# APPENDIX – B

## Whole Grain Foods Authoritative Statement Claim Notification 1999

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March 10, 1999

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**VIA COURIER**

Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

**CONFIDENTIAL**

Re: *Authoritative Statement Claim Notification*

Dear Ladies and Gentlemen:

On behalf of General Mills, Inc., we hereby submit the enclosed Whole Grain Foods Authoritative Statement Claim Notification. This notification is submitted pursuant to section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)).

If you have any questions, please feel free to contact me at the above number. Thank you for your consideration of this matter.

Sincerely,

Stuart M. Pape
Counsel, General Mills, Inc.

SMP/jjs

Enclosure

99P-2209

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# WHOLE GRAIN FOODS AUTHORITATIVE STATEMENT CLAIM NOTIFICATION

Before the
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Submitted on behalf of
General Mills, Inc.

By
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March 10, 1999

*NOTIFICATION FOR A HEALTH CLAIM BASED ON AN AUTHORITATIVE STATEMENT*

CONFIDENTIAL
NOT FOR PUBLIC DISCLOSURE

# Notification for a Health Claim Based on an Authoritative Statement Pursuant to 21 U.S.C. 343(r)(3)

## I. Executive Summary

### A. The Proposed Authoritative Statement Claim

General Mills, Inc. ("General Mills") proposes to use the following authoritative statement claim relating to diets containing whole grain foods, and coronary heart disease ("CHD") and certain cancers:

***Low fat diets rich in whole grain foods and other plant foods may reduce the risk of heart disease and certain cancers.***

The authoritative statement claim notification includes a definition for whole grain foods that ensures that the food bearing the claim contains whole grain(s) as the predominant ingredient. Also, the notification sets forth appropriate criteria to permit the Food and Drug Administration ("FDA" or the "agency") to ensure compliance.

### B. The Claim Derives From An Authoritative Statement from the National Academy of Sciences *Diet and Health* Report

The support for the whole grain foods authoritative statement claim derives from an authoritative statement from the National Academy of Sciences ("NAS") *Diet and Health: Implications for Reducing Chronic Disease Risk* report. The statement concludes that **"(d)iets 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."** The proposed authoritative statement claim repeats the importance of diets high in plant foods, and specifies "whole grain foods" as an example of a plant food cited in the statement as

beneficial.

The *Diet and Health* report reflects a comprehensive and deliberative review by the NAS Committee on Diet and Health, of the scientific literature on diet and major associations between diet and health. In reaching its conclusions about plant foods, including whole grain foods, the nineteen-member Committee considered direct and indirect evidence including epidemiological, animal, and human studies related to carbohydrates, dietary fiber, fat-soluble vitamins, water-soluble vitamins, cholesterol, and fat intake. Since the publication of the report, both the statement and its scientific basis continue to receive support from scientific studies, including those addressing whole grain foods alone. Thus, the authoritative statement, and the significant scientific agreement supporting the statement, provide a substantial basis for the whole grain foods authoritative statement claim.

**C. The Proposed Claim Will Lead to Increased Consumption of Whole Grain Foods**

Whole grain foods are consistently recommended as components of a healthy diet. The positive effect of whole grain foods on disease risk is well-recognized, and whole grain foods provide a variety of vitamins, minerals, and other dietary substances that are otherwise important for good health. This authoritative statement claim will encourage increased consumption of plant foods, especially whole grain foods, and thus provide a substantial benefit to public health.

FDA has approved health claims for fruits and vegetables, together with grains, for certain cancers and coronary heart disease. However, whole grain foods consumption has not significantly increased since approval of the claims, and remains below desired levels. In contrast, consumption of other plant foods, such as fruits and vegetables, has increased.

Consumer disinterest in whole grain foods, as compared to fruits and vegetables,

likely results from consumers not recognizing the potential benefits derived from consumption of whole grain foods. Consumers do not recognize the benefits of whole grain foods, as compared to fruits and vegetables, because the benefits of fruits and vegetables have been given significantly more attention than the benefits of whole grain foods. For example, while a health claim exists that addresses fruits and vegetables alone, whole grain foods are incorporated into health claims only as part of the "fiber-containing fruits, vegetables, and grains" claims. A health claim for whole grain foods and other plant foods will emphasize to consumers the benefits of consuming a low fat diet rich in whole grain foods. The proposed claim will impress upon consumers that not only plant foods in general, but whole grain foods themselves, are an important component of the diet, and that consumption of fruits and vegetables does not eliminate the need to consume whole grain foods.

**D. The Claim is Consistent with Currently Authorized Health Claims**

The proposed claim is consistent with already-approved claims about the relationships between fiber-containing foods and soluble fiber from whole oats, and risks of CHD and cancer. The claim broadly addresses whole grain foods and other plant foods, rather than a particular component of whole grains, such as fiber. Although fiber is one component of whole grain foods and other plant foods that might be primarily responsible for reducing the risk of heart disease and cancer, the effects on these diseases do not likely result from the food's fiber content alone. Because consumers associate fiber with laxation, and thus might not find the idea of increased fiber consumption appealing, it is important to emphasize to consumers the other benefits of whole grain foods.

In addition, the proposed claim complements existing claims about diets low in dietary lipids, saturated fat, and cholesterol, reducing the risks of CHD and certain cancers. The claim addresses the plant foods, and specifically whole grain foods,

component of a low fat diet, and therefore draws particular attention to the importance of these foods. Thus, the proposed claim educates consumers about a category of foods that they should seek out and recognize in order to make healthy food choices.

## E. Conclusion

The proposed claim appropriately reflects an authoritative statement of a scientific body that addresses the relationship between whole grain foods and other plant foods, and reduced risk of CHD and certain types of cancers. As indicated by the authoritative statement, scientific evidence supports the benefits of eating healthy diets rich in these foods. However, consumption of whole grain foods remains below recommended levels. Consumers will benefit greatly from a claim indicating a relationship between consumption of whole grain foods and a reduction in disease risk. The proposed claim will draw consumer attention to whole grain foods and the need to increase their consumption, and will lead to enhanced public health.

