



0204 9 APR 21 P3:01

MEMORANDUM

TO: Division of Dockets Management, HFA-305
Room 1061
5630 Fishers Lane
Rockville, MD
ATTENTION: Lyle Jaffe

DATE: April 21, 2009

SUBJECT: Docket No. FDA-2007-N-0198 (formerly Docket No. 2007N-0277)
Food Labeling: Use of Symbols to Communicate Nutrition Information,
Consideration of Consumer Studies and Nutritional Criteria; Public Hearing

Lyle,

Enclosed is a document containing comments on the subject line public hearing . Please include in the above-referenced docket.

Please contact me if you have any questions.

Thanks,

Vincent de Jesus
Office of Nutrition, Labeling, and Dietary Supplements
Nutrition Programs and Labeling Staff, HFS-830
phone: 301-436-1774
email: vincent.dejesus@fda.hhs.gov

FDA-2007-N-0198

C

**FDA Comments on Symbols Public Hearing and Current Plans for Addressing Issues
[Docket No. FDA-2007-N-0198]**

0203 9 APR 21 P3:01

I. Public Hearing

The agency issued a notice of public hearing entitled *Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria* in the *Federal Register* of July 20, 2007 (72 FR 39815) (the public hearing notice), and the hearing was held on September 10-11, 2007. The purpose of the hearing was for FDA to solicit information and comments from interested persons and organizations regarding the use of symbols to communicate nutrition information on food labels. The public hearing notice outlined three main issues and posed questions for each of these issues. The first issue (discussed below under the heading “Nutrition Issues”) was concerned with the types of foods that bear nutrition symbols and the nutrient requirements for those symbols. The second issue (discussed below under the heading “Consumer Issues”) was concerned with consumer understanding and use of nutrition symbols. The third issue (discussed below under the heading “Economic Issues”) was concerned with the economic impacts of nutrition symbols on food labels. The following discussion describes the questions FDA posed and the comments we received and also includes remarks from FDA. The comments discussed below include the comments provided at the public hearing as well as the comments submitted to the docket (Docket No. FDA-2007-N-0198, formerly Docket No. 2007N-0277) for the hearing.

A. Nutrition Issues

In the public hearing notice, FDA asked for input on the following questions:

In what product categories are nutrition symbols used (e.g., packaged foods, fresh produce, meat/poultry, seafood)? Which symbols are nutrient specific, and which are summary symbols based on multiple nutrients? What are the nutritional criteria, including calories, included in a symbol system and how were those particular nutritional criteria chosen for inclusion? What nutrient thresholds and/or algorithms are used to determine if a food product can display a nutrient specific or summary symbol? Are nutrition symbols presented together with front label nutrition claims, such as “low fat” or “good source of calcium” and, if so, to what extent and for what types of claims? Are there programs to educate consumers to understand the symbols or is all information contained in the symbols? When education programs are available, how are they presented?

Comments Received

The comments indicated that there are two major categories of symbols, “summary” and “nutrient-specific” symbols. Use of these symbols is not restricted to a few categories of foods; rather, the symbols are used in a broad range of food categories. Summary symbols use logos, numerical scores, or graphic schemes to communicate the overall nutritional quality of a food product to consumers and facilitate comparisons between products on the basis of overall nutritional quality. Comments stated that nutrient-specific symbols provide quantitative, evaluative, or both kinds of information on selected nutrients in a product without comparing the product’s overall nutritional quality to that of its counterparts. The nutrient-specific symbol

systems highlight the content of specific nutrients in the context of a graphical presentation. The nutrients highlighted are typically calories, total fat, sodium, and sugar; many nutrient-specific symbol systems also include one or two other nutrients that are associated with a particular food product or food group (e.g., a calcium symbol for dairy products or calcium-fortified orange juice). Comments further stated that the summary symbols have requirements that are based on limiting nutrients of concern and encouraging nutrients that are considered beneficial. The specific formulas or criteria for eligibility are specific to each program and are mostly proprietary. However, the comments indicated that these formulas and criteria are based on established dietary recommendations. Comments noted that the placement of a nutrition symbol on a food product is intended to suggest that based on its nutrient content, a particular food product is healthier than comparable food products that do not bear the symbol. According to the comments, the use of a nutrition symbol does not preclude use of other permitted nutrition claims on the food label and, in certain cases, FDA-authorized nutrient content claims and health claims provide the basis for eligibility to bear a symbol. Comments described current consumer education efforts as consisting of advertising, web sites, printed material at point-of-sale, and information on the back panels of food labels.

