakers are significantly impacted by FDA's changes to the nutrition label. Yeast-based bakery products are subject to fermentation and therefore face challenges with respect to the calculation of added sugars, even though added sugars from yeast-based products are not a high contributor to added sugars in the American diet. Bakers must now, for the first time, for products produced from enriched flours, calculate and generate records reflecting the portion of folate that must be declared as folic acid, which has presented unforeseen challenges requiring consultation and clarification from FDA. Of all the changes, however, the new definition of dietary fiber has presented significant obstacles and challenges. Given bakers' close connection with numerous dietary fiber ingredients, ABA has become aware of many unintended consequences resulting from FDA's current definition of dietary fiber. We describe many of these challenges in these comments, in addition to requesting a less burdensome approach. We hope the agency will

[1] 81 Fed. Reg. 84,516 (Nov. 23, 2016).

thoughtfully consider the challenges and alternatives provided below. ABA would like to retain an open dialogue with FDA to reach a workable solution and definition for dietary fiber.

ABA acknowledges FDA's efforts to define "dietary fiber" and to determine which ingredients have a physiological effect that is beneficial to human health. ABA recognizes FDA's efforts in releasing both its Scientific Review of 26 non-digestible carbohydrates (NDCs) and its Draft Guidance explaining how it will review scientific information in citizen petitions seeking approval of potential dietary fibers. ABA appreciates the extension of the comment period.

Nevertheless, ABA believes that the current definition of dietary fiber is not practical or workable and requests that FDA reconsider its definition. ABA has encountered numerous unintended consequences and unaccounted costs and burdens associated with the definition--likely a result of FDA's issuance of the definition prior to thoroughly understanding and addressing the impact of the definition. ABA, therefore, requests that FDA rescind the definition of dietary fiber or at least stay the definition until it has adequately addressed the numerous concerns raised since it finalized the definition, including providing a comprehensive list of ingredients that can be declared as dietary fiber.

Alternatively, ABA requests the following:

- Consider a less burdensome definition of dietary fiber.
- Include additional examples of dietary fibers that meet FDA's definition along with test methods that support declaration of these fibers on the nutrition label.
- Include additional details on FDA's scientific review process, including information on: (1) the process by which manufacturers may show that an ingredient has an identical chemical structure to an approved NDC; (2) FDA's approach toward combination ingredients; (3) additional examples of physiological endpoints and the agency's suggested duration of studies for certain endpoints; (4) what FDA considers to be appropriate statistical analysis of study results; and (5) the factors FDA will consider in evaluating scientific studies.
- Alternatives FDA will use in conjunction with the rule making requirements to publicly announce its approval that an ingredient meets its definition of dietary fiber so that a manufacturer can include that ingredient in its dietary fiber declarations in advance of and apart from the formal rulemaking process.
- Re-establish a compliance date based on a timeframe after FDA has worked out all the challenges associated with the new definition of dietary fiber, including approving pending citizen petitions. The current compliance date is less than 18 months away and FDA has indicated it will consider timing options to allow manufacturers to relabel or reformulate products once it has reviewed pending fiber petitions and comments submitted in response to the guidance and Science Review.

In addition, ABA respectfully requests that FDA issue a revised Draft Guidance that takes into account all comments it receives. This will provide stakeholders the opportunity to review the revised Draft Guidance before FDA issues a final guidance.

I. Rescind or Stay the Definition of Dietary Fiber

ABA respectfully requests that FDA rescind or stay[2] the definition of dietary fiber until it has thoroughly addressed and accounted for all the unintended consequences and unaccounted costs and burdens associated with the definition. In its haste to release the dietary fiber definition, FDA neglected to provide itself ample time to seek industry input and conduct adequate research to sufficiently understand the nature and benefits of ingredients currently declared in the definition of dietary fiber. It is clear that FDA still does not sufficiently understand dietary fiber enough to define it or to regulate a definition.

For example, there are numerous dietary fiber ingredients that are the same "dietary fiber" but are called by different names. Some of these ingredients are essentially the same as "approved" isolated or synthetic fibers, yet there is currently no regulatory pathway for ensuring that such ingredients are not at regulatory risk if they are marketed to manufacturers as meeting FDA's definition of dietary fiber. Similarly, there are ingredients that are called by the same name but that are not the same ingredient. For example, some corn hull fiber ingredients are highly processed and clearly are "isolated and synthetic" requiring prior FDA approval before being declared as dietary fiber, whereas other corn hull fiber ingredients are only mechanically processed and therefore arguably are "intrinsic and intact" and do not require prior FDA approval before being declared as dietary fiber.