## II. Introduction

General Mills intends to make an authoritative statement claim about the relationship of plant foods, and specifically whole grain foods, with coronary heart disease ("CHD") and certain cancers. An expert panel of the National Research Council ("NRC"), a subdivision of NAS, recognized these relationships and included them in NRC's renowned *Diet and Health* report on diet and disease relationships. The positive effect of whole grain foods on disease risk is consistently recognized by scientific experts. Additionally, whole grain foods provide a variety of vitamins, minerals, and other dietary substances that are otherwise important for good health.[1] In fact, an important new study shows that whole grain consumption is inversely related to total mortality.[2]

Experts continue to urge whole grain foods as an important component of a healthy diet. However, despite long-standing and general agreement that people benefit significantly from increased consumption of whole grain foods, consumption remains below desired levels. This authoritative statement claim will raise consumer awareness of the potential benefits from consuming whole grain foods. The claim will encourage increased whole grain consumption and thus, will provide a substantial benefit to public health.

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[1] DEPARTMENT OF AGRICULTURE AND DEPARTMENT OF HEALTH AND HUMAN SERVICES, NUTRITION AND YOUR HEALTH: DIETARY GUIDELINES FOR AMERICANS, December 1995, at 22.

[2] Jacobs, David R., et. al., "Is Whole Grain Intake Associated with Reduced Total and Cause-Specific Death Rates in Older Women? The Iowa Women's Health Study", *American Journal of Public Health*, 1999; 89:322-329.

## III. Background

National dietary recommendations advise a shift to a low fat, plant-based diet, founded on the consumption of adequate amounts of grain foods. Indeed, grain foods form the base of the Food Guide Pyramid, with the United States Department of Agriculture ("USDA") and the Department of Health and Human Services ("HHS") recommending 6-11 servings of grains per day – more servings than any other food type.[3] Public health policy goals as specified in *Healthy People 2000: National Health Promotion and Disease Prevention Objectives,* include reducing deaths from coronary heart disease and reversing the rise in cancer deaths through dietary measures that include increasing consumption of foods such as grains.[4]

Experts advise that of the recommended 6-11 servings of grain per day, several servings should consist of a variety of whole grain foods.[5] In fact, it has been proposed that the Food Guide Pyramid should be revised to further emphasize whole grain foods.[6] Other national nutrition policy documents also recognize the key role that whole grain foods play in achieving an optimal diet. Increased whole grain consumption is recommended in USDA's *Dietary Guidelines for Americans,*[7] the NRC's *Recommended Dietary Allowances*[8] and *Diet and Health*[9] reports, and the Surgeon General's *Report on*

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[3] DIETARY GUIDELINES FOR AMERICANS, *supra* note 1.

[4] HHS, HEALTHY PEOPLE 2000: NATIONAL HEALTH PROMOTION AND DISEASE PREVENTION OBJECTIVES, 118-119 (1990).

[5] DIETARY GUIDELINES FOR AMERICANS, *supra* note 1, at 25. *See also* Schwartz, Nancy E., "Narrowing the Gap: Practical Strategies for Increasing Whole-Grain Consumption", *Critical Reviews in Food Science and Nutrition,* 34(5&6):513-516 (1994); Welsh, Susan, et.al., "Achieving Dietary Recommendations: Whole-Grain Foods in the Food Guide Pyramid", *Critical Reviews in Food Science and Nutrition,* 34(5&6):441-451 (1994).

[6] Willet, Walter C., "The Dietary Pyramid: Does the Foundation Need Repair?", Editorial, *American Journal of Clinical Nutrition,* 1998:68:218-219. *See* Schwartz, *supra* note 5; Welsh, *supra* note 5.

[7] DIETARY GUIDELINES FOR AMERICANS, *supra* note 1, at 25.

[8] SUBCOMMITTEE ON THE TENTH EDITION OF THE RDAS, NAS, RECOMMENDED DIETARY ALLOWANCES, 10TH ed., 42 (1989).

[9] COMMITTEE ON DIET AND HEALTH, NAS, DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK, at 8 (1989).

*Nutrition and Health.*[10] In addition, the American Cancer Society[11] and American Dietetic Association[12] recommend an increased intake of whole grain foods.

Although a majority of consumers know about the Food Guide Pyramid's recommendations,[13] consumer intake of whole grain foods falls far below recommended levels.[14] Furthermore, only 30 percent of Americans report trying to include more whole grains in their diets, less than those trying to avoid too much fat in their diets, or trying to include more variety of foods in their diets.[15] Thus, consumers clearly need to increase their understanding of the benefits in order to increase their consumption of whole grain foods.

The authoritative statement that serves as the basis for this claim identifies the benefits of plant foods, including whole grain foods, fruits, vegetables, and legumes, in reducing CHD and cancer risk. However, despite the long-standing recognition of the value of these foods, consumption of whole grain foods remain below that of other plant foods such as fruits and vegetables. Even after FDA's 1993 approval of health claims for fruits, vegetables, and grains, with certain cancers and coronary heart disease,[16] whole grain foods consumption remained below the Food Guide Pyramid recommendations.

Results from a study conducted from 1994 through 1996 show that Americans ate an average of only about 6-2/3 servings of grain products daily.[17] Importantly, whole

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[10] SURGEON GENERAL, HHS, THE SURGEON GENERAL'S REPORT ON NUTRITION AND HEALTH: SUMMARY AND RECOMMENDATIONS, Pub. No. 88-51211, 12-13 (1988).
[11] AMERICAN CANCER SOCIETY, GUIDELINES ON DIET, NUTRITION AND CANCER PREVENTION: REDUCING THE RISK OF CANCER WITH HEALTHY FOOD CHOICES AND PHYSICAL ACTIVITY, 1996.
[12] *See* Schwartz, *supra* note 5.
[13] In a recent survey, 60 percent of Americans knew of the Food Guide Pyramid recommendations. Gallup Survey of Changing Food Preparation and Eating Habits. Multi-Sponsored Surveys, Inc. Princeton, NJ, 1998.
[14] Jacobs, *supra* note 2; Albertson A.M., Tobelmann, R.C., "Consumption of Grain and Whole Grain Foods by an American Population During the Years 1990 to 1992", *Journal of the American Dietetic Association*, 1995;95:703-704.
[15] Gallup Study of Changes in Food Preparation and Eating Habits, *supra* note 13.
[16] 21 C.F.R. § 101.76, § 101.77.
[17] USDA, Agricultural Research Service. 1997. Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals. On 1994-1996 Continuing Survey of Food

grain foods comprised only 1 of these servings.[18] Furthermore, 36 percent of the adults surveyed reported consuming no whole grain foods during the two non-consecutive reporting days.[19] Another study, conducted in 1995, reported a mean whole grain foods intake of only 0.5 eatings per day for adults.[20] Less than 2 percent of the study population consumed 2 or more eatings per day, and 23 percent consumed no whole grains over the 14-day collection period.[21]

