



THE VOICE OF FOOD RETAIL

Feeding Families  Enriching Lives

August 1, 2014

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; Proposed Rule; Docket No. FDA-2012-N-1210

Dear Sir or Madam,

On March 3, 2014, the Food and Drug Administration (FDA or the agency) published in the Federal Register two proposed rules on food labeling entitled: Revision of the Nutrition and Supplemental Facts Labels¹ and Serving Sizes of Foods that Can Reasonably be Consumed in One Occasion.² The proposed rules would amend the nutrition labeling requirements for conventional foods and dietary supplements, and update the regulations on serving size.

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

FMI appreciates the opportunity to submit comments to FDA regarding the agency's proposed rule on Revision of the Nutrition and Supplement Facts Labels.

¹ 79 Fed. Reg. 11880 (Mar. 3, 2014).

² 79 Fed. Reg. 11990 (Mar. 3, 2014).

Introduction

Health and nutrition is of the utmost importance to retailers and for years, FMI and its members have recognized the need to help consumers navigate the abundance of health, wellness and nutritional offerings within today's supermarket. 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. For example, retailers are providing wellness-focused programs that help customers improve their diets and overall health. These programs range from carrying more health and wellness specific products to educational programs, dietitian tips and cooking classes. It is important to note that 85% of the supermarket industry has a corporate dietitian on staff and 2/3 of shoppers agree that their food choices are an important factor affecting their health.³

While the cost is significant, FMI supports the overall approach FDA has taken in crafting the 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. We agree with the agency that a measured approach based on updated consumption data and scientifically-based dietary recommendations, as well as rigorous consumer studies, will be most effective in crafting regulations that determine how best to communicate nutrition information to consumers via the food label. FMI believes that if FDA considers the comments below, it will meet the goal of providing information to consumers to maintain healthy dietary practices without imposing substantial and unnecessary costs.

FMI believes FDA should extend the compliance date to 3-5 years following publication of a final rule

FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. FMI's associate members include the supplier partners of its retail and wholesale members, including private label manufacturers. Many retailers operate private label brands that are positioned as lower cost alternatives to regional, national or international brands. Private brands account for an average of 14.5 percent of retail sales and this figure is projected to grow as high as 20 percent.⁴

³ FMI Report, Shopping for Health 2013

⁴ The Food Retailing Industry Speaks 2009

FMI does not believe that the proposed compliance date of two years following the effective date of the final rules will give companies sufficient time to complete the label revision process given the sheer number of changes that will need to be made. The typical retailer carries approximately 40,000 different stock keeping units (SKUs). Every packaged food label that bears a Nutrition Facts Panel (NFP) will need to be revised in a short time frame adding excessive and avoidable costs for retailers. These higher costs are likely to be passed down the supply chain to consumers in the form of higher prices at retail.

In the proposed rule, FDA states that a two year compliance timeframe would allow manufacturers to coordinate approximately 65 percent of their label changes so they do not have to discard too much of their inventories. FMI believes that the two year compliance time will not give retailers adequate time to use up existing packaging stock and finished product inventory. The private brand industry is unique and strives to provide consumers with quality products at a significant savings. Unlike national brands, private brand manufacturers do not invest considerable resources on advertising and label modifications, which gives them the ability to provide lower price products that consumers rely on. Infrequent label changes permit private brand manufacturers to purchase packaging in bulk to minimize costs. For example, a small to mid-size private brand manufacturer inventories around 35 million labels at any given time and will simply not have enough time to use up such large inventories of packaging in two years. To ensure labeling capacity for the entire food supply-chain, reduce significant waste and minimize disruption, FMI believes that FDA should extend the two year compliance time to a minimum of three years for label revisions and up to five years for those companies who initiated the process within the initial three years. Consumers rely on private label alternatives as a viable money-saving option and FMI believes a compressed compliance time frame will result in higher prices and significant waste of current packaging inventories, which is in conflict with a number of government, and food industry initiatives to reduce food waste.

FMI believes that FDA largely underestimated the cost of the proposed rule on retailers and private brand manufacturers. The effort to complete label revisions under the proposed rule will directly affect multiple departments within a company including: Quality Assurance, Regulatory Affairs, Creative Services, and Packaging Coordination teams. It will also increase the workload for Brand Strategy and Category Management teams. According to our estimates a single company corporate brand with approximately 16,000 labels would incur over \$41 million dollars in compliance costs alone. This includes \$32 million in art and prepress costs and \$9 million dollars in increased labor to comply with the proposed rule.