ABA is also aware that small businesses whose sole business is innovating new, healthful, dietary fiber ingredients are on the verge of shutting their doors due to FDA's lack of understanding of novel dietary fiber ingredients and its inability to quickly and nimbly approve pending dietary fiber citizen petitions.

These are only a few minor examples of the myriad issues FDA is currently grappling with and has yet to resolve, with a compliance date that is fast approaching. ABA strongly urges FDA to rescind or stay the definition of dietary fiber until it can present to consumers and to industry a comprehensive and well thought out definition of dietary fiber and a list of ingredients that meet this definition.

II. Consider a Less Burdensome Definition of Dietary Fiber

On February 2, 2017, The White House Office of Information and Regulatory Affairs (OIRA) issued an Interim Guidance implementing Section 2 of the Executive Order, "Reducing Regulation and Controlling Regulatory Costs." The OIRA Interim Guidance applies to "significant regulatory actions" as defined in Executive Order 12866--regulatory actions that have an annual effect on the economy of $100 million or more. Notably, significant guidance documents are potentially included, and "will be addressed on a case-by-case basis." While it is still unclear whether OIRA's Interim Guidance will apply to the NFL-related guidance

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[2] ABA is aware that under 21 CFR 10.35(e), the FDA Commissioner has authority to grant a stay "in any proceeding." As examples, FDA has stayed certain aspects of its sunscreen requirements (*see* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/UCM090292.pdf) and certain provisions under the Prescription Drug Marketing Act of 1987 (*see* http://www.fda.gov/OHRMS/DOCKETS/98fr/cd0075.pdf).

documents, FDA estimated in the NFL final rule that its changes to the label--of which the agency's new definition of dietary fiber is clearly the most burdensome provision--will cost industry at least 2.47 billion dollars (based on 2014 values).

ABA requests that FDA adopt a less burdensome definition of dietary fiber. ABA provided several alternatives in its original comments it submitted to FDA on the proposed NFL changes, including the proposed definition of dietary fiber. We incorporate those comments by reference into this submission and have appended them here for easy reference.

III. Adopt Health Canada's Approach to Dietary Fiber

ABA reiterates its view (previously stated in its comments to FDA on the proposed dietary fiber definition), that FDA should adopt Health Canada's approach to dietary fiber. Health Canada reviews and accepts dietary fibers if the fiber has "at least one physiological effect demonstrated by generally accepted scientific evidence"; the non-exclusive list of benefits includes, for example, improved laxation or regularity by increasing stool bulk, reducing blood total and/or low-density lipoprotein cholesterol levels, reducing post-prandial blood glucose and/or insulin levels, and providing energy-yielding metabolites through colonic fermentation.[3] Additionally, FDA should adopt the list of dietary fiber ingredients already approved by Health Canada.

IV. Remove [beta]-Glucan Soluble Fiber and Psyllium Husk from the List of "Isolated or Synthetic Non-Digestible Carbohydrates"

In the final definition of dietary fiber, FDA included [beta]-glucan soluble fiber and psyllium husk in its list of "isolated or synthetic non-digestible carbohydrates." Both these ingredients are described in 21 CFR 101.81(c)(2)(ii)(A) and (B), respectively, as soluble fibers that are eligible to carry a health claim about reduced risk of cardiovascular disease. Except for the source of [beta]-glucan soluble fiber described in 21 CFR 101.81(c)(2)(ii)(A)(6) as "barley betafiber," all other sources of [beta]-glucan soluble fiber described in 21 CFR 101.81(c)(2)(ii)(A)(1) - (5) clearly are intrinsic and intact, including oat bran, rolled oats, whole oat flour, oatrim, whole grain barley, and dry milled barley. Similarly, psyllium husk as described in 21 CFR 101.81(c)(2)(ii)(B) is clearly intrinsic and intact and should not be included in FDA's list of "isolated or synthetic non-digestible carbohydrates" in 21 CFR 101.9(c)(6)(i).