In contrast, the consumption of fruits and vegetables increased as a result of the 1993 health claims and related promotional campaigns.[22] Fruits and vegetables intake increased from 3.4 servings per day before approval of the health claims,[23] to 4.9 servings per day after approval of the health claims.[24] From 1994-1996, while 60-76 percent of men and women perceived it important to follow dietary guidelines to consume plenty of fruits and vegetables, only 26-35 percent perceived it as important to consume plenty of bread, cereal, rice, and pasta.[25] Currently, 52 percent of Americans believe eating more fruits and vegetables is the most important dietary habit, while only 6 percent believe that eating more whole grain foods is the most important dietary habit.[26]

Lack of understanding of the benefits of whole grain foods might be one of the primary reasons consumers do not perceive whole grain foods to be as necessary and beneficial to the diet as fruits and vegetables. According to a recently conducted

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Intakes by Individuals and 1994-1996 Diet and Health Knowledge Survey. CD-ROM.

[18]Contribution to this 1 serving derived from a variety of foods including breads, snacks, ready-to-eat cereals, hot cereals, sweet snacks/pancakes, and rice/pasta/tortillas. *Id.*

[19] *Id.*

[20]Albertson, *supra* note 14.

[21] *Id.*

[22]An example of a promotional campaign is the "5 A Day for Better Health Program", sponsored by the National Cancer Institute and the Produce for Better Health Foundation, which encourages consumers to eat five or more servings of fruits and vegetables per day.

[23]USDA, Continuing Survey of Food Intake by Individuals, 1988-1991.

[24]USDA's 1994-96 Continuing Survey of Food Intake by Individuals and 1994-96 Diet and Health Knowledge Survey, Food Surveys Research Group, Beltsville Human Nutrition Research Center, ARS, Riverdale, MD.

[25] *Id.*

[26]Market Facts, Inc., Chicago IL, 1998 (see Attachment 1).

survey, 67 percent of consumers indicate a willingness to eat whole grain products more often if they believed they could help reduce their risk of heart disease and cancer.[27] An authoritative statement claim specifying whole grain foods as a type of plant food would help to educate consumers about whole grain foods and their benefits, and lead to more widespread and frequent consumption of whole grain foods.[28] Increased consumer awareness and demand for whole grain foods also will encourage development of more whole grain products by the food industry.[29]

In addition to approving health claims encompassing fruits, vegetables, and grains,[30] FDA also approved a health claim specific to fruits and vegetables and cancer.[31] FDA has not, however, approved a health claim specific to grains, nor whole grain foods. An authoritative statement claim highlighting whole grain foods would focus consumer attention on whole grain foods specifically, just as the fruits and vegetables health claim does for those foods. The claim would emphasize the benefits of whole grain foods as an important element of a healthy diet.

Finally, the ability to identify whole grain foods may also be a barrier to consumers achieving an adequate intake of whole grain foods. Consumers may not clearly understand which foods are significant sources of whole grains and which are not. An authoritative statement claim on qualifying products would help Americans

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[27] *Id.*

[28] General Mills research and market share data indicate increased awareness of health benefits and increased purchases of CHEERIOS® following approval and placement on the package of the soluble fiber from whole oats and CHD health claim (21 C.F.R. § 101.81). Approximately four to six months following the announcement of the approval of the soluble fiber from whole oats health claim, the CHEERIOS® base business increased 5 to 6 percent.

[29] *See* Levy, Alan S., et. al., Division of Market Studies, Center for Food and Applied Nutrition, "Consumer Impacts of Health Claims: An Experimental Study", January 1997.

[30] 21. C.F.R. § 101.76, 101.77.

[31] 21 C.F.R. § 101.78. FDA approved the fruits and vegetables/cancer claim because, although FDA did not find significant scientific agreement that antioxidant vitamins, specific component of fruits and vegetables, reduce the risk of cancer, FDA did find that the foods in their whole form may reduce the risk of cancer. Thus, FDA approved a health claim for the foods despite not knowing the exact mechanism in the foods causing the reduced risk. Similarly, even though scientists might not agree on the mechanisms that cause whole grains to have beneficial effects, scientists and governmental bodies do agree that whole grain foods may reduce the risks of CHD and certain cancers. 58 Fed. Reg. 2639 (January 6, 1993).

identify these foods across a variety of categories, while restating an important nutrient/disease relationship recognized by the NRC in the *Diet and Health* report.

## IV. Statutory Basis for Authoritative Statement Claim

Section 303 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA")[32] permits health claims without prior FDA approval if the claim refers to a relationship between a nutrient and a disease, about which a qualified governmental scientific body has published an authoritative statement. The provision requires that the scientific body making the statement belong to the United States government and have official responsibility for public health protection or research directly relating to human nutrition, or be NAS or any of its subdivisions.[33] The authoritative statement must be published, currently in effect, and about the nutrient and disease or health-related condition to which the claim refers.[34] The claim and its referenced food must comply with existing regulations.[35] The claim must accurately represent the authoritative statement so as to enable the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of the total daily diet.[36]

## V. The Authoritative Statement Claim

General Mills intends to make the following model authoritative statement claim:

> **Low fat diets rich in whole grain foods and other plant foods may reduce the risk of heart disease and certain cancers.**

The authoritative statement claim is based on the authoritative statement made in the

[32] 21 U.S.C. 343(r)(3).
[33] 21 U.S.C. 343(r)(3)(C)(i).
[34] *Id.*
[35] 21 U.S.C. 343(r)(3)(C)(iii).
[36] 21 U.S.C. 343(r)(3)(C)(iv).

