



June 3, 2005

VIA E-MAIL AND FEDERAL EXPRESS

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Re: Notification for a Health Claim Based on an Authoritative Statement

Dear Dr. Moss:

On February 1, 2005, Frito-Lay, Inc. submitted to the Food and Drug Administration (FDA) a Notification for a Health Claim Based on an Authoritative Statement: Whole Grain Foods and Coronary Heart Disease. This notification was submitted pursuant to section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)). FDA subsequently advised Frito-Lay that the notification was received by the agency on February 4, 2005, and the statutory, 120-day notification period would expire on June 4, 2005.

During a telephone conversation last week with you and Dr. Kathleen Ellwood, the agency encouraged Frito-Lay to revise the FDAMA Notification. The agency expressed a concern with our position that the 10 percent minimum nutrient contribution found in 21 C.F.R. 101.14(e)(6) did not apply to the FDAMA whole grain health claim. The agency further stated that it considered it appropriate under these circumstances to consider foods eligible for the claim under 21 C.F.R. 101.14(e)(6) if the food contained at least 7 percent of the daily reference value (DRV) for fiber. Stated differently, for those foods that contain less than 10 percent of the DRV or reference daily intake (RDI) for protein, vitamin A, vitamin C, calcium or iron, the agency would consider the requirements of 21 C.F.R. 101.14(e)(6) satisfied if the product contained at least 7 percent of the DRV for fiber.

Julie Moss, PhD, RD
June 3, 2005
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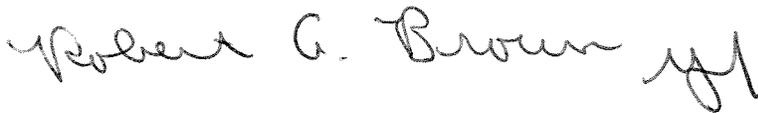
Frito-Lay continues to believe that the provisions of 21 C.F.R. 101.14(e)(6) do not apply to whole grain health claims. Frito-Lay, nonetheless, is revising the FDAMA notification to clarify that foods eligible to bear the claim must contain at least 7 percent of the DRV for fiber. Regardless of the applicability of 21 C.F.R. 101.14(e)(6), Frito-Lay and FDA agree that products containing less than 10 percent of the daily value for protein, vitamin A, vitamin C, calcium or iron are eligible for the whole grain health claim when they contain at least 7 percent of the DRV for fiber.

The exact wording of the proposed claim is: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease." The claim will be used on foods that (1) contain at least 51 percent whole grains (using dietary fiber as a marker), (2) meet the regulatory definitions for both "low saturated fat" and "low cholesterol," (3) bear quantitative amounts of trans fat as part of the nutrition labeling, (4) contain less than 6.5 grams total fat and 0.5 grams or less trans fat per reference amount customarily consumed (following standard rounding rules), (5) meet the applicable general requirements for health claims, per 21 C.F.R. § 101.14, and (6) contain at least 7 percent of the DRV for fiber (following standard rounding rules).

We are submitting the attached revised FDAMA notification with the understanding that the 120-day notification period will continue to be June 4, 2005.

Please do not hesitate to contact me if you have any questions concerning this submission.

Sincerely,

A handwritten signature in cursive script that reads "Robert C. Brown" followed by a stylized flourish.

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**Notification for a Health Claim
Based on an Authoritative Statement:**

**Whole Grain Foods
and Coronary Heart Disease**

Submitted on: February 1, 2005; Revised June 3, 2005

Submitted by: Robert C. Brown, PhD, MPH
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**Notification for a Health Claim
Based on an Authoritative Statement
Pursuant to FFDCA § 403(r)(3)(C)**

**Whole Grain Foods
and Coronary Heart Disease**

I. INTRODUCTION

The undersigned submits this Food and Drug Administration Modernization Act of 1997 (FDAMA) notification that there is an authoritative statement supporting the use of a health claim regarding the relationship between whole grain foods and a reduced risk of coronary heart disease (CHD). This notification clarifies that foods containing less than 10 percent of the daily value for vitamin A, vitamin C, calcium, iron or protein are eligible to bear the FDAMA whole grain health claim provided such foods contain at least 7 percent of the Daily Reference Value (DRV) for fiber and meet the other criteria established below for the whole grain health claim.

Frito-Lay is submitting this FDAMA Notification because the previously submitted notifications did not specifically address the applicability of 21 C.F.R. 101.14(e)(6) to products bearing the whole grain health claim. This regulatory provision restricts the use of health claims on foods that do not contain, prior to fortification, at least 10 percent of the daily value for vitamin A, vitamin C, calcium, iron, protein, or fiber. As will be discussed in more detail below, the underlying records for the previously submitted FDAMA notifications establish that the 10 percent minimum nutrient contribution of 101.14(e)(6) is not intended to apply to foods bearing the whole grain health claim. This notification explains the basis for concluding that whole grain foods are not subject to the 10 percent minimum nutrient contribution under the existing notifications, the justification for establishing a requirement that eligible foods contain at least 7 percent of the DRV for fiber and the justification for establishing the other requirements for eligible foods.

