

Division of Dockets Management (HFA-305)

Food and Drug Administration

2011 JUL 27 P 2:13

5630 Fishers Lane, rm. 1061

Rockville, MD 20852

Kellogg Company Comments

Re: Docket No. FDA-2011-N-0320

**Experimental Study on Consumer Responses to
Whole Grain Labeling Statements on Food Packages**

Dear Sir or Madam:

Introduction and Basis for Comment

Kellogg Company was founded by W.K. Kellogg in 1906 with a focus on health and nutrition, a commitment that continues today. We have a long history of developing and marketing great-tasting, nutritious products designed to help consumers choose products that provide nutritional relevance and a variety of choice to the diet. Kellogg Company has a long tradition of utilizing food labels to help educate consumers about the relationships between nutrition, diet and health. As a leader in the manufacture of grain-based food products, Kellogg Company is supportive of FDA's guidance and public policy pronouncements that will encourage and facilitate the manufacture and labeling of food products that can contribute to healthful dietary practices, as well as help educate consumers about how to make wise and healthy choices to achieve important dietary guidance goals, including disease risk reduction.

Kellogg Company (Kellogg) files these comments in response to the notice of opportunity for public comment on the Food and Drug Administration (FDA) proposed Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages, 76 Fed. Reg. 30725 (May 26, 2011).

FDA-2011-N-0320¹



Necessity and Practical Utility of FDA's Proposed Research

FDA specifically invites comments on “[w]hether the proposed collection of information is necessary for the proper performance of FDA’s function, including whether the information will have practical utility.”¹ Among the proper performance of FDA’s function and duties is enforcement of the Food, Drug and Cosmetic Act, which includes preventing misleading labeling statements on food packages. Kellogg filed comments in June, 2010, in FDA Docket No. 2006D-0066 (prior comments), regarding the Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements (Draft Guidance). In these prior comments, Kellogg shared with FDA its consumer research which shows there is significant confusion and misunderstanding by consumers regarding whole grain label statements on food packages.

The Kellogg research, described in and submitted with the prior comments², shows an overwhelmingly significant number of consumers are choosing products with whole grain label statements as a means to increase fiber in their diet. Nearly 75% of consumers indicated that seeing “made from whole grains” on a cereal, bread, or pasta product raises the expectation that the food will provide at least a good source of fiber, i.e., 10% Daily Value. Moreover, a significant percentage of consumers actually expect a 1 to 1 correspondence or more of whole grain grams to fiber grams when the label statement reports grams of whole grain.

Kellogg has also conducted an annual consumer insight survey, tracking consumer attitudes toward whole grain since 2008. This consumer survey, conducted annually online,³ shows consistent results. Two-thirds of consumers (67%) agree with the statement that whole grain foods are high in fiber.

¹ 76 Fed. Reg. at 30726

² See Appendix A for copy of prior comments

³ The annual online survey uses 1500 respondents, at least 18 years old, who do at least half of the grocery shopping and recently purchased from at least one of several identified food categories. Kellogg would be willing to provide this research data to FDA, if desired and at FDA’s request.

Half of consumers agree with the statement that whole grain and fiber provide the same health benefits. There has even been an increase since 2008 in the number of consumers who think there is no difference between fiber and whole grain.

As Kellogg reported in its prior comments, many of the products containing whole grain label statements in the marketplace do not provide even a good source of fiber. Kellogg conducted a food packaging audit using the Mintel Global New Products Database (Mintel database), which showed a myriad of products had whole grain label statements on front-of-pack, totaling approximately 3,000 individual products appearing on shelf since 2005. When Kellogg specifically considered food packaging for nationally-distributed ready-to-eat cereals (RTEC) and cereal/granola bars, entered into the Mintel database from January, 2005 through July, 2008, the audit showed that consumer misperception of and reliance upon whole grain claims worked to the detriment of those who were seeking to add fiber to their diet.