NAS publication, *Diet and Health: Implications for Reducing Chronic Disease Risk.*[37] This report states that **"(d)iets 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."**[38] Furthermore, it states that the mechanisms for this effect, although not fully understood, might be explained by the low saturated fatty acid and cholesterol content of such diets, as well as high levels of complex carbohydrates, certain vitamins and minerals, trace elements, and nonnutritive constituents. [39]

For purposes of this claim, "whole grain foods" means foods which contain 51 percent or more whole grain ingredient(s) by weight per Reference Amount Customarily Consumed ("RACC").[40] To consider a food as a "whole grain food", whole grain should be present in sufficient quantity to characterize the food. The "whole grain foods" definition conforms to the policy that a food is characterized by its predominant ingredient(s).[41] Such a definition also ensures that the food provides a minimum of 16 grams of whole grain (the equivalent of a whole grain food serving under the USDA's research relating to the Food Guide Pyramid).[42]

The definition measures whole grain percentage by weight per RACC because the RACC provides a consistent point of reference for foods of the same type. The

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[37] DIET AND HEALTH, *supra* note 9 (See Attachment 2).
[38] *Id.*
[39] *Id.*
[40] General Mills interprets the term "whole grain foods" to be interchangeable with the term "whole grain products". Note that foods bearing the claim must also be low in fat and meet the other general health claim requirements of 21 C.F.R. § 101.14.
[41] *See* letter to Dr. Michael F. Jacobson, Center for Science in the Public Interest, from David A. Kessler, M.D., Commissioner of Food and Drugs, Food and Drug Administration, November 1, 1993. The Commissioner was responding to a citizen's petition requesting that FDA regulate the use of the term "whole wheat." Although General Mills does not adopt the petition in its entirety, the whole grain foods definition suggested here parallels the proposal to limit the "whole wheat" claim to products containing whole wheat flour as the predominant ingredient. For an analogous example, *see* 7 U.S.C. 6505(c)(1); the Organic Foods Production Act of 1990 characterizes a food as "organic" if it contains at least 50 percent organically produced ingredients.
[42] USDA Pyramid Servings Data, *supra* note 17.

RACC currently serves as the measurement standard for other health claims.[43] Furthermore, the RACC measurement produces a better representation of the foods providing whole grain benefits because the RACC, unlike the serving size, will not result in foods being disqualified merely due to moisture content. For example, using bread's standard serving size of 30 – 35 grams, the majority of whole grain breads would not qualify as whole grains foods. However, using the 50 gram RACC, whole grains breads, which serve as important sources of whole grains, do qualify for the claim.

Compliance with the "whole grain foods" definition will be determined by reference to the fiber level of whole wheat. Whole wheat is the predominant grain in the U.S. diet, containing 11 grams of fiber per 100 grams of whole wheat. The fiber content creates a measure by which FDA can ensure that a product meets the definition; at the specified levels of fiber, whole grains clearly constitute the predominant ingredient(s). Thus, compliance can be verified by comparing the food's fiber content to the following compliance formula: (11 grams x 51% x RACC) /100. For example:

(11 grams x 51% x 55 grams)/100 = 3.0 grams fiber

(11 grams x 51% x 50 grams)/100 = 2.8 grams fiber

(11 grams x 51% x 45 grams)/100 = 2.5 grams fiber

(11 grams x 51% x 30 grams)/100 = 1.7 grams fiber

The fiber level will be determined according to the methods and procedures set forth in 21 C.F.R. § 101.9(g)(2).

General Mills intends to display this authoritative statement claim on the labels of qualifying whole grain cereals listed in Attachment 3, as well as Pop Secret 94% Fat Free popcorn.[44] General Mills asserts that to the best of its knowledge, labels bearing the claim will not be false or misleading. General Mills also asserts that to the best of its knowledge, foods bearing the claim will comply with the provisions of 21 C.F.R.

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[43] 21 C.F.R. §§ 101.76, 101.77, 101.81.

[44] Attachments 3 and 4 also set forth other products that would be eligible to bear the claim.

§ 101.14.

This claim qualifies as an authoritative statement claim by referring to a relationship, between a nutrient and a disease, about which a qualified scientific body has published an authoritative statement. The claim refers to the relationship between whole grain foods and CHD and certain cancers.[45] The statement was made by NRC, a subdivision of NAS, and published by NAS in the *Diet and Health* report. NAS and its subdivisions are specifically cited by the FDAMA provision as qualified scientific bodies.[46]

The statement qualifies as authoritative because it reflects a deliberative review of plant foods, including whole grain cereals, and their relationship to CHD and cancer. The *Diet and Health* report constitutes a comprehensive analysis of the scientific literature and of the strength of evidence on major associations between diet and diseases undertaken by the NRC's 19-member Diet and Health Committee. Committee members possessed expertise in areas including biochemistry, biostatistics, clinical medicine, epidemiology, foods and food consumption patterns, human genetics, metabolism, nutrition, public health, and toxicology.[47] The Committee's conclusions on foods containing complex carbohydrates derived from a review of direct and indirect evidence, including epidemiologic, animal, and human studies related to carbohydrates, dietary fiber, fat-soluble vitamins, water-soluble vitamins, cholesterol, and fat intake.[48] The report was reviewed by additional scientists using procedures approved by the

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[45]Although FDAMA stipulates that the statement relate to a "nutrient", FDAMA also stipulates that the claim be made "with respect to" a food. Thus, a claim about a type of food containing a particular nutrient would qualify. Furthermore, in FDA's health claim regulations, FDA permits claims for "substances," including foods that refer either expressly or implicitly to a substance within the food, *i.e.*, fiber-containing fruits and vegetables. 58 Fed. Reg. 2478, 2480 (January 3, 1993).