The proposed rule will require the re-labeling of nearly every product in the marketplace and FMI believes that the packaging and labeling industry will simply not have the capacity to handle the label revisions for all packaged food companies in such a compressed time frame. In addition to the total financial costs involved in label revisions, FMI believes that the added labor required for reformatting information and analyzing new nutritional parameters will make it impossible for our members to comply within a two-year timeframe. Currently an internal review of existing labels for a single company corporate brand with 16,000 SKUs will take a minimum of five years. Even if our members were to stop all other internal initiatives or ongoing projects to complete the proposed revisions the estimated compliance time is 4 ½ to 5 years, FMI believes this is an entirely unrealistic assumption. In addition to staffing challenges, some level of design work will be required for all updated labels, including full printing plate changes. Additionally, FDA's proposed revision on dual labeling panels will require significant amounts of design work, including reorienting side panels, additional design, prepress, and plate charges, all of which are in conjunction with the new analytical testing that will be required. FMI notes that these projected efforts do not include the additional necessary training across the Regulatory, Creative Services, and Packaging Coordinator teams, which will be essential to ensure compliance.

In order to complete the revisions within two years our members will be required to enlist help of outside labs and labeling firms, which will significantly overburden the packaging and printing industry. FMI has serious concerns as to whether graphic design and print companies will be able to handle the influx of demand for updated labels and packaging. In addition to the vendor community and outside laboratories, prepress houses and printers will certainly feel the effects of the changes and FMI anticipates increased print lead times as the effective date for the requirements moves closer. FMI estimates that third party label review costs for very simple labels, without claims will range from \$200-\$300 per label and the limited supply and increase in demand for label review and print services will likely lead to even higher prices following a final rule.

Aside from the challenges of revising labels and packaging, some companies will be reformulating products based on the finalized changes to the nutrition labeling rules. Reformulation may be prompted by the desire to maintain eligibility for nutrient content or health claims, or to keep declared nutrition values the same, in light of the anticipated changes to the percent daily values, changes to the reference amounts customarily consumed (RACCs), and other proposed requirements that contemplate label revisions. For example, a company that currently makes a "good source of fiber" claim may need to reformulate foods to continue to qualify for that claim, based on the proposed revisions to the definition of dietary fiber as well as the proposed higher daily reference value (DRV) for fiber. FDA recognized in the proposed rule the desirability of such reformulations. For example, in proposing to require an added sugars declaration, FDA notes that such a requirement "may also prompt product reformulation of foods high in

added sugars like what was seen when trans fat labeling was mandated.” In order to encourage companies to reformulate products to increase the vitamin or mineral content, reduce the serving size, or make other changes, the agency should provide sufficient time to make such changes. To reformulate a single product, a company must identify alternative ingredients and/or quantities for each ingredient that will effectuate the desired changes to the finished product. The new formulation must be tested both from a manufacturing standpoint, as well as with consumers to ensure it meets expectations. This is a painstaking process that requires research and time. The time for reformulation is typically 9-12 months and in some cases can take much longer.

FMI believes significant product reformulations by national brand products will significantly impair a private brand manufacturer from completing the proposed revisions within two years. Consumers draw parallels to national brands when purchasing private brand products and in order to maintain competitive, private brands must reformulate to emulate the national brand equivalent. The analysis and testing alone following a national brand reformulation is extremely time consuming. Many of FMI's private brand members take at least nine months and up to 12 months following a national brand reformulation to complete packaging design and prepress printing. FDA should provide sufficient time for compliance under the proposed revisions and recognize the drastic impact this will have on the private brand industry.

As explained in the comments above, FMI requests that FDA provide compliance time to a minimum of three years for label revisions and up to five years for those companies who initiated the process within the initial three years. While some of our members expect to be able to complete the process of revising their labels within three years, others have reported that even if they start to implement the required changes immediately following publication of the final rule, they will need five years to roll out the changes across all products. Rather than establishing an insufficient period for implementation, resulting in individual requests to the agency for enforcement discretion, we ask that FDA provide a flexible timeframe at the outset. By allowing for a compliance period of at least three years, and ideally five years, the agency will facilitate an orderly, efficient, and timely changeover to new labels that reflect the planned final rules.