The 2005 to 2008 Mintel food packaging audit indicated that 72 RTEC with front package whole grain claims, including “rich in whole grain” and “whole grain guaranteed,” had fiber content that varied greatly, ranging from 0 to 11 grams per serving. Nearly half contained less than the minimum amount of fiber to be labeled as a good source of fiber. Of the 46 nationally-distributed cereal/granola bars with whole grain label statements, only a small number contained the minimum amount of fiber to be labeled a good source, and two-thirds of the products that did not provide a good source of fiber contained just 1 gram or less per serving.

The fact that consumers are being misled by whole grain labeling statements on food packages is particularly important in view of the fact that the 2010 Dietary Guidelines for Americans (2010 DGA) encourage whole grain consumption for the specific purpose of increasing fiber intake.⁴

⁴ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010 (2010 DGA Report).

In addition, the 2010 DGA Report explicitly recognizes that whole grains vary in their fiber content and that consumers should choose and consume whole grains that are higher in fiber⁵. The 2010 DGA recognize that intakes of fiber are low enough to be of critical public health concern, one of only four nutrients to pose a concern and be included as needing a significant increase in intake.⁶ Expected health benefits motivating the 2010 DGA recommendation to increase consumption of whole grains are largely derived from increased fiber intake.

However, unless whole grain label statements are limited to products that contain at least a good source of fiber [at least 10% of the Daily Value (DV)], specifically for those products with a mid- to large Reference Amount Customarily Consumed (RACC), such as ready-to-eat breakfast cereals, consumers will continue to be misled and will likely not achieve the increased fiber intake recommended by the 2010 DGA. The utility of FDA's research is that it will facilitate aligning regulation of food label statements with the important objectives of the 2010 DGA. As FDA stated in the May 26, 2011 Federal Register Notice announcing its proposed research: "The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets."⁷

Likely also contributing to consumer confusion are the numerous different types of whole grain statements that appear on food packaging. In a recent search of the Mintel GNPD database, conducted June 29, 2011, more than 70 different variations of statements were identified on new products launched in the previous six-month period, including:

- Made with whole grain
- Premium whole grain
- Whole grain guaranteed
- X grams whole grain
- X% whole grain
- X grams whole grain per serving

⁵ Id. at 36, 41, 66 and 75

⁶ Id. at 33 and in Executive Summary at xi

⁷ 76 Fed. Reg. at 30726

- X grams whole grains per slice
- Excellent source of whole grain
- X% of the recommended daily intake for whole grains
- Whole grain goodness
- Heart healthy whole grains
- The goodness of whole grain in every bite

It is not surprising that consumers are confused about whole grain in the face of these myriad claims. Among the purposes for the Nutrition Labeling and Education Act of 1990, and the requirement to regulate both implied and express nutrient content claims, the expected benefit for consumers is that they can rely upon a limited number of food labeling claims to have a specific meaning. FDA should likewise regulate whole grain label statements for the benefit of consumers' understanding and health.

In its Draft Guidance, FDA set forth examples of acceptable label statements related to whole grains:

- 100% whole grain
- X grams of whole grains
- ½ ounce of whole grains

However, FDA specifically disallowed statements that would imply a particular level of the ingredient, such as “high” or “excellent source.”⁸ Despite this admonition, such claims are being made in the marketplace for whole grains, whether expressly or implied. Use of defined terms for nutrient content claims simply exacerbates the problem by implying the ingredient, whole grain, is synonymous with a nutrient, fiber. When such terms are used, the whole grain claim should be viewed as an implied nutrient content claim for fiber and the product must meet the requirements for the fiber nutrient content claim.