[46]FDA requests that an authoritative claim notification provide additional proof of consensus within a scientific body if a subdivision of the body made the statement. *See* "Guidance for Industry Notification of a Healthy Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body," June 11, 1998, at 2. However, because FDAMA specifies that NAS subdivisions themselves qualify as acceptable scientific bodies, there is no need to further demonstrate consensus.

[47]DIET AND HEALTH, *supra* note 9, at x.

[48]*Id.* at 8.

NAS, National Academy of Engineers, and Institute of Medicine Report Review Committee.[49]

The 1989 report makes clear that the whole grain foods/CHD and cancer relationships have been recognized for at least ten years. The most current scientific literature supporting these relationships, along with the absence of contradictory literature or statements, show that the statement is currently in effect. Furthermore, the statement does not merely reflect preliminary results, inconclusive research, or guidance for future research. As is clear from the statement itself, the context of the statement in the report, and the relevant scientific literature, the statement reflects conclusive scientific consensus supporting the relationship. In fact, as stated in the report, any uncertainty about the effects of whole grain foods relates solely to details about the particular *mechanisms* that contribute to or cause the health benefits, not to the effects of plant foods including whole grain foods on CHD and certain cancers. Thus, under FDAMA, this statement creates a valid basis for an authoritative statement claim.[50]

The claim itself accurately represents the authoritative statement. The authoritative statement acknowledges the benefit of diets high in plant foods, including whole grain cereals, fruits, vegetables, and legumes. The claim parallels the statement by recognizing the value of diets rich in plant foods, and highlights one type of plant food mentioned in the statement: whole grain foods.[51] Although the claim specifically

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[49] *Id.* at *ii.*

[50] *See id.*, at 8. Although FDA had available the *Diet and Health* report in 1993 when it reviewed the existing research regarding diet/disease relationships for potential health claims under the Nutrition Labeling and Education Act, FDA did not review the literature with whole grain food claims in mind. FDA responded to Congress's mandate to review certain nutrients and foods for potential claims, and these did not include whole grains. Thus, FDA concentrated on the mandated nutrients with particular attention to fruits and vegetables, not whole grain foods. The *Diet and Health* report statement represents a comprehensive review of plant foods and whole grains, and the current scientific literature supports this statement.

[51] While the claim uses the term "whole grain foods", the authoritative statement references "whole grain cereals." However, the term "whole grain cereals" encompasses all whole grains such as barley, oatmeal, rye, and other whole grains. *See* M.J. Hill (1997), "Cereals, Cereal Fibre and Colorectal Cancer Risk: A Review of the Epidemiological Literature," *European Journal of Cancer* 6: 219-225, Benito, et. al.,

recognizes one example of plant foods from the statement, the claim does not ignore the importance of all plant food types in the diet, and encompasses other plant foods such as fruits, vegetables, and legumes, through the term "plant foods". As does the statement, the claim recognizes the benefits to both CHD and certain cancers.[52]

Finally, the claim enables the public to comprehend the information provided in the claim and to understand its relative significance in the context of the total daily diet. The claim specifies whole grain foods as a type of plant food, because consumers are more apt to perceive fruits and vegetables as plant foods, than to perceive whole grain foods as plant foods. However, the claim makes it clear that a diet low in fat and high in whole grain foods should include other plant foods.

## VI. Scientific Literature Relating to Whole Grain Foods/Disease Relationships[53]

The *Diet and Health* report provides strong evidence that diets high in plant foods reduce the risk of CHD and certain cancers. The report includes whole grain foods in its examples of plant foods, and strong evidence verifies that whole grain foods are an

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"A Population-Based Case-Control Study of Colorectal Cancer in Majorca. I. Dietary Factors", *International Journal of Cancer* 45:69-76, 1990. Because the proposed definition of "whole grain foods" requires 51 percent whole grain components, "whole grain foods" merely characterizes the food group that contains significant amounts of "whole grain cereals". Consumers will benefit more from use of the term "whole grain foods" because consumers often identify "cereals" with a narrower group of breakfast food that does not include other foods containing whole grains, such as bread and rice.

[52]Under the statute, a health claim refers to "a nutrient" and "a disease". However, under FDA's health claim regulations, health claims refer to the relationship between a substance and a disease, because FDA inferred that Congress intended to permit health claims for substances other than just nutrients. 58 Fed. Reg. at 2480. Similarly, Congress clearly did not state nor intend to exclude from the definition of health claim any claims that refer to more than one disease, but rather intended that any claims about the relationship between a nutrient and a disease qualify as health claims. Furthermore, already-approved claims such as the cancer claims and the folic acid claim encompass several diseases (different types of cancers, and anencephaly and spina bifida). 21 C.F.R. § 101.73(a), 101.79(a). Finally, if FDA adopted a policy that health claims can only refer to one disease despite the proven benefits for more than one disease, manufacturers would be forced to include several claims on their labels, making the claims less effective and potentially leading to consumer confusion. Thus, the proposed claim not only mimics the authoritative statement, but reflects Congress's clear intent that claims may encompass more than one disease.

[53]*See* Attachment 5 for a comprehensive bibliography of scientific literature on the relationship of whole grain foods to CHD and certain cancers (short cites in the text and footnotes, consisting of the author's last name and year of publication, are cited in full in the bibliography).

integral part of a diet high in plant foods.[54] The *Diet and Health* report reaches its conclusions based on numerous studies existing at the time documenting the association between whole grain food intake and reduced risk of CHD and certain cancers. These relationships continue to be supported by scientific literature published since the *Diet and Health* report (*see e.g.*, Chatenoud, et. al., 1998; Hill, 1998; Jacobs et. al., 1998; Slavin et. al., 1997; Hill, 1997; Jacobs, et. al., 1995).

