

Why the Confusion between Health Claims and Whole Grains?

Mariam K. Kassem

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Dr. Neil Fortin

Michigan State University

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I. Introduction:

The Food and Drug Administration (FDA) has authorized eleven health claims.¹ Health claims shows a relationship between a nutrient or other substances in a food and its ability to reduce a disease or a health related condition.² There are two types of health claims: expressed and implied. The differences between these two health claims will not be discussed in this paper. Of these eleven health claims, two pertain to whole grains.³ These two were sanctioned in 1999 and 2003, respectively. The first claim refers to low-fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some cancers and the second claim refers to soluble fiber content and its connection to a diet low in saturated fat and cholesterol which may reduce the risk of coronary heart disease.⁴

In both health claims, the wording is fiber and not ‘whole grains’. A source of fiber may be from whole grains but whole grain is not the true nutrient that is stated in the health claim. Fiber is the food component that has the relationship to the health condition. Is this the main issue or one of the possibilities that have consumers being confused with label statements and health claims? In this paper, the author will explore reasons for the confusion with whole grains and their connection to misleading claims and food labeling.

II. Background:

FDA allows truthful and non-misleading statements for the use or presence of whole grain ingredients, for instance, “whole grain” or “multi-grain” if the grain contains all three layers of the grain: starchy endosperm, the bran, and the germ.⁵ To qualify for the health claim

¹ 21 C.F.R. §§ 101.72 – 101.82 (2006).

² 21 C.F.R. § 101.14 (a) (1) (2006).

³ 21 C.F.R. §§ 101.76 and 101.77 (2006).

⁴ *Speech, Whole Grains & Health, A Global Summit (May 20, 2005), available at <http://www.fda.gov/oc/speeches/2005/wholegrains0520.html>* (last visited Oct. 7, 2006).

⁵ *Id.*

the food product must contain at least 51% whole grain by total weight of the ingredients, contain at least 11% of fiber, and meet the other requirements within the health claim, such as, low in saturated fat and/or cholesterol.⁶ In order to help clarify what claims manufacturers can make, FDA published the “Guidance for Industry and FDA Staff: Whole Grain Label Statements” in draft form on February 17, 2006. The guide indicates what factual statements about the amount or percentages of whole grain the manufacturer can make.⁷ The draft cautions against using wording such as “good” or “excellent source” of whole grain or “high” in whole grain. The draft also counsels against the use of unqualified whole grain statements in food products that contains refined grain ingredients.⁸ Refined (processed) grain contains little or no fiber which is the nutrient that is connected to the health condition.

Using wording like “100% whole grain” should not be used for products that contain refined (processed) grains nor is the wording “whole grain” equivalent to “100% whole grain”.⁹ To have a truthful label, manufacturers must meet all the above requirements such as containing 51% whole grain and so on. For consumers to understand these subtleties, they must take Food Regulation courses, learn to identify and weed out false advertising, or rely upon their government to help impart the knowledge. The latter method is the most practical since it will reach more consumers; hence, the arrival of the new dietary guidelines in 2005.¹⁰

⁶ FDA and USDA Guidance on Whole Grains and Labeling, *available at* <http://www.wholegrainscouncil.org> (last visited Oct. 6, 2006).

⁷ In the Matter of Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements, (April 18, 2006), *available at* <http://www.ftc.gov/os/2006/04/v060014FTCStaffCommentstotheFDAREdocketNo2006-0066.pdf>. The draft guidance document is available at <http://www.cfsan.fda.gov/~dms/flragui.html>.

⁸ *Id.*

⁹ *Id.*

¹⁰ Dietary Guidelines for Americans, 2005, (HHS/USDA 2005), at Chapter 5, *available at* <http://www.healthierus.gov/dietaryguidelines> (last visited Oct. 11, 2006).

III. Unraveling the Confusion:

Where does the confusion lie? Is it with the manufacturers marketing and advertising false food labels and misleading health claims (the item does not contain the correct amount of necessary nutrients), or the consumers' lack of knowledge in the meaning of the words? Is the ambiguous wording the cause for the confusion? It is this author's opinion the answer is the combination of all of the above. Consumers rely upon food labels to help them improve their diet. FDA's mandates are to ensure that consumers' needs are met by preventing false and misleading food labels. To help educate the public in making wiser choices in their diet, the United States Department of Agriculture (USDA) released a new Food Guide Pyramid in April 2006.¹¹ One of the most noticeable changes is the absence of the words "complex carbohydrates" and replaced with the wording "whole grains". Instead of 6 - 11 servings of carbohydrates, the new pyramid stresses 6 servings, of which, "three or more ounce equivalents should be whole grains per day."¹²

As mentioned above, the wording "whole grain" is more complicated than the wording "carbohydrate". A slice of white bread is a complex carbohydrate but whole wheat bread cannot be presumed to be "whole grain" unless it meets the appropriate percentages detailed above. Also, one must understand wording such as "good source", "contains", "provides", "high in", "excellent source of", and "rich in". Manufacturers cannot list these on their labels unless the

¹¹ The new interactive food pyramid may be found at <http://www.mypyramid.gov> (last visited Oct. 14, 2006).

¹² In the Matter of Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements, (April 18, 2006), available at <http://www.ftc.gov/os/2006/04/v060014FTCStaffCommentstotheFDAREdocketNo2006-0066.pdf> (last visited Oct. 6, 2006).

first three contains in between 10-19% of the Daily Value per reference amount and the last three contains 20% or more of the Daily Value per reference amount.¹³

How can an average consumer understand the differences between whole grain and fiber and good versus excellent when the context of such items are so convoluted? Using the word “fiber” in health claims loses the connection with “whole grains”. Unless consumers’ knowledge of fiber and whole grains is current even the USDA’s Food Pyramid does not help to enlighten the public. Food labels themselves do not “give consumers enough context to determine easily how much of their recommended daily amount of whole grains they are getting from one serving of food.”¹⁴ Currently, consumers’ awareness of dietary recommendations and whole grain label statements are still in the learning process.¹⁵ Until consumers and manufacturers interpret expressions such as “whole grain”, “made with whole grain”, and other similar phrases consistently, then the confusion between whole grains and health claims will continue.

IV. Conclusion:

Health claims show a relationship between a food substance and the likelihood of reducing a health condition. Both the FDA and USDA are striving to minimize the confusion between whole grain, fiber, and health claims by creating mechanisms such as the Whole Grain Draft Guide and The Food Pyramid. They have made headway but evidence still reveals consumers are baffled when it comes to relating how much or what truly is a whole grain. Perusing the internet, one encounters numerous articles describing that the public is perplexed

¹³ 21 C.F.R. § 101.54 (b) and (c) (2006).

¹⁴ In the Matter of Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements, (April 18, 2006), *available at* <http://www.ftc.gov/os/2006/04/v060014FTCStaffCommentstotheFDAREdocketNo2006-0066.pdf> (last visited Oct. 6, 2006).

¹⁵ *Id.*

with this topic as evident by the references used this paper. Short of being a Food Nutritionist, one must understand the components in whole grain, have the ambition or desire to research the information to gain the knowledge, and/or have the tenacity to unravel and interpret the food labels. This consumer is a little more knowledgeable and hopes to be well prepped to tackle food labels, whole grains, and health claims.