Pursuant to section 403(r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 343(r)(3)(C), the undersigned intends to use the following claim:

***Diets rich in whole grain foods and other plant foods,
and low in saturated fat and cholesterol, may help
reduce the risk of heart disease.***

Similar to the most recently authorized health claim relating consumption of whole grain foods and the reduced risk of CHD, the claim will be used on foods that (1) contain a minimum of 51 percent whole grains (using dietary fiber as a marker), (2) meet

the regulatory definition for both “low saturated fat” and “low cholesterol,” (3) bear quantitative amounts of trans fat as part of the nutrition labeling, (4) contain less than 6.5 grams total fat and 0.5 grams or less trans fat per reference amount customarily consumed (following standard rounding rules), (5) meet all applicable general requirements for health claims, per 21 C.F.R. § 101.14, and (6) contain at least 7 percent of the DRV for fiber (using standard rounding rules).

The FDAMA health claim is based on an authoritative statement issued by the Committee on Diet and Health, established by the Food and Nutrition Board (FNB) of the National Research Council (NRC), the working arm of the National Academy of Sciences (NAS). The report entitled *Diet and Health: Implications for Reducing Chronic Disease Risk* (hereinafter referred to as the *Diet and Health* report) contains the following authoritative statement:

Diets high in plant foods – i.e., fruits, vegetables, legumes, and whole-grain cereals – are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach.

(*Diet and Health*, at 8.). The Committee on Diet and Health published the *Diet and Health* report in 1989. The conclusions of the 1989 *Diet and Health Report* are consistent with the current science. Indeed, as described in the joint U.S. Department of Health and Human Services (USDHHS)/U.S. Department of Agriculture (USDA) *2005 Dietary Guidelines Advisory Committee Report*, the Advisory Committee reviewed the currently-available data, reaffirmed the connection between consumption of whole grain foods and the reduced risk of CHD, and specifically recommended an increase in the consumption of whole grain foods. Increased intake of whole grains is a key recommendation in the *Dietary Guidelines for Americans, 2005 (2005 Dietary Guidelines)*.

The aforementioned health claim will educate consumers about the importance of incorporating whole grain foods into their diets. By making it clear that the health claim is available for foods that do not meet the minimum nutrient contribution, there will be no needless limitations on the foods eligible to bear the claim. Such clarification will encourage more companies to offer whole grain versions of products, provided the food is formulated to meet the qualifying criteria and other requirements of the FDAMA notifications. As more whole grain products are made available to consumers, it will be easier for them to learn about the benefits of whole grains and increase consumption of whole grain products as recommended by the Advisory Committee and the *2005 Dietary Guidelines*.

II. AUTHORITATIVE STATEMENT

The *Diet and Health* report reflects a comprehensive and deliberate review by the NAS Committee on Diet and Health of the scientific literature on diet and its association with health, including its effect on major chronic diseases. The report presents the findings of the Committee on Diet & Health, a group of 19 renowned,

interdisciplinary scientists and medical professionals, who were tasked with analyzing the direct and indirect evidence relating chronic disease risks, foods, and dietary patterns. The report is highly regarded in the nutrition arena and has served as the source of three health claims based on authoritative statements pursuant to FDAMA: whole grain foods and reduced risk of CHD (1999) 1/; potassium and the risk of high blood pressure and stroke (2000) 2/; and whole grain foods with moderate fat content and reduced risk of CHD (2003). 3/

The authoritative statement upon which the proposed health claim is based appears in the executive summary of the *Diet and Health* report (attached as Appendix A). In the executive summary, the Committee on Diet & Health concludes that:

Diets high in plant foods – i.e., fruits, vegetables, legumes, and whole-grain cereals – are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach.

Diet and Health, at 8.

III. EXACT WORDING OF THE HEALTH CLAIM

This notification covers the use of the following authoritative statement claim on the label or in the labeling of certain whole grain foods:

Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease.

This claim is identical to the currently-authorized health claim relating consumption of whole grain foods and the reduced risk of CHD submitted by Kraft Foods in 2003.

IV. STATUTORY BASIS FOR THE HEALTH CLAIM

Section 303 of FDAMA (21 U.S.C. § 343(r)(3)) authorizes the use of health claims on the label or labeling of food products without prior FDA approval if specific requirements are met. In enacting this notification process, Congress sought to provide “streamlined procedures” and a flexible regulatory mechanism for the dissemination of scientifically sound nutrition information to the public. H.R. Rep. No. 105-399, at 98 (1997).

1/ FDAMA notification submitted by General Mills, Inc. on March 10, 1999 (assigned FDA Docket No. 99P-2209; hereinafter referred to as the “General Mills notification” and attached as Appendix B).

2/ FDAMA notification submitted by Tropicana Products, Inc. on July 3, 2000 (assigned to FDA Docket No. 00Q-1582).

3/ FDAMA notification submitted by Kraft Foods on August 8, 2003 and amended on November 25, 2003 (assigned to FDA Docket No. 03Q-0547; hereinafter referred to as the “Kraft Foods notification” and attached as Appendix C).