The studies consistently demonstrate reduced risk for cancer and CHD when demographic and other lifestyle factors (fruits and vegetables, energy and exercise) are controlled or adjusted in the statistical model, and regardless of the dietary questionnaire used to collect dietary data. For example, the findings are consistent for males and females across a variety of populations in the United States and Europe, and consistent in countries with dietary consumption patterns ranging from relatively high to low whole grain food intake. The scientific evidence is strongest for those studies that assess digestive cancers; however, the consistency and magnitude of association is similar to other types of cancer. Studies which examined the effect of whole grain food consumption on lower blood cholesterol levels further support the inverse relationship between higher whole grain intake and reduced risk for CHD. Thus, the studies reflect significant scientific agreement that low-fat diets rich in whole grain foods may help reduce the risk of CHD and certain cancers.

### A. Supporting Scientific Evidence: Cancer

Thirty-seven case-control studies, one ecologic study, and three review articles published to date pertaining to whole grain food intake support a relationship between whole grain intake and reduced risk for various types of cancer (Chatenoud, et. al.,

[54] Kune, 1987; Potter, J.D., "Food and Phytochemicals, Magic Bullets and Measurement Error: A Commentary", *American Journal of Epidemiology* 1996;144:1026-1027; Reddy, B.S., "Diet and Colon Cancer: Evidence From Human and Animal Model Studies, *in* B.S. Reddy and L.A. Cohen, eds. "Diet, Nutrition, and Cancer – A Critical Evaluation", Vol. 1: Macronutrients and Cancer, CRC Press: Boca Raton, FL, 1986; Slavin, 1997.

1998; Jacobs, et. al., 1998; Goodman, et. al., 1997; Slattery, et. al., 1997; Slavin, et. al., 1997; Tavani, et. al., 1997; Witte, et. al., 1996; Jacobs, et. al., 1995; Giles, et. al., 1994; Boeing, et. al., 1993; Hansson, et. al., 1993; Levi, et. al., 1993; Levi, et. al., 1993; Bidoli, et. al., 1992; Franceschi, et. al., 1992; Tuyns, et. al., 1992; Boeing, et. al., 1991; Boeing, et. al., 1991; Bueno de Mesquita, et. al., 1991; Franceschi, et. al., 1991; Serraino, et. al., 1991; Wu-Williams, et. al., 1990; Franceschi, et. al., 1989; LaVecchia, et. al., 1989; Olsen, et. al., 1989; Peters, et. al., 1989; LaVecchia, et. al., 1988; LaVecchia, et. al., 1988; McLaughlin, et. al., 1988; Tuyns, et. al., 1988; Yu, et. al., 1988; Decarli, et. al., 1987; LaVecchia, et. al., 1987; LaVecchia, et. al., 1987; LaVecchia, et. al., 1986; Mack, et. al., 1986; Gold, et. al., 1985; Rosen, et. al., 1988; Trichopoulos, et. al., 1985; Pickle, et. al., 1984; Winn, et. al., 1984). Only three studies do not support such a relationship (Centonze, et. al., 1994; Talamini, et. al., 1992; LaVecchia, et. al., 1987). Of these studies, one used a daily dose of whole grain too low to show an association with colon cancer (Centonze, et. al., 1994), and the other two studies (on breast and prostate cancer) had odds ratios under 1.0.

In addition, twenty-four studies of cereals/cereal fiber support an inverse relationship with colon cancer (Hill, 1998; Hill, 1997; Olsen, et. al., 1994; Meyer and White, 1993; Zaridze, et. al., 1993; Arbman, et. al., 1992; Thun, et. al., 1992; Freudenheim, et. al., 1990; Willett, et. al., 1990; Heilburn, et. al., 1989; Kune, et. al., 1987; Risch, et. al., 1985; McKeown-Eyssen and Bright-See, 1984; Englyst, et. al., 1982; Jensen, et. al., 1982; Bingham, et. al., 1979; Liu, et. al., 1979; Yanai, et. al., 1979; IARC Working Party, 1977; Knox, 1977; Schrauzer, 1976; Howell, et. al., 1975; Armstrong, et. al., 1974; Irving and Drasar, 1973).[55] Seven do not, of which most were foreign studies in countries where the intake was probably not high enough to reduce

[55]Substantial evidence exists in whole grain studies to demonstrate scientific agreement about the benefits of whole grain foods. In addition, throughout time, numerous studies on whole grain wheat referred to whole grain as "cereal fiber". *See* Hill, 1997, at 223. Thus, cereal fiber study results pertain to whole grain foods and should be included in any evaluation of whole grain studies.

colon cancer risk (Benito, et. al., 1990; Freudenheim, et. al., 1990; Macquart-Moulin, et. al., 1986; Potter and McMichael, 1986; Bingham, et. al., 1985; Miller, et. al., 1983; Martinez, et. al., 1975). Taken as a whole, these studies demonstrate the significant scientific agreement linking whole grain food intake to reduced cancer risk.

An analysis of the scientific literature published between 1984 and 1997 (Jacobs, et. al., 1998) evaluating the relationship between various forms of whole grain food intake and 20 types of cancer, and using a statistical analysis controlling for confounding variables (demographic, BMI, lifestyle behaviors, reproductive and/or dietary factors), indicates the following:

(1) Reduced risk for cancer is observed for higher whole grain food intake despite the type of dietary intake methodology used.

(2) There is a strong consistency and moderately strong magnitude of association (approximately 30%) between whole grain food intake and reduced risk for cancer.

(3) There is a moderately strong dose-response relationship between increased whole grain food intake and reduced risk for various cancers.

(4) The association between whole grain food intake and reduced risk of cancer persists even when other confounding variables (e.g. diet, exercise, smoking, alcohol use) are controlled. Confounding with other dietary and lifestyle factors does not explain the apparent protective effect of whole grain foods against cancer. Many studies tested associations for confounding with a variety of variables; risk indicators for high versus low whole grain food intake did not decrease as the number of adjusting factors increased.

Of particular significance is a very recent study finding that a higher frequency of whole grain food intake is an indicator of reduced risk of several neoplasms. Using data from an integrated series of case-control studies conducted in northern Italy between 1983 and 1996, Chatenoud, et. al. (1998) found with statistical significance that high

intake of whole grain foods consistently reduced risk of neoplasms by 30-70% (oral cavity and pharynx, esophagus, stomach, colon, rectum, liver, gallbladder, larynx, breast, ovary, prostate, bladder, kidney, and non-Hodgkin's lymphomas). No significant heterogeneity was found for age of diagnosis, gender, education, smoking habits, alcohol intake, and body mass index. The study found only negligible effects of fruits and vegetables on the association of whole grain food intake and reduced risk for these cancers.

