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

Via Email: oir_submission@omb.eop.gov
Fax: 202-395-728525

RE: Docket No. FDA-2012-N-1210, RIN 0910-AF22: Food Labeling: Revision of the Nutrition and Supplement Label Facts

Dear FDA Desk Officer,

The Natural Products Association (NPA) is submitting this letter as general comments to Docket No. FDA-2012-N-1210, RIN 0910-AF22 and "Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions" published in the Federal Register on July 27, 2015 (80 FR 17928), regarding the proposal to modify the existing Nutritional and Supplement Facts labeling requirements. The NPA would like to thank the FDA for the opportunity to comment. NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. NPA is a non-profit 501(c) (6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. We are the oldest and largest trade association in the natural products industry representing over 1,900 members accounting for almost 10,000 retail, manufacturing,

wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. Many, if not most, NPA members make or sell food or dietary supplement products and will therefore be impacted by the proposed revisions.

The NPA applauds the Food and Drug Administration's (FDA) goal to increase public knowledge and awareness of sugars and promote human health and nutrition. The NPA additionally supports the FDA's efforts to update the Nutritional and/or Supplement Facts label when it has empirical evidence that such changes for consumers is warranted. The NPA has an interest in changes and revisions made to the long-standing Nutritional and/or Supplement Facts labeling regulations and therefore would like to take advantage of the opportunity to comment on the evidence published in the Federal Register (80 FR 17928) regarding the addition of added sugars and establishment of a DRV and %DRV for added sugars.

Development of the DRV and %DRV for Added Sugars¹

Based on the evidence that was presented in the 2015 DGAC², the FDA has proposed to establish a Daily Recommended Value (DRV) of 50g for added sugars and will mandate labeling of %DRV of added sugars on the Nutritional Facts label: *"As a result of our review of the science underlying the 2015 DGAC report, we are proposing to establish a DRV for added sugars and to require the percent DV declaration of added sugars on the Nutrition Facts and Supplement Facts labels. We are not proposing to establish a DRV for total sugars or to require the mandatory declaration of a percent DV for total sugars because there is no quantitative intake level or other reference amount for which there is sufficient scientific evidence upon which we can base a DRV for total sugars. We are proposing to establish a DRV for added sugars because science underlying the 2015 DGAC report provided a scientific basis for a reference amount for added sugars upon which we can propose a DRV (a recommended maximum of 10 percent of total energy intake). We also received many comments suggesting that, if added sugars are declared on the label, a percent DV declaration would assist respondents in putting the amount of added sugars in a serving of a product into the context of their total daily diet."*

The NPA offers two points for consideration on the establishment of a DRV for added sugars. First and foremost, the FDA is setting an unprecedented standard by using only DAGC

¹ Federal Registrar 80 FR 17928. July 27, 2015. "Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions"

² USDA "Scientific Report of the 2015 Dietary Guidelines Advisory Committee" February 2015

recommendations to develop the 50g DRV for added sugars. Previous changes made by the FDA to the DRV have been the result of recommendations made by several scientific and health organizations.³ In the past these have included but are not limited to the Institute of Medicine, National Cancer Institute, World Health Organization, American Heart Association and United States Department of Agricultural/Human Health Services (USDA/HHS). Second, by establishing DRV and % DRV value for added sugar without establishing recommendations for total sugars the Nutritional Facts label will mislead consumers. While the NPA recognizes the FDA is without the current means to support establishing a DRV for sugar consumption we believe, by singling out added sugars, it is implied that added sugars are somehow metabolically different than naturally occurring sugars in dietary ingredients and food additives. This is not the case. Furthermore, by including the added sugars to the Nutritional Facts label, consumers may base purchases solely on added sugars content while disregarding total sugars. Products containing no additional added sugar may still have exceptionally high levels of sugar and may not necessarily be the “healthier” option. The misconception among consumers has the potential to cause the added sugars label addition to completely miss the FDA’s original goals of the declaration of added sugars. The NPA agrees that moderate sugar consumption should be encouraged to promote healthier eating behaviors; however isolating added sugar from total sugars will lead to increased consumer confusion. The NPA would encourage the FDA to further explore consumer understanding regarding DRV, added sugars, and total sugars.