A. Requirements for Health Claims Based on Authoritative Statements

Health claims based on authoritative statements are authorized by the FFDCA, as amended by FDAMA, provided the following requirements are met:

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions, has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

FFDCA § 403(r)(3)(C). The FFDCA provides the additional requirement that the statement “shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.” *Id.*

In subsequent guidance, FDA described the types of statements that qualify as FDAMA authoritative statements and set forth the regulatory procedures for submitting a FDAMA health claim notification to the agency. The guidance document, entitled “Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body” (issued June 11, 1998), listed the following six criteria to clarify what constitutes an authoritative statement under FDAMA:

- 1) is about the relationship between a nutrient and a disease or health-related condition;
- 2) is “published by the scientific body”;
- 3) is “currently in effect”;
- 4) “shall not include a statement of an employee of the scientific body made in the individual capacity of the employee”;
- 5) should reflect a consensus within the identified scientific body if published by a subdivision of one of the federal scientific bodies; and
- 6) should be based on a deliberative review by the scientific body of the scientific evidence.

The first four of these criteria are derived directly from the plain language of FDAMA, while the last two are derived from the legislative history surrounding the statute. In addition, the guidance document specifies that FDAMA upholds the “significant scientific agreement” standard for health claims. Also, FDA has clarified that, under FDAMA, a health claim based on an authoritative statement cannot be authorized if it is equivalent to a health claim that is the subject of an authorizing regulation issued by the agency pursuant to section 403(r)(3)(B) of the FFDCA. See 63 Fed. Reg. 34101, 34102 (June 22, 1998) for agency interpretation of 21 U.S.C. § 343(r)(3)(C).

B. Authoritative Status of the *Diet and Health Statement*

The proposed health claim relating consumption of whole grain foods and the reduced risk of CHD is based on an authoritative statement as required by section 403(r)(3)(C) of the FFDCA as amended by FDAMA. The statement is made by the Committee on Diet and Health, established by the Food and Nutrition Board (FNB) of the National Research Council (NRC), the working arm of the National Academy of Sciences (NAS), in the report, *Diet and Health: Implications for Reducing Chronic Disease Risk*. The *Diet and Health* report is a compilation of the Committee’s findings following a deliberate and exhaustive review of scientific literature relating chronic disease risks, foods, and dietary patterns. The NAS is an agency that is specifically listed in the FFDCA, as amended by FDAMA, as an authoritative body that can serve as the source of such statements. The statement appears in the executive summary of the report and can be reasonably characterized as reflecting consensus within NAS.

Furthermore, the exact same statement has been used as the authoritative statement in support of health claims relating whole grain foods and CHD submitted by General Mills in 1999 and Kraft Foods in 2003 and reviewed favorably by FDA. Once again, the wording of the proposed claim is the same as the health claim submitted by Kraft Foods.

As required by FDAMA, the authoritative statement is currently in effect. In fact, the findings and recommendations in the *2005 Dietary Guidelines Advisory*

Committee Report and the *2005 Dietary Guidelines*, which benefit from an additional 15 years of scientific study of the diet-health relationship between whole grain foods and CHD, reinforce the validity of the statement.

C. Form and Content of the Health Claim

In addition to specifying the necessary criteria for a statement to be considered “authoritative” for the purpose of supporting a health claim, FDAMA specifies criteria on the form and content of the health claim itself. A health claim must provide an accurate representation of the authoritative statement; not be false or misleading, consistent with sections 403(a) and 201(n) of the FFDCFA; and enable the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet. The form and content of the proposed claim meet all of these criteria.

The health claim is supported by significant scientific agreement that diets rich in whole grain foods and low in saturated fat and cholesterol help reduce the risk of heart disease. Moreover, the health claim is not equivalent to any health claim FDA has authorized by regulation, including those relating the consumption of soy protein, plant stanol and sterol esters, or certain types of fiber-containing foods and the risk of CHD. As stated in the previously submitted notifications by General Mills and Kraft Foods and emphasized in the *2005 Dietary Guidelines Advisory Committee Report*, the anticipated benefits of whole grains are not attributed to fiber, *per se*, or any other isolated component of whole grains. Therefore, the proposed health claim is distinct from fiber-related, FDA-approved health claims because whole grain foods in total – and not solely the fiber component of these foods – have been demonstrated to provide beneficial health effects, including the reduced risk of CHD.

V. NATURE OF THE FOOD ELIGIBLE TO BEAR THE HEALTH CLAIM

In order to bear the proposed health claim, a food must meet specified criteria. First, the food must consist of at least 51 percent whole grain by weight per reference amount customarily consumed (RACC), using dietary fiber as a compliance marker. Second, a food must meet the FDA definitions for “low saturated fat” and “low cholesterol” and must not exceed 6.5 grams of total fat and 0.5 grams of trans fat per RACC. Third, the nutrition labeling for the food must state the trans fat content, consistent with the trans fat final rule. Fourth, foods containing less than 10 percent of the RDI or DRV for vitamin A, vitamin C, iron, calcium, or protein must contain at least 7 percent of the DRV for fiber (using standard rounding rules).