Agency Remarks

The information FDA received about the nutritional basis of nutrition symbol programs will aid the agency in its ongoing consideration of the issue. It is clear from the comments that the nutrition symbols used on food labels are very broad and diverse in their messages, presentation, and nutritional basis. It appears that some programs want to provide information to consumers in an easily noticed and understood manner, but leave it up to consumers to determine if the food product fits into their diet. Other programs appear to make that determination for consumers with messages that a food product is “good for you,” “better for you,” or something similar. The number and type of nutrients that are included in the nutrition symbol systems differ greatly, and the nutrients that are highlighted in a particular system, as well as the nutritional criteria for bearing the symbols, are chosen by the entity that develops the system. Typically, the nutritional criteria are based on dietary recommendations (such as the Dietary Guidelines for Americans) or federal regulations (such as FDA’s nutrient content claim regulations). Because of the diverse nature of the nutritional claims and criteria in the numerous nutrition symbol systems, the ability of consumers to use these symbols to make nutritional comparisons between products or to determine how a food fits into a diet is uncertain. FDA received little information regarding consumer studies intended to assess consumers’ understanding of these various symbols. In contrast to the diverse systems for nutrition symbols, with FDA-authorized nutrient content claims on food labels, the intent is to have a consistent point of reference and framework for the claim. For both foods that bear nutrition symbols and foods that bear FDA-authorized nutrient content claims, consumers also have nutrition information available at the point of purchase in the form of the mandatory Nutrition Facts label. This information allows consumers to use nutrition labeling to compare food products and to fit the food choice into the context of the total daily diet.

B. Consumer Issues

In the public hearing notice, FDA asked for input on the following questions:

What are consumer attitudes toward nutrition symbols? What are consumer attitudes toward products or brands that carry a nutrition symbol compared to other products or brands in the same product category (e.g., cereals) and in other categories that do not carry a symbol? What are consumer interpretations of symbol-carrying products or brands in terms of their overall healthfulness, specific health benefits, featured nutrition attributes, non-featured nutrition attributes, quality, safety, and any other non-nutrition attributes? What is consumer perception of the presence of multiple and different symbols on front labels of different brands in a given product category, e.g., cereals? What is consumer interpretation of the co-existence on the food label of symbols and/or other nutrition messages, when present, and quantitative nutrition information (e.g., the Nutrition Facts label that appears on food in the United States)? What is consumer interpretation of the co-existence of front-label nutrition symbols and nutrition symbols present on the tags of supermarket shelves, when available? When do consumers use symbols and what do they use them for? Do nutrition symbols on food labels direct consumers toward purchase of foods that bear them and, if so, to what extent? Do symbols affect the nutritional quality of the total diet of consumers who use the symbols and, if so, to what extent?

Comments Received

The comments indicated that consumers find nutrition symbols helpful in purchase decisions and also that consumers are willing to accept both nutrient-specific and summary symbols. Some comments stated that consumer awareness of nutrition symbols is likely to be modest when they first appear on food packages. Promotional and educational campaigns, however, can widen and enhance consumer awareness. Some comments stressed the importance of visual designs, such as colors and words, in helping consumers identify nutrient amounts or healthier products. Other comments indicated that simplicity and credibility are important considerations in using symbols to communicate with consumers about nutrition information. Comments also suggested that, despite the presence of a nutrition symbol on a product, some consumers would still use other nutrition information on the package before making a final purchase decision. Comments stated that consumers use symbols to select products, as well as to identify specific nutrient information. Many consumers interpret summary symbols as a signal of healthier product options. As for possible influences of nutrition symbols on product choices, some comments observed increases in sales of products carrying symbols relative to sales of products carrying no symbols. Meanwhile, other comments cited research suggesting that nutrition symbols have only a limited influence on the frequency and quantity of consumption of products carrying such symbols. Comments also provided some information suggesting an association between the presence of nutrition symbols on food products, or purchase of symbol-carrying products, and higher intakes of certain nutrients or products. Yet other comments raised the possibility that nutrition symbols may have an insignificant role in actual purchase decisions.

Agency Remarks

Though the public hearing generated some information on consumer issues related to nutrition symbols, the public hearing produced little usable research or other information on the majority of consumer issues listed in the public hearing notice. Many of the questions asked in the public hearing notice remain unanswered (e.g., consumer interpretations of symbol-carrying products or brands, consumer perception of the presence of multiple and different symbols on different products in a food category, and consumer interpretations of multiple symbols or nutrition messages on a single product). In addition, it was difficult for FDA to evaluate the usefulness of

some comments, especially regarding the influences of nutrition symbols on product sales. These comments often provided summary information without discussing details on the source of the information or on data collection and analysis methodologies. Without such background information, the agency is not able to ascertain how the summary information was developed or to assess the strengths and limitations of the comments.

FDA is developing a plan to gather consumer information on preference, understanding, and use of nutrition symbols using qualitative and quantitative research techniques. The agency already has commissioned a focus group study and is currently analyzing qualitative information collected from the study to explore varieties and ranges of consumers' understanding of and reactions to a selected sample of existing and alternative nutrition symbols. The information obtained from the focus group study will further our understanding of the role that nutrition symbols play in consumers' dietary decisions and how symbols interact with other nutrition information on food packages. The agency plans to build on the focus group study and commission a series of quantitative and qualitative consumer research studies.