**B. Supporting Scientific Evidence: Coronary Heart Disease**

The available scientific evidence clearly supports the relationship between higher whole grain food intake and reduced risk of CHD. Large prospective epidemiological studies which controlled for demographic and other lifestyle variables demonstrate an inverse association for CHD with high versus low whole grain food intake. In addition, ecologic and case-control studies, along with experimental and clinical interventions, have shown a positive effect on CHD risk factors with higher whole grain food intake.

To date, fourteen studies support the relationship between whole grain foods and reduced risk of CHD and CHD risk factors (Jacobs, et. al., 1998; Johnston, et. al., 1998; Appel, et. al., 1997; Pietinen, et. al., 1996; He, et. al., 1995; Fraser, et. al., 1992; Ripsin, et. al., 1992; Davidson, et. al., 1991, Van Horn, et. al., 1991; Reynolds, et. al., 1989; Van Horn, et. al., 1988; Van Horn, et. al., 1986; Fraser, et. al., 1981; De Groot, et. al., 1963). Only two studies do not support the relationship (Gramenzi, et. al., 1990; Judd and Truswell, 1979).[56] Ten published studies on whole grain cereal fiber support the relationship (Salmeron, et. al., 1997; Salmeron, et. al., 1997; Rimm, et. al., 1996; Ripsin, et. al., 1992; Davidson, et. al., 1991; Karlstrom, et. al., 1984; Burr and Sweetnam, 1982;

[56]The *Diet and Health* report considered the Judd et. al., 1979 study and still concluded that whole grain foods reduce CHD risk. Similarly, the Gramenzi, et.al.1990 study has not changed perceptions of the overwhelming evidence that whole grain foods reduce CHD risk.

Anderson and Ward, 1979; Morris, et. al., 1977; Knox, 1977).[57]

The studies on the effects of whole grain foods and cereal fiber on CHD indicate:

(1) Strong prospective epidemiological evidence supporting the association between whole grain foods intake and reduced risk for CHD. De novo analyses conducted in the large prospective Iowa Women's Health Study (Jacobs, 1998), and a Finnish study of rye food intake, suggest whole grain food intake reduced risk for CHD by about 25-30 percent (Pietinen, et. al., 1996). Another prospective study of Seventh Day Adventists (Fraser, et. al., 1992) reported reduced CHD risk in those who preferred whole grain bread to white bread. A large prospective study, Rimm et. al. (1996) examined the association between whole grain cereal fiber intake and risk for myocardial infarction ("MI"). Cereal fiber was associated with reduced risk for MI with 29% decrease in risk for each 10 grams increase in cereal fiber intake.

(2) Strong clinical evidence indicating that whole grain foods modify risk factors for CHD. Numerous randomized clinical studies have demonstrated that whole grain oats reduce total blood cholesterol (Johnston, et. al., 1998; Van Horn, et. al., 1991; Reynolds, et. al., 1989; Van Horn, et. al., 1988; Van Horn, et. al., 1986). Another study by Fraser et. al. (1981) found a reduction of 9 mg/dl in serum cholesterol using a diet containing whole wheat (40 g/day), popcorn and cornmeal plus germ (30 g/day), and oatmeal (30 g/day).

Several studies demonstrate an association between cereal fiber intake and reduced risk for diabetes--a major risk factor for CHD. (Salmeron, et. al., 1997; Salmeron, et. al., 1997). This research further suggests whole grain foods should be consumed, rather than consuming grains lower in known and unknown protective components. In the dietary clinical trial DASH (Appel, et. al., 1997), whole grain foods administered as part of a total diet elicited a blood pressure reduction of both systolic and diastolic pressures by 5.5/3.0 mm Hg. Although total grain intake did not differ

[57] *See* note 55.

between treatment groups, whole grain foods were increased in the DASH dietary pattern (Sacks, et. al., 1995) as well as fruits, vegetables and low fat dairy products.

(3) One clinical study has directly assessed the effect of whole grain food intake on risk for CHD. The randomized clinical trial, DART, linked the effect of whole-grain intake to a clinical outcome (Burr, et. al., 1989; Burr, et. al., 1989). While DART results are not definitive in ascribing health benefits to whole grain foods intake alone, the results are supportive of the notion that whole grain foods intake together with other healthful dietary practices (which is the context of the authoritative statement claim proposed) may be beneficial. Based on clinical, prospective, and experimental studies, the weight of evidence indicates whole grain foods consumption reduces risk for CHD.

### C. Potential Whole Grain Food Mechanisms

The exact mechanisms for whole grain food action are not known. The physiological and nutrient roles of the whole grain food constituents have not been defined, but it is likely that at least some of the constituents act synergistically when consumed by humans.[58] In fact, it is considered advantageous to consume the nutrients and non-nutrients found in whole grains in the native whole grain form, as many potentially important whole grain components are not present in refined grains.[59] Numerous epidemiological, clinical and experimental studies support a role for individual components of whole grain foods in reducing risk for chronic diseases such as cancer and CHD.[60]

For example, poorly-absorbed carbohydrates present in whole grains such as resistant starch are fermented in the gut to short chain fatty acids, which have been shown to lower serum cholesterol and which may protect against colon cancer.[61]

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[58] Potter, *supra* note 54.
[59] Jacobs, *supra* note 2.
[60] Slavin, et. al., 1997; Thompson, L. U. "Antioxidants and Hormone-Mediated Benefits of Whole Grains." *Critical Review of Food and Science Nutrition*, 1994; 34: 473-497.
[61] Stephen, A., "Whole Grains--Impact of Consuming Whole Grains on Physiological Effects of Dietary

Whole grain components may provide a protective effect by binding carcinogenic compounds and blocking DNA damage.[62] Whole grains also are rich sources of antioxidants that can delay the onset or slow down the rate of oxidation in biological systems, and thus may reduce cancer risk.[63]