A. Whole Grain Content

The criterion for whole grain content that was specified in the General Mills and Kraft Foods notifications will continue to apply. This criterion requires that at least 51 percent of the weight of the food per RACC consist of whole grains, using dietary fiber as a compliance marker. As fully elucidated in these earlier whole grain notifications, the formula based on the fiber content of whole wheat, the most prevalent whole grain in the

U.S. diet, is used to calculate the minimum amount of fiber necessary for foods. The formula is set forth below:

$$\text{Requisite dietary fiber} = (11 \text{ g fiber}/100 \text{ g whole wheat}) \times 0.51 \times \text{RACC}.$$

B. Fat and Cholesterol Content

The criteria for fat and cholesterol content are the same as those specified in the earlier whole grain notifications, as well. In short, a whole grain food must meet the FDA definitions for “low saturated fat” and “low cholesterol” described in 21 C.F.R. §§ 101.62(c)(2) and 101.62(d)(2), respectively. Furthermore, subject to the Kraft Foods notification, a whole grain food must contain less than 6.5 grams of total fat and 0.5 grams of trans fat per RACC in order to bear the health claim.

The prior notifications contain a detailed analysis supporting the establishment of the criteria for saturated fat, cholesterol and total fat. We concur with the assessment of the earlier submitted notifications and, in the interest of administrative efficiency, do not repeat here the rationale provided in those notifications. Copies of the previously submitted notifications can be found in Appendix B (General Mills notification) and Appendix C (Kraft Foods notification).

C. Trans Fat Labeling

A whole grain food bearing the health claim must comply with the nutrition labeling regulations for trans fat as specified in the final rule published in the Federal Register on July 11, 2003 (68 Fed. Reg. 41434 (amending 21 C.F.R. § 101.9(c)(2))). The quantitative listing of trans fat content in the Nutrition Facts box will be required of all applicable foods by this rule as of January 1, 2006; therefore, this criterion serves to mandate early compliance with the rule for whole grain foods bearing the claim.

D. Application of the Minimum Nutrient Contribution

1. The Minimum Nutrient Contribution is Not Intended to Apply Under the Prior Notifications

The FDAMA health claim is available for whole grain foods that meet the preceding qualifying criteria even if they contain less than 10 percent of the nutrients listed in 21 C.F.R. § 101.14(e)(6), provided such foods contain at least 7 percent of the DRV for fiber. Section 101.14(e)(6) requires that, in addition to meeting the required definition and other criteria necessary to bear a health claim, a food must also contain one or more of the six nutrients – vitamin A, vitamin C, iron, calcium, protein, and fiber – in an amount at or above 10 percent of the RDI or DRV per RACC for that nutrient. The General Mills and Kraft Foods notifications did not specifically address whether whole grain foods must contain at least 10 percent of the nutrients listed in 21 CFR § 101.14(e)(6). A review of these notifications, however, establishes that the minimum nutrient contribution is not intended to apply to whole grain foods.

The previously submitted notifications identified the types of foods that would be eligible for the FDAMA health claim. Appendix F lists the foods identified in the previous notifications as being eligible for the whole grain health claim. Included in these lists are many foods that do not meet the minimum nutrient contribution prior to fortification. We have highlighted those foods that do not meet the minimum nutrient contribution – although they appear to contain at least 51 percent whole grain based on their fiber content. For example, the General Mills notification contained several tables of “qualifying whole grain products.” Included in those tables are foods such as Multigrain Cheerios® Plus, Raisin Bran®, Life®, Cinnamon Life®, tortilla chips (baked) and brown rice (prepared) that do not satisfy the minimum nutrient contribution. The tables in Appendix F establish that the previous notifiers did not intend the minimum nutrient contribution to apply because they identified numerous eligible whole grain foods that did not comply with this regulatory provision.

It is not surprising that many of the foods identified in the earlier notifications do not meet the minimum nutrient contribution because whole grains are not significant sources of vitamin A, vitamin C, calcium, iron or protein, which leaves fiber as the one nutrient that has the potential to be present at the 10 percent level. While many whole grain foods contain more than 10 percent of the DRV for fiber, a variety of whole grain foods, particularly those with smaller RACCs, have difficulty meeting the 10 percent minimum nutrient contribution for fiber even though they contain greater than 51 percent whole grains. A whole grain food would need to provide 2.5 grams or more fiber per RACC for a product to provide at least 10 percent of the DRV for fiber. Many of the whole grain foods covered by the earlier notifications have slightly under 2.5 grams of fiber per RACC and would declare “7%,” “8%,” or “9%” as the DRV for fiber.

The previously submitted notifications convincingly establish that the effect of whole grain foods cannot be attributed solely to the fiber or any other component of the food. In the *2005 Dietary Guidelines Advisory Committee Report*, the Advisory Committee reached a similar conclusion after reviewing the available data. It would be seemingly inappropriate to require whole grain foods to supply at least 10 percent of the DRV for fiber (*i.e.*, the only nutrient that is likely to be meet the minimum nutrient contribution in these type of products) when the data convincingly establish that many other components of the whole grain, in addition to cereal fiber, contribute, in a synergistic manner, to the heart healthy benefits of whole grains.