C. Economic Issues

In the public hearing notice, FDA asked for input on the following questions:

To what extent, if any, have products been developed or re-formulated to qualify them for a given symbol? What are the costs associated with product development, re-formulation, or both? What are the costs associated with putting symbols on packages? What, if any, are the price differences between symbol-carrying products and other products within the same category? Has inclusion of symbols on the labels of food products affected the sales of those products?

Comments Received

Little information on the economic impacts of nutrition symbols in food labeling was provided by presenters at the hearing or in the comments submitted to the docket. The comments that were provided were primarily from food manufacturers with front-label nutrition symbol programs. These comments gave contrasting views of the economic impact of such programs on manufacturers. Some comments indicated that costs for implementing a front-label nutrition symbol program were no different than costs associated with typical product formulation and marketing. These comments suggest that costs associated with product reformulation or development of products bearing a symbol are just part of standard development costs for manufacturers and that any labeling changes associated with a front-label nutrition symbol are included in typical labeling costs. Education and advertisement costs specific to front-label symbols are included in usual marketing costs. As a result, these comments indicate that total costs for product formulation and marketing do not result in increased product costs for companies. Comments from other manufacturers, however, reported increased costs and broke out the costs related to the implementation of a nutrition symbol program. For these companies, additional costs were seen with the purchasing of new types of ingredients for the formulation of these foods, new staff for program implementation, costs associated with label changes, and additional costs for program education and outreach. Many commenters remarked that product lines that bore nutrition symbols are growing at a much faster rate than other product lines and account for an increasing share of product sales. One comment noted that products bearing a symbol did not differ in price from comparable products without the symbol.

Agency Remarks

From the few comments related to economic impact that we received, it appears that the cost of implementing a nutrition symbol program is dependent on the specific manufacturer.

Manufacturers that continually develop and reformulate their products and those that refresh their product labels often may not notice any increase in costs associated with the program compared to the typical costs of product development, as long as they can control the timing of the label change. Manufacturers that develop fewer new products and reformulate and relabel existing products less often may, however, notice new costs associated with the implementation of a nutrition symbol program. The comments do not indicate that consumers have higher or lower costs for choosing products labeled with a nutrition symbol. Although increased sales were reported in the comments, sales data were not provided for products bearing a nutrition symbol, and it is difficult to determine whether consumers are actually buying more of these products. Access to sales data would certainly be important to demonstrate that nutrition symbols on food labels lead to increased product sales.

II. Current Plans

The public hearing provided a constructive dialog between FDA, industry, consumers, and other stakeholders regarding the use of symbols to communicate nutrition information on food labels. However, the comments that FDA received did not respond to all of the questions posed by the agency in the *Federal Register* notice for the public hearing. While we do have a clearer understanding of the nutritional basis for many existing nutrition symbol programs and of the types of foods that bear nutrition symbols, there are many gaps in our understanding of consumer interpretation and use of such symbols. The agency already has taken actions to collect relevant information and data for the purpose of addressing these research gaps. The agency is also evaluating a citizen petition submitted by a consumer organization requesting that the agency explore the development of a uniform front-label symbol program to indicate the nutritional quality of foods (Docket No. FDA-2006-P-0455, formerly Docket No. 2006P-0498). FDA will continue to evaluate information provided at the public hearing, in comments submitted to the docket, in the citizen petition on front-label nutrition symbols, and in discussions with stakeholders. The agency's current plans for evaluating issues regarding the use of nutrition symbols in food labeling are:

1. Evaluating nutrition symbol systems individually in relation to applicable federal regulations and statutes. Use of certain nutrition symbols may fall under nutrient content claim or health claim regulations and, if so, would be evaluated for compliance with the particular regulations for those types of claims. In the absence of a specific regulatory framework that applies to a particular nutrition symbol or system, FDA intends to evaluate the symbol or system for compliance with all applicable labeling statutes.
2. Planning additional quantitative research into consumer use and understanding of nutrition symbols. As described in Section I.B., FDA already has conducted some initial qualitative research on the issue, and the findings will guide the development of our next phase of consumer research. In addition to the issues and questions posed for the hearing, the agency is interested in understanding whether consumer use of nutrition symbols is restricted to

comparisons of products within a certain category, or if consumers might also use such symbols to compare products across categories (e.g., milk vs. soda). The agency hopes to address as many of the questions as possible in the upcoming research.

In summary, FDA will continue to actively evaluate the issues regarding the use of nutrition symbols in food labeling. The agency is considering all nutrition labeling schemes in its effort to help consumers construct healthful diets consistent with the current Dietary Guidelines for Americans. The agency thanks all those who provided comments at the public hearing and who submitted comments to the docket.