Even if “source” claims are not allowed regarding whole grain content, Kellogg research shows that any label statement about whole grain carries an implication

⁸ U.S. Department of Health and Human Services, Food and Drug Administration. Draft Guidance: Whole Grain Label Statements, Guidance for Industry and FDA Staff, February 17, 2006, p. 2

regarding fiber content. Kellogg, therefore, encourages FDA to revise its Draft Guidance to provide clear guidance to industry as to the types of claims that may be made about whole grain, and also to limit whole grain claims to foods that provide at least a good source of fiber (10% DV) for foods with a mid to large size RACC, such as those associated with ready-to-eat cereals.

Considering the importance of the 2010 DGA to improving public health and their emphasis on consuming whole grains that are higher in fiber, FDA should take action to bring some order to the marketplace so consumers can make choices that align with the 2010 DGA. Throughout the 2010 DGA Report, consumption of whole grains is tied to their fiber benefit. As stated in the Executive Summary:

“Choose foods that provide more potassium, dietary fiber, calcium, and vitamin D, which are nutrients of concern in American diets. These foods include vegetables, fruits, whole grains, and milk and milk products.”⁹

Chapter 4 of the Report, which discusses Foods and Nutrients to Increase, states:

“Whole grains vary in their dietary fiber content. . . . Consuming enough whole grains helps meet nutrient needs. Choosing whole grains that are higher in dietary fiber has additional health benefits.”¹⁰

Further, recent research continues to show that cereal fiber plays an important role in the health benefits of whole grains.¹¹ At the 2011 annual meeting of the Federation of American Societies for Experimental Biology (FASEB), three systematic reviews of observational research presented at the meeting highlighted that cereal fiber intake was more protective than whole grain intake in areas of heart disease risk, type 2 diabetes risk, and weight management, which are benefits linked to whole grains in the 2010 DGA Report.

⁹ 2010 DGA Report, Executive Summary at xi

¹⁰ 2010 DGA Report at 36

¹¹ Lu Qi, Susan Cho, George Fahey, In Kim, and David Klurfeld. A comparison of the literature on the association between intakes of bran, cereal fiber, and whole grains and risk and biomarkers of heart disease, *FASEB J March 17, 2011 25:971.4*; George Fahey, Jr., Susan Cho, Lu Qi, In Kim, and David Klurfeld. A comparison of the literature on the association between intakes of bran, cereal fiber, and whole grains and risk of adiposity measures, *FASEB J March 17, 2011 25:776.8*; Susan Cho, Lu Qi, George Fahey, Jr., In Kim, and David Klurfeld. A comparison of the literature on the impact of bran, cereal fiber, and whole grain intakes and risk reduction of type 2 diabetes, *FASEB J March 17, 2011 25:776.9*. See Appendix B for copies of abstracts.

Validity of Methodology and Assumptions

The second topic about which FDA seeks comment is “the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.” Kellogg agrees with the proposed methodology for conducting the consumer perception research. The sample size seems appropriate; the anticipated time to complete the survey (i.e., 15 minutes) does not appear too burdensome for respondents; and it is assumed that a standard randomization method will be employed. Since the focus of FDA’s proposed research is on interpretation of whole grain label statements, Kellogg would recommend that, during the data analysis phase, the label statements should be treated as fixed effects, and the product categories and nutrition profiles should be treated as random effects.

Based upon its own research experience, Kellogg believes it is particularly important to minimize methodology bias and encourages FDA to identify and limit all potential sources of bias. One potential source of bias in label interpretation is the graphics utilized. In FDA’s Draft Study Protocol, dated March 2011, in the section titled Study Design, paragraph IV, it is clearly stated that “front panels will be full-color and patterned after existing labels in the market.” Kellogg assumes and supports that this means graphics will be held consistent between all labels presented to respondents, including graphic style, size and color.