The previous notifications did specify, however, that a food must contain at least 51 percent whole grain to be eligible for the claim. This 51 percent requirement serves as an effective substitute for the minimum nutrient contribution. By requiring whole grain foods to contain 51 percent whole grain, the claim is limited to those foods that provide a significant level of whole grains. The requirements that eligible products be “low in saturated fat,” “low in cholesterol,” and meet the specified criteria for total and trans fat provide further assurance that the health claim will be limited to those foods that are consistent with dietary recommendations.

The previous notifications also included a minimum fiber content requirement per RACC to serve as a compliance marker for whole grain content. The

minimum fiber content for foods with a RACC less than 45 grams is less than 2.5 grams. Specifically, as detailed below, any food with a 30 gram RACC is required to contain a minimum of 1.7 grams of dietary fiber, which is 7 percent of the DRV for fiber (using standard rounding rules). The presence of this compliance marker as a criterion for the health claim substantiates the fact that whole grain foods need not be a “good source” of dietary fiber.

Application of the minimum nutrient contribution would unnecessarily disqualify a number of foods that contribute beneficial amounts of whole grains to the U.S. diet. Moreover, such a restriction is at odds with the true purpose of the minimum nutrient contribution, which is to avoid the promotion of foods that provided little or no nutritional benefit and fall outside current dietary guidelines. Because whole grain foods provide a distinct nutritional benefit – albeit not one that is fully characterized by the six nutrients for which minimum levels are established in 21 C.F.R. § 101.14(e)(6) – and the increased consumption of these foods is strongly recommended in current dietary guidelines, the strict application of the minimum nutrient contribution for whole grain foods is unnecessary.

When the administrative records for the previously submitted whole grain FDAMA notifications are reviewed in their entirety, they support a position that whole grain foods are eligible for the health claim when they contain less than 10 percent of the daily value for vitamin A, vitamin C, calcium, iron or fiber. The additional information in this notification establishes that such foods would be eligible for the whole grain health claim provided they contribute at least 7 percent of the DRV for fiber.

2. History of the Minimum Nutrient Contribution

The use of (non-FDAMA) health claims on the label or in labeling of a food is limited by, among other restrictions, the minimum nutrient contribution delineated in 21 C.F.R. § 101.14(e)(6). As noted previously, § 101.14(e)(6) provides that, in addition to meeting the required definition and other criteria necessary to bear a health claim, a food must also contain one or more of the six nutrients – vitamin A, vitamin C, iron, calcium, protein, and fiber – in an amount at or above 10 percent of the RDI or DRV per RACC for that nutrient. The regulation further provides that the levels of these six nutrients in the food must not be derived from fortification of the food. 21 C.F.R. § 101.14(e)(6). FDA selected these six nutrients as a subset of the 12 nutrients for which nutrition labeling is mandatory and for which intake need not be limited to develop a diet that corresponded to existing dietary guidelines. See 58 Fed. Reg. 2478, 2522 (Jan. 6, 1993).

As explained in the preamble to the final rule that established the minimum nutrient contribution regulation, FDA included this provision to ensure “...that foods bearing health claims ...be those consistent with dietary guidelines, and that the value of health claims ...not be trivialized or compromised by their use on foods of little or no nutritional value.” *Id.* In further justification of this regulation, “...FDA conclude[d] that it is appropriate to provide a basis for health claims that takes into account the nutritional contribution of the food beyond its role as a source of calories.” *Id.* Furthermore, FDA stated:

In addition to being inconsistent with section 403(r) of the [FFDCA], claims intended to promote the consumption of a food that is incompatible with dietary guidelines would be misleading to consumers and, thereby, be in violation of section 403(a). Such claims would be misleading because consumers would be purchasing the food, in part, to achieve a more healthful diet. However, foods inconsistent with dietary guidelines should not be associated with the more healthful diets recommended by Federal agencies

Id. Thus, it is fully apparent from these statements that FDA intended the minimum nutrient contribution to serve merely as a general filter for prohibiting the use of (non-FDAMA) health claims on foods that provide such minimal nutritional value as to be inconsistent with current dietary guidance.

Furthermore, the plain language of the FFDCA does not subject FDAMA health claims to the minimum nutrient contribution. Unlike FDAMA nutrient content claims – which must comply with all nutrient content claim regulations issued by FDA under section 403(r) – Congress did not specifically subject FDAMA health claims to all health claim regulations promulgated by FDA under this section. Instead, FDAMA only requires that health claims based on authoritative statements comply with the disqualifying nutrient level requirements, which are found in the statute at 403(r)(3)(A)(ii) and are described in full in the regulations at 21 C.F.R. §101.14(a)(4). Both FDAMA health and nutrient content claims must otherwise be in compliance with 403(a) and 201(n) of the FFDCA.