We presume FDA did not intend to identify these intrinsic and intact dietary fibers as "isolated or synthetic." In the Draft Guidance, FDA gives examples of intrinsic and intact fibers that "by their very nature . . . meet the definition of 'dietary fiber' in the final rule," including cereal bran, . . . parts of a food (e.g., outer coat of peas)." The Draft Guidance states that these intrinsic and intact fibers are produced "using mechanical processes, (e.g., milling)." Based on the definition of dietary fiber and supported by FDA's statements in the Draft Guidance, [beta]-glucan soluble fiber and psyllium husk are intrinsic and intact dietary fibers, not "isolated or synthetic."

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[3] *See* Health Canada, Bureau of Nutritional Sciences, Food Directorate, Health Products and Food Branch, *List of Dietary Fibres Reviewed and Accepted by Health Canada's Food Directorate.*

Identifying these fibers as "isolated or synthetic" has already caused significant confusion on top of an already extremely confusing and unworkable definition of dietary fiber. Examples are helpful, however, so if FDA chooses to include these two examples of dietary fiber in the definition of dietary fiber, it should include them as examples of intrinsic and intact dietary fiber. For example, FDA could amend the existing definition as follows (underlined is new text),

> " . . . and lignin that are intrinsic and intact in plants (including [beta]-glucan soluble fiber (as described in 101.81(c)(2)(ii)(A)(1) - (5)) and psyllium husk (as described in 101.81(c)(2)(ii)(B))) . . . The following isolated or synthetic non-digestible carbohydrates . . shall be included in the calculation of the amount of dietary fiber: barley betafiber, cellulose, . . . "

In the interim, as FDA revises its definition of dietary fiber through formal rulemaking, FDA should make clear on its webpage or through some announcement that [beta]-glucan soluble fiber and psyllium husk fiber as described in 21 CFR 101.81(c)(2)(ii) are intrinsic and intact dietary fibers, not "isolated or synthetic."

V. Include Additional Examples of Dietary Fibers

ABA appreciates the examples of dietary fibers FDA included in the Draft Guidance, but requests that FDA include the additional examples provided below. The Draft Guidance confirms that dietary fiber includes NDCs that are intrinsic and intact in plant-based foods and that these ingredients, by their very nature, meet the definition of dietary fiber (e.g., fruits, vegetables, whole grains, legumes, and nuts). The Draft Guidance also provides examples of NDCs present in fiber-containing foods that are produced using mechanical processes that FDA also considers to be dietary fibers such as the fiber in fiber-containing foods that are produced using mechanical processes (e.g., milling) if the food contains other nutrients normally found in the food (cereal bran, cocoa powder, flours, vegetable purees or pomace, vegetable protein extracts, parts of a food); and NDCs (e.g., resistant starch) that are created during the normal processing of a food (flaked corn cereal). In addition to the examples provided by FDA, we request that FDA add rice hull fiber, corn hull fiber, and other hull fibers that have only been mechanically processed as additional example of dietary fiber to the revised Draft Guidance.

- ABA would like to point out that FDA's Draft Guidance is confusing with respect to certain "intrinsic and intact" dietary fibers. In its list of "intrinsic and intact" dietary fibers, FDA's Draft Guidance includes "parts of a food (e.g., outer coat of peas)." In the next paragraph of the Draft Guidance, however, FDA distinguishes these dietary fibers from NDC's "that no longer contain or contain lower amounts of food components, such as vitamins and minerals" and that therefore "are not considered to be intact and intrinsic." ABA requests that FDA clarify that parts of a food (e.g., outer coat of peas, cereal brans, other part plants) that have been mechanically separated from other plant components meet FDA's definition of "intrinsic and intact" dietary fiber, even though they "no longer contain or contain lower amounts of food components, such as vitamins and minerals" because they have been mechanically separated from other plant components.

ABA opposes FDA's conclusion that, as a category, NDCs obtained "from non-food sources, such as stems, branches, and trunks of trees, inedible hulls and husks, seaweed and

fungus" do not meet FDA's definition of dietary fiber. ABA requests that FDA reconsider this conclusion and include food ingredients derived from plants that can be tested as insoluble fiber, contain zero calories, and hold additional water within a food product (resulting in lower overall calories in a food) in its definition of dietary.

Finally, when FDA approves a dietary fiber ingredient, ABA requests that FDA include the test method that will accurately capture the amount of dietary fiber the ingredient contributes that should be declared on the NFL, if the test methods are not included in the AOAC methods cited by FDA in the preamble to the final NFL rule.