Labeling of Added Sugars⁴

The FDA’s own consumers studies did not support the addition of added sugars to the Nutritional Facts label. The FDA reported in the Federal Registrar (80 FR 17928) *“Although the majority of the respondents correctly identified the total amount of sugars in a serving of food with each label presented that included an added sugars declaration, the added sugars experiment results show that a number of participants were confused about the distinction between sugars and added sugars, regardless of whether added sugars declarations appeared on the Nutrition Facts label.”* The data was published in the memorandum “Experimental Study on Consumer Responses to the Nutritional Facts Labels with Declaration of Amount of Added

³ Federal Registrar 58 FR 31502 January 6, 1993. “Food Labeling; Reference Daily Intakes and Daily Reference Values”

⁴ Federal Registrar 80 FR 17928. July 27, 2015. “Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions”

Sugar”.⁵ The NPA does not disagree that the majority (65%) of the respondents correctly reported the total sugars per serving using the proposed changes. However, we assert it is worth noting that the 65% is significantly less than the 81% of consumers who already are able to correctly report total sugars per serving using the current Nutritional Facts labeling. This indicates the proposed changes would result in increased consumer confusions regarding the amount of sugars that are consumed in a given product.

Support for this consumer confusion surrounding added sugars can be found in an additional study entitled *“Including Added Sugars on the Nutrition Facts Panel: How Consumers Perceived the Proposed Changes”* published in 2014 in the *Journal of the Academy of Nutrition and Dietetics*.⁶ In this study the authors examined consumer understanding of the three proposed Nutritional Facts labeling changes and further demonstrated consumer confusion surrounding added sugars. The study reported 92% of respondents were able to correctly report the total sugars using the current labeling, the percentage fell to only 66% correct reporting when the proposed Nutrition Facts label were used. This study additionally demonstrated the language of added sugar used in the proposed Nutritional Facts labels will have an effect on consumer purchasing behaviors. *“Most consumers perceive that products with an “Added Sugars” declaration have a higher sugars content than is actually present. This misperception affects purchasing behavior.”*

More recently, a larger consumer research study, backed by several food industry groups including the American Bakers Association, Corn Refiners Association, International Dairy Foods Association, National Confectioners Association, and the Sugar Association, involved a sample size of 1007 respondents per group, considerably larger than the one provided as evidence by FDA. Their large empirical dataset further demonstrated the confusion surrounding the language of added sugars⁷ and suggests the need for FDA to reconsider and punt their proposed recommendations to include added sugars in nutrition labeling. Their consumer research study sampled a total of 2,014 participants and was comprised of a range of

⁵ FDA Memorandum to File- “Experimental Study on Consumer Responses to the Nutritional Facts Labels with Declaration of Amount of Added Sugar” (OMB No. 0910-0764) 2015

⁶ Laquatra, I., Sollid, K., Edge, M. S., Pelzel, J., & Turner, J. (2015). Including “Added Sugars” on the Nutrition Facts panel: how consumers perceive the proposed change. *Journal of the Academy of Nutrition and Dietetics*.

⁷ “Nutrition Facts Label Daily Reference Value for Added Sugars Summary of Key Findings from Consumer Message Testing Research Survey”; American Bakers Association, Corn Refiners Association, International Dairy Foods Association, National Confectioners Association, and Sugar Association. October 13, 2015

demographics and included a group for “Food Assistance Consumers”. These consumers were defined as having received or having had an immediate family member receive benefits from food assistance programs within the last year. In all populations surveyed, roughly half of the participants inappropriately believed that added sugars had more calories than other sugars. More importantly, this study demonstrated consumers had more difficulty deciding on a healthier product when added sugars were introduced to the label stating, *“The pejorative image of added sugars is strong enough to impact consumer understanding and perceptions of identical food products.”* The NPA believes this compelling study is justification for the exclusion of added sugars from the Nutrition Facts label until a time where more in-depth research can be conducted on how the reasonable consumer understands and perceives added sugars.

The FDA additionally reported in the Federal Register published July 27, 2015 (80 FR 17928): *“When participants were viewing Nutrition Facts labels without added sugars declarations, they could not accurately determine the amount of added sugars in the products, with the majority reporting that the total sugars amount was the amount of added sugars. Moreover, many participants who viewed Nutrition Facts labels without added sugars declarations assumed that the more nutritious products in the study had less added sugars.”* The NPA would like the FDA to clarify the preceding statement. In documents submitted supporting the Federal Register (80 FR 17928), *“Experimental study of proposed changes to the Nutrition Facts label formats”*⁸ and *“Eye-tracking experimental study on consumer responses to modifications to the Nutrition Facts label outlined in the Food and Drug Administration’s proposed rulemaking”*⁹ it was stated on numerous occasions *“...respondents assigned to view the Current label were not asked to identify the grams of added sugars”*. The NPA would like transparency in how the FDA was able to arrive at the conclusion referenced in the Federal Register (80 FR 17928). The two statements appear contradictory as respondents in the study who viewed the Current label were not asked questions regarding the amount of added sugar.