In short, FDAMA does not contain any reference to the minimum nutrient contribution. FDA promulgated the minimum nutrient contribution regulation in 1993 after concluding that, in general terms, such a regulation is necessary for health claims to be consistent with dietary guidelines. FDA never cited specific statutory authority for promulgating the minimum nutrient contribution regulation, although consistency with (pre-FDAMA) section 403(r) and compliance with sections 403(a) and 201(n) of the FFDCA are noted in the preamble to the final rule. *See id.* Because FDAMA became part of the FFDCA several years after the minimum nutrient contribution regulation was promulgated, Congress could have required FDAMA claims to comply with this regulation (and others under the health claim provisions) as it did for FDAMA nutrient content claims. Instead, Congress chose to specify that FDAMA health claims are only subject to disqualifying nutrient levels.

The observation that FDAMA health claims are not subject statutorily to the minimum nutrient contribution is supported by FDA's comments in the course of rulemaking to prohibit FDAMA-based health claims for antioxidant vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts. *See* 63 Fed. Reg. 34084 (June 22, 1998). In this interim final rule, FDA stated that the FFDCA authorizes use of a health claim based on an authoritative statement only when the food (1) provides an appropriate level of the nutrient that is the subject of the health claim, (2) does not exceed the disqualifying levels identified in 21 C.F.R. §

101.14(a)(4), and (3) otherwise complies with section 403(r)(3)(C) and all other provisions of the act. See *id.* Notably absent from this list is the minimum nutrient contribution.

FDA does expand on the list described above by stating that it requires any FDAMA-based health claim to be “truthful and not misleading, including compliance as *appropriate* with existing § 101.14.” *Id.* at 34087 (emphasis added). However, compliance with the minimum nutrient contribution regulation is not specified. While we recognize that there may be some instances in which it would be appropriate to apply the minimum nutrient contribution, the FDA statements establish that it should be applied only *as appropriate*. As described in detail in section V.D.4. of this petition, below, because (1) increasing consumption of whole grains is a central theme to the dietary guidelines, (2) none of the six nutrients listed in the minimum nutrient contribution regulation serve as an adequate surrogate for the nutritional value of whole grain, and (3) there is FDA precedence for excepting FDAMA health claims from the regulation, we believe that the 10 percent minimum nutrient contribution regulation in § 101.14 is not appropriate for the health claim relating whole grain foods and CHD.

We recognize, however, the importance of ensuring that eligible foods provide a meaningful level of whole grains. Therefore, we are establishing that foods eligible for the claim contribute at least 7 percent of the DRV for fiber. Furthermore, we understand that, while FDA may disagree with our position that the 10 percent minimum nutrient contribution does not apply to foods eligible for the whole grains health claim, the agency has agreed to consider the exercise of its enforcement discretion for such foods that contain at least 7 percent of the DRV for fiber. Regardless of the applicability of 21 C.F.R. 101.14(e)(6), the agency and notifier are in agreement that foods containing less than 10 percent of the daily value for vitamin A, vitamin C, calcium, iron and protein are eligible for the FDAMA whole grain health claim when they provide at least 7 percent of the DRV for fiber.

3. 2005 Dietary Guidelines Advisory Committee Report and Dietary Guidelines for Americans, 2005

Pursuant to the National Nutrition Monitoring and Related Research Act of 1990 (7 U.S.C. § 5301 *et seq.*), USDHHS and USDA are required to publish the *Dietary Guidelines for Americans* at least every five years. These guidelines provide science-based advice to promote health and to reduce risk for major chronic diseases through diet and physical activity, and thus, form the basis of federal food, nutrition education, and information programs. In 2003, at its first meeting, the 13-member 2005 Dietary Guidelines Advisory Committee decided that the science surrounding diet, nutrition, and disease had changed since the issuance of the 2000 edition of the *Dietary Guidelines for Americans* and further evaluation of the science was necessary. On August 27, 2004, after critically reviewing relevant scientific evidence, requesting special analyses relating to nutrients and dietary patterns, and obtaining useful information and insights from invited experts and from the public oral and written testimony, the Advisory Committee issued the *2005 Dietary Guidelines Advisory Committee Report*. This Report serves as the basis for the 2005 edition of the *Dietary Guidelines for Americans*, which was issued on January 12, 2005.

The Advisory Committee's findings support the development of dietary guidelines that convey, among other major messages, that increased daily intake of whole grains can reduce the risk of CHD. The relevant section of the *2005 Dietary Guidelines Advisory Committee Report*, Part D: Science Base, Section 6: Selected Food Groups (Fruits and Vegetables, Whole Grains, and Milk Products), is attached as Appendix D. The Advisory Committee concluded that "[w]hole grain intake has been found to be consistently associated with a reduction in the risk of CHD among both men and women" ...and "[c]ollectively, the studies suggest a 20 to 30 percent reduced risk of CHD with three or more servings of whole grain foods per day." Thus, the Advisory Committee recommended the daily intake of three ounces (i.e., three servings) of whole grains per day, preferably by substituting whole grains for refined grains. *2005 Dietary Guidelines Advisory Committee Report*, Part D, Section 6 at 8. This recommendation also is conveyed in the final guidelines, which are attached as Appendix E. *2005 Dietary Guidelines* at 36.