VI. Provide Additional Examples on FDA's Three-Step Scientific Evaluation Process for Dietary Fiber Petitions

In order to assist industry in participating in the process of submitting dietary fiber citizen petitions, ABA requests that FDA include in the Draft Guidance additional examples to clarify its three-step scientific evaluation process. Specifically, we request additional detail on: (1) the process by which manufacturers may show that an ingredient has an identical chemical structure to an approved NDC; (2) FDA's approach toward combination ingredients; (3) additional examples of endpoints and the agency's suggested duration of studies for certain endpoints; (4) further detail on what FDA considers to be appropriate statistical analysis of study results; and (5) elaboration on what factors FDA will consider in evaluating scientific studies.

A. Provide a process for manufacturers to establish that an ingredient is already approved as a dietary fiber

In the final rule, FDA concluded that only seven of the NDCs it reviewed met its definition of dietary fiber, including beta-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. 21 C.F.R. 101.9(c)(6)(i). As part of Step 2 of its three-step process, FDA will approve additional NDCs based on their chemical structure. It is unclear how FDA will treat an ingredient that has an identical chemical structure to that of one of the seven approved NDCs or a later-approved NDC. For example, FDA has listed cellulose as an approved NDC, but there are other sources of cellulose, such as sugar cane fiber or sugar beet fiber, that may have an identical chemical structure to the approved dietary fiber.

ABA member bakeries use a multitude of cellulosic fiber products, which contain over 80 percent intrinsic fiber. The most common powdered cellulose products used in foods contain approximately 75 to 80 percent cellulose and 20 to 25 percent hemicellulose. When tested using the FCC Monograph assay for powdered cellulose, these ingredients assay as 96 to 104 percent cellulose. ABA requests that FDA clarify how the cellulose content will be measured and what FDA will use as a standard for such measurements. For example, will FDA count the cellulose/hemicellulose portion of cereal-based fibers as dietary fiber? ABA has similar concerns regarding oat, wheat, sugarcane, soy, and rice fibers.

ABA requests that FDA include in the final guidance a process manufacturers can follow to confirm that an ingredient is sufficiently the same as an approved dietary fiber to be declared as dietary fiber in the NFL, including that the ingredient(s) will automatically be considered "dietary fibers" and the proportion of the chemical structure that must comprise the ingredient in order to provide a beneficial physiological effect. As an initial matter, for the seven approved

dietary fibers, we request that FDA include the chemical structure and the amount/proportion of the dietary fiber that provided a beneficial physiological effect so that manufacturers can determine whether their ingredients meet FDA's definition of dietary fiber. Second, we request that FDA clarify whether manufacturers may consider ingredients with an identical chemical structure to an approved dietary fiber and in the same amount/proportion to meet its definition of "dietary fiber" without undergoing the citizen petition process.

ABA believes that if an ingredient has the same chemical structure as an approved NDC and is in the same amount/proportion that demonstrated a beneficial physiological effect, then there is no reason to submit a citizen petition for that ingredient. Instead, for such ingredients, FDA should revise the Draft Guidance to include an alternative to the citizen petition process, such as recommending that manufacturers keep records of such determinations.

B. Provide additional examples to clarify Step 2 of the three-step scientific evaluation process

To streamline the citizen petition process, ABA requests that FDA provide additional examples in Step 2 of the scientific review process of what FDA will and will not consider relevant in a study submitted in a citizen petition. First, we request that FDA clarify its approach toward combination ingredients. The Draft Guidance provides that the NDC of interest "should be provided in its isolated form" and "should not be added in combination with other [NDCs] or other food components that may affect the physiological endpoint being measured." The Draft Guidance, therefore, does not contemplate or provide guidance on evaluating an ingredient that is itself a combination of NDCs, and where the petition seeks approval of the combination as a dietary fiber and includes a scientific evaluation of the combination of NDCs. We request that FDA revise the Draft Guidance to account for combinations of NDCs that are being submitted to FDA for approval as a dietary fiber.