In the event FDA issues other food labeling regulations that have a compliance date within the same calendar year as the compliance date for the nutrition labeling and serving size/RACC requirements, FMI asks that the agency provide a uniform compliance date for all of the food labeling regulations. The agency has taken this approach in the past and has found that it minimizes the economic impact of label changes.

Voluntary Front-of-Pack Labeling Initiatives

In developing the final rule, 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. FMI and GMA members represent approximately 80 percent of retail food and beverage products and have pledged \$50 million to encourage consumers to use the icon in planning a healthy and balanced diet for themselves and their families.⁵ By calling consumer attention to the number of calories and other nutrients in a food, and providing a balanced picture of the nutritional profile of the food (i.e., calories, saturated fat, sodium, and sugars), the program is compatible with the goals of the proposed rule.

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 proposed rule did not address front-of-pack labeling, nor did FDA propose any changes that would frustrate the ability 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.

FMI opposes FDA's alternative format for the revised nutrition facts panel

FMI supports the measured approach proposed by FDA in revising the NFP format. In particular, we believe that giving increased prominence to calories and serving size information is a reasonable way to implement the recommendations of the Obesity Working Group's Calories Count report and is consistent with other consumer research and data. We oppose a more prescriptive approach, such as the alternative visual format that would include separate sections for "Quick Facts," and nutrients for which consumers should "Avoid Too Much," or "Get Enough." This marked departure from both the current NFP, and the proposed updated NFP, is significant and it is unclear how consumers will understand or use information presented in this way. We are not

⁵ <http://esadmin.factsupfront.org/FileUploads/Files/7957fed8-e1c2-4949-b3e4-1896bc9c7c85.pdf>

aware of any evidence that consumers would prefer or understand such a format, and therefore request that FDA reject such an approach.

FDA should clarify the term added sugar

Under the Proposed Rule FDA defines 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.”⁶ 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.

FDA has indicated that additional studies are currently underway regarding consumer perception of the added sugars line and the proposed footnote to enhance FDA’s understanding of how consumers would comprehend and use the new information. FMI believes the agency should publish the results of the study when they become available and make them available for public comment.

In the proposed rule, FDA recognizes that “there are currently no analytical methods to distinguish between dietary fiber (soluble and insoluble fiber) and non-digestible carbohydrates that do not meet the definition of dietary fiber; added and naturally occurring sugars; various forms of vitamin E; or folate and folic acid and there are 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.”⁷ FDA is therefore proposing the maintenance of records to support declarations of these nutrients.

⁶ Id.

FMI Comments on Proposed NFP Rule
79 Fed. Reg. 11880
August 1, 2014
FDA-2012-N-1210

FMI does not believe that recordkeeping for certain nutrients 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. The change in emphasis of these nutrients may cause some FMI members to collect information from their own suppliers on amounts of nutrients such as potassium, and vitamin D. This may also cause additional work for any company that is using a database to track ingredients and formulations as additional work may be needed in order to bring the database into compliance with the newer nutrient demands.

In the event, FDA moves forward with the proposed recordkeeping for certain nutrients, FMI seeks greater clarity on the types of records FDA is proposing to require. Under the proposed rule, 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.

FMI appreciates the opportunity to provide comments to FDA regarding the proposed revisions to the nutrition labeling requirements. We applaud FDA for a reasoned, science-based approach to the proposed rules on the updated nutrition and supplement facts panel, but recommend constructive changes to improve the effectiveness of the proposed rules. FMI believes that a 3-year to 5-year compliance deadline will greatly increase private brand manufacturers' and retailers' ability to properly implement the label and package changes at reduced costs to food retailers and manufacturers. In addition, clarifying the term and simplifying recordkeeping associated with "Added Sugars" and other nutrients will reduce consumer confusion and retailers' administrative burden with FDA's proposed changes to the nutrition and supplement facts panel.

FMI Comments on Proposed NFP Rule
79 Fed. Reg. 11880
August 1, 2014
FDA-2012-N-1210

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

Sincerely,

Stephanie Barnes
Regulatory Counsel

FMI Comments on Proposed NFP Rule
79 Fed. Reg. 11880
August 1, 2014
FDA-2012-N-1210