Moreover, the Advisory Committee noted that the beneficial effects of consuming whole grains are distinct from that of dietary fiber. It found that "in the studies that have evaluated fiber as a confounder, whole-grain intake has still remained protective against CHD." *Id.* at 10. That is to say, cereal fiber may be just one of many protective components of whole grains. In addition, the Advisory Committee noted that "...whole grain consumption is protective beyond what would be predicted if the protection found with the individual compounds were simply additive." *Id.* This statement clearly delineates the Advisory Committee's position that whole grains are healthy *per se*.

4. Current Dietary Guidance Support an Exclusion of Whole Grain Foods from the Minimum Nutrient Contribution

For a number of reasons, the concerns raised by FDA in promulgating the minimum nutrient contribution are not valid for whole grain foods. As a result, this provision, as codified, does not apply to the use of a health claim relating whole grain foods and CHD. Most notably, the *2005 Dietary Guidelines Advisory Committee Report* and the *2005 Dietary Guidelines* recommend the increased intake of whole grains, preferable by substituting whole grains for refined grains. Thus, the use of the proposed health claim to promote the consumption of whole grain foods – regardless of the level of protein, fiber, vitamin A, vitamin C or iron – is "consistent with dietary guidelines, and ... the value of health claims ... [is] not ... trivialized or compromised by [its] use on foods of little or no nutritional value." 58 Fed. Reg. at 2522.

Furthermore, none of the six nutrients listed in the minimum nutrient contribution fully represents the nutritional value of whole grains in the diet. Significantly, the Advisory Committee found that the cardioprotective effects of whole grains are arguably more comprehensive than that of dietary fiber. Thus, a measure of dietary fiber contribution, in isolation – i.e., whether a food contains 10 percent of the DRV for dietary fiber (2.5 grams per RACC) – short-changes the true nutritional benefits of whole grains. Viewed in this light, whole grains arguably are important unto themselves and their value is independent of the level of fiber, protein, vitamin A, vitamin C, calcium or iron in the product.

The use of the proposed health claim on whole grain foods, particularly whole grain snack foods, which serve as a substantial source of whole grains in the U.S. diet (Cleveland, 2000), would provide an incentive for consumers to choose whole-grain foods in lieu of non-whole grain-containing foods. Any concerns that the use of the proposed health claim on snack foods would lead to the increased intake of fat and cholesterol are mitigated by the qualifying criteria that whole grain foods must meet in order to bear the proposed claim, most notably the limits on total fat, saturated fat, trans fat, and cholesterol, as described above.

The Advisory Committee also recognized the value of including whole grain foods in the diet, regardless of the source. When addressing the amount of whole grains that should be consumed, the Advisory Committee noted that a recent report (i.e., the *Professionals Follow Up Study* (Jensen *et al.*, in press 2004)) found “the beneficial effects for whole-grain consumption are greatest for a daily whole-grain intake above 30 g, regardless of the food source.” *2005 Dietary Guidelines Advisory Committee Report*, Part D, Section 6 at 14. The Advisory Committee then concluded that “the protected quintile of intake [against CHD incidence] appears to be three servings (equivalent to three ounces) of whole grains per day.” *Id.* The Advisory Committee emphasis on increasing whole grain intake, regardless of the food source, further supports the exclusion of whole grain foods from the minimum nutrient contribution.

Finally, FDA has acknowledged that in specific circumstances that merit its exception, the agency will consider exercising enforcement discretion for health claims used on foods that fall short of the minimum nutrient contribution. For sugar alcohols, plant sterol/stanol esters, whole or chopped walnuts, and, most recently, monounsaturated fats from olive oil, FDA stated that it will consider exercising enforcement discretion for eligible foods containing these substances (or in the case of walnuts, the walnuts, themselves) that do not meet the provisions of 101.14(e)(6) because they provide important public health benefits that can be effectively communicated to consumers via appropriate health claims. The reduced risk of CHD that can result from the increased consumption of whole grain foods is in line with these prior agency positions.

5. It is Appropriate to Set a Minimum Fiber Content of 7 Percent of the DRV

Foods eligible for the whole grains claim must contain at least 7 percent of the DRV for fiber (using standard rounding rules) to ensure that these foods provide a meaningful level of whole grains. This level of fiber is based on the criterion for whole grain content that was specified in the General Mills and Kraft Foods notifications applied to a whole grain food with a RACC of 30 grams. This criterion requires at least 51 percent of the weight of the food per RACC to consist of whole grains, using dietary fiber as a compliance marker. The minimum amount of dietary fiber is calculated using a formula that is based on the fiber content of whole wheat (i.e., 11 g fiber/100 g whole wheat). Thus, for a whole grain food with a RACC of 30 grams, the minimum dietary fiber content to qualify for the whole grain health claim would be:

$$\begin{aligned} \text{Requisite dietary fiber} &= (11 \text{ g fiber}/100 \text{ g whole wheat}) \times 0.51 \times 30 \text{ g RACC} \\ &= 1.7 \text{ g fiber} \end{aligned}$$

The requisite dietary fiber content of such a food, as a percentage of the DRV would be:

$$\begin{aligned} \text{Requisite dietary fiber content} &= 1.7 \text{ g fiber}/25 \text{ g fiber/day} \times 100 \\ &= 6.8\% \end{aligned}$$

Using standard rounding rules, this level of fiber in a 30 gram RACC would be listed as 7 percent in the nutrition labeling.

