



October 13, 2015

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

Re: Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule; Docket No. FDA-2012-N-1210

Dear Sir or Madam,

In the Federal Register of March 3, 2014 (79 FR 11879), the Food and Drug Administration (FDA or the agency) published a proposed rule entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (proposed rule). The proposed rule would amend FDA labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the Nutrition Facts Panel. In the Federal Register of July 27, 2015 (80 FR 44303), FDA published a supplemental proposed (supplemental proposed) rule that would revise certain provisions of the proposed rule, issued in March 2014.

In the preamble to the proposed rule, the agency agreed to perform additional research during the rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label. FDA also stated that they would publish the results of the research for public review and comment. FMI appreciates the agency’s commitment to provide the public an opportunity to comment on the additional research and proposed changes prior to publication of final rules. FMI believes that if FDA considers the comments below, it will meet the goal of providing useful, clear information to consumers to maintain overall healthy dietary practices.

The Food Marketing Institute (FMI) proudly advocates on behalf of the food retail industry. FMI’s U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost \$770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains



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and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

Background

FMI members are supportive of labeling initiatives to inform consumers about nutrients of interest in foods. While the cost is significant, FMI supported the overall approach FDA took in crafting the original proposed revisions to the nutrition labeling rules and commends the agency for recognizing the need for updated nutrition information to aid consumers in making healthier choices. FMI submitted comments on the proposed rule, and while the agency has limited input on comments to the supplemental proposed rule, we urge FDA to revisit FMI's comments, particularly the need for adequate time for companies to implement label changes following publication of a final rule.

The Proposed Added Sugars Declaration Could Lead to Customer Confusion

FMI members support labeling and educational approaches which aim to provide consumers with essential information, provided those approaches ensure that consumers will correctly interpret the relationship between added and total sugars in the context of their daily caloric needs. However, FMI questions whether consumers will correctly interpret the proposed added sugars declaration in the context of an overall, balanced diet. For example, certain products with a higher percentage of added sugar could be perceived as less healthy when viewed alone, instead of how nutrients were intended, as part of a diverse and complete diet. Additionally, consumers may be more likely to view the percent added sugars declaration without assessing the overall nutrition profile of a particular product. FDA acknowledges that survey subjects often identified more nutritious food as less healthy when they contained greater amounts of added sugars than less nutritious foods. In contrast, when the more nutritious product had more added sugars, the percentage of respondents identifying that product as healthier decreased.¹

¹ "The effect of the added sugars declarations on product judgments varied depending on the food category and the level of added sugars in the product. When declared, higher amounts of added sugars tended to produce more negative judgments about the product's healthfulness. 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 label."



FMI Supports “Total Sugars”

In the event FDA moves forward with the added sugars declaration, FMI supports using the term “Total Sugars” opposed to “Sugars” on the label. We believe this term will help consumers understand the relationship between total and added sugars in a food more clearly.

FDA Should Clarify the Definition of “Added Sugars”

Under the proposed rule, FDA defined the term added sugar as sugars that are “either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners. If FDA moves forward with the proposed requirement to declare added sugar, FMI requests clarification on the definition of “added sugars.” Specifically, we would like clarification on when a juice concentrate would be considered an added sugar. We believe that a juice that is concentrated by crushing the fruit and removing the water, without removing the nutrients in the juice, should not be considered an added sugar. We also question how certain ingredients that are natural sweeteners could be considered added sugars. For example, the sugars in honey are intrinsic to that ingredient; not added. Ingredients that naturally contain sugars should not be treated as added sugars for the purpose of nutrient declaration. Should the agency determine that some or all juice concentrates must be declared as added sugars, we request guidance on how to determine the amount of added sugars in the finished food where the amount of the concentrate used varies, depending on the Brix level of the concentrate. The definition of added sugar is too broad and includes ingredients that should be categorized as minimally refined sweeteners (honey, fruit juice concentrate, molasses) as an alternative to highly refined sugar and corn syrups. Calling out added sugar eliminates the incentive to use and find innovative sources of sweet ingredients for consumers. Consequently, a product that sweetens with fruit juice would be disadvantaged on a label compared to one sweetened exclusively with HFCS.

FMI Does Not Believe That Recordkeeping for Added Sugars Should be Required under a Final Rule

In the proposed rule, FDA recognizes that “there are currently no analytical methods to distinguish between added and naturally occurring sugars.” There are also no analytical methods that can determine the amount of added sugar in specific foods containing added sugars alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation.” FDA is therefore proposing the maintenance of records to support declarations of these nutrients.



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FMI does not believe that recordkeeping for certain nutrients, including added sugars, should be required under a final rule. Supermarkets source ingredients from a vast range of suppliers, creating greater logistical challenges in calculating nutrition information for the products in which they are utilized. We are also concerned that the information subject to recordkeeping requirements will not be readily available from suppliers. As FDA makes clear, there are currently no analytical methods to distinguish certain ingredients in a product and FMI questions whether, in practice, this information would be readily available from suppliers. Requiring suppliers to provide proprietary records documenting added sugars raises serious logistical challenges and privacy concerns.

Currently the amounts of added sugars from supplier formulations are not readily available and FMI questions how the change in emphasis on certain nutrients may impact proposed recordkeeping requirements. Additionally, FDA's recordkeeping requirements for documenting the amount of added sugars are not sufficiently clear and the lack of specificity in the proposal would make it difficult if not impossible, for companies to determine if they are in compliance. Further, FMI strongly believes that any recordkeeping requirements and the corresponding oversight and enforcement should not be required for retailers, but should be the sole responsibility of the supplier

The Final Rule Should Not Disrupt Voluntary Front-of-Pack Initiatives

If the agency decides to move forward with the added sugar declaration, FMI urges the agency to minimize the disruption on voluntary front-of-pack labeling initiatives. The supermarket industry is committed to providing consumers with nutrition information and has been held up as a model for other segments of the food industry to follow. Retailers have created a marketplace for nutrition information in response to consumer demand and continue to strive for innovative new ways to provide nutritional information. These innovations are benefiting consumers by making it easier for them to identify nutritious foods. In light of these innovations, FMI requests that the agency ensure that any changes made to the nutrition labeling requirements will not disrupt the ability of food companies to continue to use voluntary front-of-pack labeling initiatives, such as the Facts Up Front program designed to help consumers make more informed choices when grocery shopping. FMI member companies along with the Grocery Manufacturers Association voluntarily adopted the Facts Up Front program to provide consumers with a simple and easy-to-use labeling system that displays key nutrition information on the front of food and beverage packages.

Further, FMI asks FDA to consider that changes to the NFP can result in changes to label material on every panel of the label and overall package, including front-of-pack icons and nutrient content claims. Companies will need time to not only ensure the revised NFP complies with the new requirements, but also to confirm that other claims and label material remains accurate in light of the changes. We recognize that the supplemental proposed rule did not address front-of-pack labeling, nor did FDA propose any changes that would frustrate the ability



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of firms to continue with such labeling practices. FMI simply asks the agency to keep these voluntary programs in mind as it finalizes the rules. Any required changes to voluntary front of pack programs would hamper the dissemination of vital nutrition information to consumers and impose unnecessary regulatory costs and burdens on participating companies.

Thank you for consideration of these comments. If you have any questions or would like additional information, please feel free to contact Stephanie Barnes at sbarnes@fmi.org or 202-220-0614.

Sincerely,

Stephanie K. Barnes

Regulatory Counsel