⁸ FDA Memorandum to File- “Experimental Study of Proposed Changes to the Nutrition Facts Label Formats” (OMB No. 0910-0774) 2015

⁹ FDA Memorandum to File- “Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration’s Proposed Rulemaking” (OMB No. 0910-0774) 2015

Data Published in Eye-Tracking Experimental Study¹⁰

The NPA would additionally like to address several points regarding the data published in the *“Eye-tracking experimental study on consumer responses to modifications to the Nutrition Facts label outlined in the Food and Drug Administration’s proposed rulemaking”*. These points include: (1) participant sample size, (2) participant sampling locations, and (3) lack of meaningful analysis between the Current, Alternative and Proposed Nutritional Facts labels concerning the added sugar proposals. The memorandum stated the experimental study sample size was 160, but the cohort group sizes within the study actually ranged in size from 160 to 23 and generally fell between 30 to 50 participants. The NPA is concerned that this cohort and sample size is too small to perform meaningful statistical analysis to be considered competent and reliable scientific empirical evidence. The memorandum additionally stated the authors selected participants that represented a wide variety of demographics. This statement would appear misleading as the authors only selected participants from major center locales, primarily northern cities, and excluded the South and Midwest regions. Additionally, 69% of the participants sampled had a college or advanced degree. Sampling from higher-educated, urban populations creates a sampling bias that was not addressed by the authors of the study. Finally, the NPA would like to address the statistical analysis between the Current, Alternative, and Proposed Nutritional Facts labeling regarding carbohydrates and added sugars. When examining dwell time, measured as total duration of eye fixation, on the Area of Interest (AOI), how did the FDA make the distinction between the carbohydrates AOI and added sugars AOI on the Alternative and Proposed Nutritional Facts label? The NPA believes there is valuable information to be collected by comparing the fixations on sugars (carbohydrate AOI) on the Current label with the added sugars AOI on the Alternative and Proposed label. Using the raw eye-tracking data, the NPA independently analyzed the dwell time on the carbohydrate AOI on the Current Nutritional Facts label and compared that to the number of fixations on the added sugars AOI. The dwell time of eye fixation value on the added sugars AOI was significantly lower than the dwell time of eye fixation value of the carbohydrate AOI, $p < 0.000,1$ for both Alternative and Proposed labels. The NPA then combined the dwell times of the added sugars

¹⁰ FDA Memorandum to File- *“Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration’s Proposed Rulemaking”* (OMB No. 0910-0774) 2015

AOI and the carbohydrate AOI on the Alternative and Proposed label and compared those values to the dwell time of eye fixations on the carbohydrate AOI on the Current label. Even when the scores for the two AOIs were combined there was no statistical difference between the Current, Alternative, and Proposed formats. This additional analysis of FDA's own study results, received under the Freedom of Information Act, suggests that adding a declaration for added sugars did not serve to provide any added benefit to the participant by increasing their dwell time of eye fixation on the AOI.

Using the FDA's own empirical study data in addition to the much larger food industry consumer research study, it would suggest that mandating a label requirement to include added sugars in the declaration is not "material" and holds no added importance to a consumer's decision to buy or use the product. FDA's evidence to require such a change should be demonstrated to be "material" before adding this change to the regulations. In accordance with *Central Hudson*,¹¹ FDA must assert a substantial interest to justify the regulation change, FDA, FDA must demonstrate that the regulation change directly advances their interest, and the regulation change should be no more extensive than is necessary to serve the interest asserted by FDA. The NPA does not see how the eye tracking empirical evidence, sponsored and conducted by FDA, and the food industry's consumer research study, which was not addressed by FDA, support a separate regulatory requirement for declaring added sugars in accordance with *Central Hudson*.

In the preceding comments the NPA addressed its concerns regarding proposed changes to the Nutritional and/or Supplement Facts labeling, specifically regarding the addition of added sugars and the establishment of a DRV for added sugars. The NPA would like the FDA to: (1) follow the current precedent and use recommendations from several scientific bodies when making changes to the DRVs, (2) develop a strategy to further explore consumer understanding of added sugars labeling prior to mandating a label change, (3) incorporate data from other consumer research studies available to them and (4) provide transparency in how the FDA arrived at its conclusions regarding its own added sugar study, presented in the *Federal Register* (80 FR 17928). We would like to thank the FDA for the opportunity to comment on

¹¹ *Central Hudson* is the general test for commercial speech restrictions set forth in *Central Hudson*, 447 U.S. at 566.

this significant issue and welcome the opportunity to help contribute to this important regulatory public rule making process.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan Fab". The signature is fluid and cursive, with the first name "Dan" and the last name "Fab" clearly distinguishable.

Daniel Fabricant, Ph.D.

CEO and Executive Director

Natural Products Association