E. Product Categories

The health claim may be used on all whole grain foods that meet the criteria described above, including, but not limited to, cereals, crackers, breads, whole grain-based snacks and whole grain-based snack bars. These foods comprise all of the product categories that serve as major sources of whole grains and dietary fiber consumed by Americans: breads, cereals, pasta, and snack foods (i.e., chips, popcorn, and crackers). (See *2005 Dietary Guidelines Advisory Committee Report*, Table D1-11b (attached to Appendix D); Cleveland, 2000).

Tables of products that are eligible for the claim are found in Appendices F and G. Appendix F identifies the products included in the previous FDAMA notifications as being eligible for the claim and highlights those products that do not meet the minimum nutrient contribution. Appendix G contains a listing of other qualifying whole grain health products, including several products that would not meet the minimum nutrient contribution.

VI. BRIEF SUMMARY OF THE SCIENTIFIC LITERATURE REGARDING THE RELATIONSHIP BETWEEN WHOLE GRAIN FOODS AND CHD

The scientific literature regarding the relationship between consumption of whole grain foods and the reduced risk of CHD is described in detail in the whole grain notifications submitted by General Mills and Kraft Foods, both of which are incorporated by reference in this notification and can be found in Appendix B and C, respectively. Because such detailed descriptions of the relevant literature have been submitted to FDA in direct connection with health claims relating whole grain foods and CHD, these descriptions are not recounted here.

It also is unnecessary to provide in the text of this notification an in-depth analysis of the current science supporting the relationship between whole grain foods and reduced risk of CHD because such an analysis has been completed recently by the Dietary Guidelines Advisory Committee. In its report, the Advisory Committee concluded:

Consuming at least 3 servings (equivalent to 3 ounces) of whole grains per day can reduce the risk of diabetes and coronary heart disease (CHD) and

helps with weight maintenance. Thus, daily intake of 3 ounces of whole grains per day is recommended, preferably by substituting whole grains for refined grains.

2005 Dietary Guidelines Advisory Committee Report, Part D, Section 6 at 7-8. A similar conclusion is reached in the *2005 Dietary Guidelines*. See *2005 Dietary Guidelines* at 36.

In support of this conclusion, the Advisory Committee notes that it reviewed 46 published papers pertaining to coronary heart disease, diabetes, and obesity and that the recommended number of servings is based on evidence presented in 12 large prospective studies. A copy of the relevant portion of the *2005 Dietary Guidelines Advisory Committee Report* is attached to this notification as Appendix D and it is incorporated into this notification. This report convincingly establishes that there continues to be significant scientific agreement regarding the relationship between whole grain foods and a reduced risk of CHD.

VII. SUMMARY AND CONCLUSIONS

In summary, the health claim, which relates the consumption of whole grain foods with the reduced risk of CHD, is based on an authoritative statement from *Diet and Health* that has supported two previously authorized whole grain health claims. The recently issued *2005 Dietary Guidelines Advisory Committee Report* and the *2005 Dietary Guidelines* establish that the authoritative statement continues to reflect the views of the scientific community and that there is significant scientific agreement in support of the claim. This notification clarifies that foods with less than 10 percent of the daily value for vitamin A, vitamin C, calcium, iron, or protein will be eligible for the whole grain health claim provided such products contain at least 7 percent of the DRV for fiber and meet the other criteria of the health claim.

The proposed claim is identical to the claim that is the subject of the Kraft Foods notification in that the claim will be used on foods that (1) contain a minimum of 51 percent whole grains (using dietary fiber as a marker), (2) meet the regulatory definition for both "low saturated fat" and "low cholesterol," (3) bear quantitative amounts of trans fat as part of the nutrition labeling, (4) contain less than 6.5 grams total fat and 0.5 grams or less trans fat per reference amount customarily consumed (following standard rounding rules), (5) meet the applicable general requirements for health claims, per 21 C.F.R. § 101.14 and (6) contain at least 7 percent of the DRV for fiber (using standard rounding rules).

Respectfully submitted,

A handwritten signature in black ink that reads "Robert C. Brown" followed by a stylized monogram "yfl".

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VIII. LITERATURE CITATIONS

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IX. APPENDICES

- A. Authoritative Statement from *Diet and Health***
- B. 1999 Whole Grains Health Claim Notification (General Mills)**
- C. 2003 Whole Grains Health Claim Notification (Kraft Foods)**
- D. *2005 Dietary Guidelines Advisory Committee Report; Part D: Science Base; Section 6: Selected Food Groups (Fruits and Vegetables, Whole Grains, and Milk Products)***
- E. *Dietary Guidelines for Americans, 2005***
- F. Previously Listed Whole Grain Products Eligible to Bear the Health Claim**
- G. Other Selected Whole Grain Products Eligible to Bear the Health Claim**