Second, we request that FDA revise the Draft Guidance to include additional endpoints associated with the consumption of dietary fibers shown to have a beneficial physiological effect. The endpoints listed in the Draft Guidance include: lowering blood glucose, lowering cholesterol levels, lowering blood pressure, improved laxation and bowel function, increased mineral absorption in the intestinal tract, and reduced energy intake. ABA asks that FDA include two additional endpoints: (1) increases in insulin sensitivity and (2) colonic fermentation with production of beneficial microorganisms and short chain fatty acids.[4] In addition, ABA

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[4] ABA is aware of FDA's position that FDA does not agree that colonic fermentation itself is sufficient to demonstrate a beneficial physiological effect, but ABA requests FDA to reconsider based on the evidence that production of beneficial microorganisms and short chain fatty acids has links to reduced risk of colon cancer and obesity reduction. (*See* e.g., linkage to reducing risk of colon cancer is summarized as follows: Colonic fermentation of dietary fiber/resistant starch produces short chain fatty acids such as acetate, propionate and butyrate. Histone deacetylase inhibitors have been widely used for cancer therapy (Koh et al 2016). Butyrate, the primary energy source for colonocytes, and, to a lesser extent, propionate are known to act as histone deacetylase inhibitors thereby conferring short-chain fatty acids the role of modulators of cancer (Johnstone 2002; Sealy and Chalkley 1978; Riggs et al 1977; Khouraklis and Theocharis 2006; Flint et al 2012).) (*See, e.g.*, linkage to obesity reduction outcome is summarized as follows: Obesity is closely tied to phylum and group-specific changes in human gut microbiota. A (continued...)

members ask that FDA harmonize the acceptance criteria for laxation with Canada and the European Union, which accept a significant increase in fecal bulk as an acceptable marker for improved laxation.

Third, we request that FDA provide acceptable study durations for all endpoints mentioned in the Draft Guidance. The Draft Guidance provides examples of appropriate study durations for two endpoints (a three week minimum for demonstrating cholesterol lowering effects and a one-week minimum for improved laxation (to ensure sufficient amount of time for collecting stool samples)).

Finally, we request that FDA provide additional information on the statistical analyses it expects to receive that assess study results. For example, the Draft Guidance states that when

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significant reduction of Bacteroidetes and a corresponding increase in Firmicutes is observed within individual humans on weight reduction diets (reviewed in Ley 2010). Resistant wheat starch decreases the ratio of Firmicutes/Bacteroidetes in humans after a 3-week feeding study (Martinez et al 2010). These alterations in relative proportions of Firmicutes and Bacteroidetes were correlated with observations in lean and obese humans (Ley et al 2006), and suggest that the microbiota of an obese person is more efficient at extracting energy from the diet than that of a lean individual. Results by Turnbaugh et al (2009) also found higher Firmicutes/Bacteroidetes ratio in obese individuals compared to lean individuals demonstrating that obesity is associated with reduced bacterial representation of Bacteroidetes.) References include:

Flint, H.J., Scott, K.P., Louis, P., and Duncan, S.H. 2012. The role of the gut microbiota in nutrition and health. Nat. Rev. Gastroenterol. Hepatol. 9:577-589.

Johnstone, R.W. 2002. Histone deacetylase inhibitors: Novel drugs for the treatment of cancer. Nat. Rev. Drug Discov. 1:287-299.

Koh, A., De Vadder, F., Kovatcheva-Datchary, P., and Bakhed, F. 2016. From dietary fiber to host physiology: Short-chain fatty acids as key bacterial metabolites. Cell 165:1332-1345.

Kouraklis, G. and Theocharis, S. 2006. Histone deacetylase inhibitors: a novel target of anticancer therapy (review). Oncology Reports 15(2):489-494.

Ley, R.E., Turnbaugh, P.J., Klein, S. et al. 2006. Microbial ecology: human gut microbes associated with obesity. Nature 103:12511-12516.

Ley, R.E. 2010. Obesity and the human microbiome. Curr. Opin. Gastroenterol. 26:5-11.

Martinez, I., Kim, J., Duffy, P.R., Schlegel, V.L., and Walter, J. 2010. Resistant starches types 2 and 4 have differential effects on the composition of the fecal microbiota in human subjects. PLoS ONE 5(11):e15046.doi:10.1371/journal.pone.0015046.

Riggs, M.G., Whittaker, R.G., Neumann, J.R., and Ingram, V.M. 1977. n-Butyrate causes histone modification in HeLa and Friend erythroleukemia cells. Nature 268(5619):462-464.

Sealy, L. and Chalkley, R. 1978. The effect of sodium butyrate on histone modification. Cell 14(1):115-121.

Turnbaugh, P.J., Hamady, M., Yatsunenko, T. et al 2009. A core gut microbiome in obese and lean twins. Nature 457:480-484.

conducting statistical analysis among more than two study groups, the data should be analyzed by a test designed for multiple comparisons (e.g., Bonferroni, Duncan). FDA further provides that scientific conclusions cannot be drawn when statistical analyses are not performed between the control and intervention group or are conducted inappropriately. ABA respectfully requests that FDA elaborate on what it intends to consider as acceptable statistical analyses so manufacturers can align their analyses accordingly.