FDA has also asked for comments on “ways to enhance the quality, utility, and clarity of the information to be collected.”¹² In the Draft Study Protocol, thirteen different whole grain statements were identified for inclusion in the research study. Kellogg agrees with the inclusion of both factual statements, such as “contains whole grain” or “made with whole grain” and non-factual, and somewhat meaningless, claims that are currently being made on food packages, such as “whole grain guarantee.” Kellogg is supportive of FDA’s plan to test numerous different types of whole grain label statements. Kellogg also supports testing these claims across an appropriate representation of product categories where the consumer may commonly see such claims such as cereal, mixed grain

¹² 76 Fed. Reg. at 30726

dishes, and grain-based snack items. It is important that FDA gets the most complete information possible about the potential confusion currently existing in the marketplace.

In the Draft Study Protocol, FDA indicates it will test two nutritional profiles – “one high in fiber amount; one low in fiber.” Kellogg urges FDA to present at least one product that provides a good source of fiber in the higher fiber nutritional profile.

Conclusion and Recommendations

Kellogg supports FDA’s proposed research to test consumer perception of whole grain label statements. Kellogg believes it is necessary and has practical utility to assist FDA in preventing consumers from being misled to their detriment. Moreover, FDA should ensure that food labeling claims will align with and facilitate implementation of the 2010 DGA recommendations. Kellogg agrees with the overall Draft Study Protocol, but encourages FDA to limit any potential for methodological bias.

Kellogg suggests that its own consumer perception research clearly shows that whole grain label statements are implied nutrient content claims for fiber. In its prior comments, Kellogg urged FDA to modify and finalize its Draft Guidance to recognize the fact that consumers clearly expect products with whole grain label statements to deliver at least a good source of fiber. Providing a good source of fiber is an achievable amount for many products, including most RTEC, and creates a stepwise approach to increasing fiber in the diet of Americans without requiring significant behavioral change. To the extent FDA’s proposed research replicates the Kellogg research results, FDA will then have the support and confidence it needs to identify a limited number of whole grain label statements that can be made on food packages and limit those statements to foods containing at least a good source of fiber (i.e., 10% DV) for foods with mid to large RACC serving sizes. Kellogg believes that such action by FDA is required in order to prevent consumers from being misled to their detriment. In addition, limiting whole grain claims to foods that provide at least a good source of fiber will facilitate implementation of, and alignment with, the 2010 DGA. During this time

of significant attention to the health of the U.S. population, coordination of efforts to make dietary goals achievable necessitates clear and consistent messaging regarding those components of food that can truly make a positive impact on nutrient intake. We commend the FDA for taking this important step toward assessing the current state of whole grain claims in the marketplace.

Respectfully submitted,



Lisa A. Sutherland, Ph.D.
Vice President
North America Nutrition



Nelson Almeida, Ph.D.
Vice President
Global Nutrition & Regulatory Science

Division of Docket Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

KELLOGG COMPANY COMMENTS

FDA Docket No. 2006D-0066;

Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements

CONTENTS OF COMMENTS

- A. Introduction and Basis for Comments**
 - B. Government and Industry are Partnering to Educate Consumers**
 - C. Whole Grain Recommendations are Related to Fiber Intake**
 - D. Consumer Perception Research is Important as a Basis for Regulating Claims**
 - E. Consumers Perceive Whole Grain Label Statements as Claims for Fiber Content**
 - F. Whole Grain Label Statements Mislead Consumers to Their Detriment**
 - G. Fiber Content of Products with Whole Grain Label Statements Vary**
 - H. Science Supports Fiber as a Marker for Health Outcomes and Basis for Whole Grain Health Claims**
 - I. Current State of Scientific Research Shows the Benefits of Whole Grains are Related to the Fiber Components**
 - J. Conclusion and Recommendations**
-

A. Introduction and Basis for Comments

By Federal Register Notice on February 17, 2006 (71 Fed. Reg. 8597), the Food and Drug Administration (FDA) announced the availability of a draft guidance document, as referenced above (hereafter referred to as "the draft guidance"). The draft guidance was intended to inform industry about what the agency considers to be "whole grain" and assist manufacturers in labeling their products. The Notice invited

Kellogg's®

545 W. Lamont Road
Elmhurst, IL 60126

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