VII. Provide A Process For Notifying the Public of Approved Dietary Fibers and Allow Such Fibers to be Declared as Dietary Fiber Prior to Amending the Regulation

ABA requests that FDA provide a process to notify manufacturers, in advance of and separate from the rulemaking process, that an ingredient has received approval as a dietary fiber. FDA explains that it will amend its regulatory definition of dietary fiber to include new dietary fibers as it approves such fibers. Amending the regulation, however requires formal rule making, which is a long process.

ABA, therefore, requests that FDA provide a process in conjunction with, but outside of, the required formal rule making process to notify the public that an ingredient has been approved as a dietary fiber. In addition, ABA specifically requests that FDA allow manufacturers to declare such ingredients as dietary fiber as soon as an ingredient is approved, without waiting for completion of the rule making process.

The viability of some of ABA members' businesses (particularly the smaller businesses) hinges on FDA's approval of their ingredients as dietary fiber. ABA strongly requests that FDA expedite the review of citizen petitions it has already received. This swift action from FDA will lessen the burden currently experienced by the food/beverage industry and the fiber manufacturers, and promote the continuity of existing business of fiber users.

Finally, we ask FDA not to wait to issue decisions on citizen petitions until it has reviewed all citizen petitions and/or the comments received in response to FDA's Science Review. Rather, as soon as FDA has determined that an ingredient meets its definition of dietary fiber, FDA should provide notice to the petitioner and the public that the ingredient is a dietary fiber. Currently, because of FDA's definition of dietary fiber, there is an unfair market advantage for ingredients that were not swept into uncertainty by FDA's definition of dietary fiber and FDA's expansive reading of "isolated or synthetic" resulting from FDA's inclusion of [beta]-glucan soluble fiber and psyllium husk in the list of "isolated or synthetic" non-digestible carbohydrates.

VIII. Provide Options to Address Timing Issues

It has been over six months since FDA issued its final definition of dietary fiber. Our members, like a plethora of other food manufacturers in the food industry, are still waiting on FDA's final word on whether several NDCs currently under review via the citizen petition process meet FDA's definition of dietary fiber. ABA's members would like to ensure that they have sufficient time to meet FDA's compliance date of July 26, 2018 to revise their nutrition information and/or their products.

ABA reminds FDA that in its original comments on FDA's revisions to the nutrition facts, ABA requested a compliance time of at least five years. Additionally, ABA reminds FDA of the

letter it submitted on behalf of the Food and Beverage Issue Alliance (FBIA) last November, requesting that FDA and USDA consider harmonizing the compliance timeframes of label changes (e.g., nutrition information, GMO labeling, partially-hydrogenated oils) so that manufacturers are only required to relabel their products once. In light of the time constraints industry is encountering because of the absence of sufficient guidance and understanding from FDA, ABA requests that FDA work with USDA to harmonize a single compliance date that provides industry with adequate time to relabel their products a single time.

ABA appreciates that FDA has acknowledged in its *Questions and Answers for Industry on Dietary Fiber* Question 11[5] that there might be some timing issues with respect to accurately declaring dietary fiber, given the pending citizen petitions and the comments FDA will receive in response to FDA's science review of 26 NDCs. Consequently, ABA requests that FDA provide options for how it will address these timing issues.

IX. Additional Issues

ABA asks that FDA provide additional guidance regarding which approved dietary fiber analytical methods are considered "equivalent" under FDA's current and forward-looking thinking.

X. Conclusion

ABA appreciates the opportunity to provide this input to FDA as the Agency considers the substance and form of its guidance on how FDA will review scientific evidence in dietary fiber citizen petitions. ABA respectfully requests that FDA issue a revised Draft Guidance so that FDA can incorporate stakeholder feedback. We look forward to continuing to partner with the FDA throughout this process. Should there be any questions or if additional information is needed, the contact regarding ABA's comments is Lee Sanders, SVP, Govt. Relations & Public Affairs. Ms. Sanders can be reached at LSanders@americanbakers.org.

Sincerely,

Lee Sanders
Senior Vice President
Government Relations & Public Affairs

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[5] FDA responds, "If the Agency is unable to update the list of dietary fibers in time for companies to either relabel or reformulate in advance of the first compliance date, we are committed to exploring options to address the timing issue."