Whole grains contain nonnutrients which previously were thought to have only negative consequences. More recently, protease inhibitors, phytic acid, phenolics and saponins, all classified as nonnutrients and present in whole grains, have been found to reduce risk of cancer of the colon and breast in animal models. Phytic acid, phenolics, amylase inhibitors and saponins have been found to lower plasma glucose, insulin and/or plasma cholesterol and triglycerides.[64] Plant sterols in whole grains such as beta sitosterol may lower cholesterol in humans,[65] and tumor incidence in rats.[66]

Two recent studies emphasize that the protective effects of whole grains may reflect in part unknown or unmeasured dietary constituents in whole grain foods (Slattery, et. al., 1997; Witte, et. al., 1996). After controlling for several nutrients and other constituents abundant in whole grains, these studies found that whole grain food intake remained protective against polyps and colon cancer in men. These findings

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Fiber and Starch," in Clydesdale, F.M. ed. Critical Reviews in Food Science and Nutrition 1994; 34:499-511; McIntyre, A., Gibson, P.R., and G.P. Young, "Butyrate Production From Dietary Fibre and Protection Against Large Bowel Cancer in a Rat Model." *Gut*, 1993; 34:386-391; Cummings, J., Bingham S., Heaton, K., Eastwood, M. "Fecal Weight, Colon Cancer Risk and Dietary Intake of Nonstarch Polysaccharide (Dietary Fiber). *Gastroenterology*, 1992; 103:1783-1787.

[62] Wattenberg, L.W., "Chemoprevention of Cancer By Naturally Occurring and Synthetic Compounds." *Proceedings of the American Association of Cancer Research*, 1990; 32:461-463; Wattenberg, L. W., "Chemoprevention of Cancer." *Cancer Research*, 1985; 45:1-8.

[63] Thompson, *supra* note 60.

[64] Onyeneho, S.N., and N. S. Hettiarachchy, "Antioxidant Activity of Durum Wheat Bran." *Journal of Agricultural Food Chemistry*, 1992; 40:1496-1500; Steinmetz, K.A., and J.D. Potter, "Vegetables, Fruit, and Cancer. II. Mechanisms." *Cancer Causes and Control*, 1991; 2:427-442.

[65] Jones, P.J., MacDougall, D.E., Ntanios, F., and C.A. Vanstone, "Dietary Phytosterols as Cholesterol-Lowering Agents in Humans." *Canadian Journal of Physiology & Pharmacology*, 75:217-27, 1997; Heinemann, T., Leiss, O., and K. von Bergmann, "Effect of Low-Dose Sitostanol on Serum Cholesterol in Patients with Hypercholesterolemia." *Atherosclerosis*. 1986; 61:219-223; Mattson, F.H., Grundy, S.M., and J.R. Crouse, "Optimizing the Effect of Plant Sterols on Cholesterol Absorption in Man." *American Journal of Clinical Nutrition*, 1982; 35:697-700.

[66] Raicht, R.F., Cohen, B.I., Sarwal, A.N., Fazzini, E.P., Takahashi, M., "Protective Effect of Plant Sterols Against Chemically Induced Colon Tumors in Rats", *Cancer Research*, 1980; 40;403-405.

suggest that any protective effect of whole grains on cancer does not simply reflect dietary fiber or commonly measured antioxidants in foods.[67] Unknown constituents of whole grain foods may be protective, and constituents may act synergistically (Slavin, et. al., 1997; Jacobs, et. al., 1995: Jacobs et. al.,1998).

### D. Scientific Conclusion

Based on epidemiological studies and known biologically plausible mechanisms identified in feeding and physiological studies, the scientific evidence shows that whole grain foods intake provides a health benefit in terms of reduced rates of CHD and several forms of cancers. Taken as a whole, the epidemiologic and constituent studies are consistent in finding that people who eat more whole grain foods have a reduced risk of CHD and cancer compared to people who eat less whole grain foods. Thus, there is significant scientific agreement that diets rich in whole grain foods are associated with a decreased risk of CHD and some types of cancer. Given the current scientific hypothesis that plant food diets involve components of whole grain foods, legumes, fruits, and vegetables that may work synergistically,[68] it would be prudent for Americans to eat more whole grain foods.

## VII. Consistency with Currently Authorized Health Claims

FDA has taken the view that if the agency has already approved a health claim for a nutrient/disease relationship, then a prospective authoritative statement claim must not conflict with the previous claim.[69] In a recent authoritative statement health claim notification, FDA found that a proposed claim about calcium increasing bone density to prevent fractures was not consistent with an already existing claim because the

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[67] Potter, *supra* note 54.
[68] Jacobs, et. al., 1998; Slavin, et. al., 1997; Potter, *supra* note 54, Kune, et. al., 1987; Reddy, et. al., 1986.
[69] 63 Fed. Reg. 34084 (June 22, 1998).

proposed claim mischaracterized the mechanism by which calcium consumption reduces the risk of osteoporosis.[70] Unlike that claim however, the whole grain foods claim is consistent with, and complements, existing claims. The whole grain foods claim is consistent with already-approved claims about (1) dietary lipids and cancer;[71] (2) saturated fat and cholesterol and risk of CHD;[72] (3) fiber-containing grain products, fruits, and vegetables and cancer;[73] (4) fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of CHD;[74] (5) fruits and vegetables and cancer;[75] and (6) soluble fiber from whole oats and risk of CHD.[76]

First, the whole grain foods claim complements both the dietary lipids/cancer claim and the saturated fat and cholesterol/CHD claim. Whole grain foods are low in both fat and cholesterol, and thus, the whole grain foods claim is consistent with the fat and cholesterol claims. The fat and cholesterol claims however, do not specify qualifying foods in the model claims. The whole grain foods claim complements the fat and cholesterol claims because it specifies whole grain foods as desirable foods, and thus educates consumers about a food type they should seek and recognize in order to make healthy food choices. Furthermore, the whole grain foods claim effectively combines two diseases, cancer and CHD, so consumers focus their attention on the importance of whole grain foods, rather than get confused by two different claims each specifically referring to whole grain foods.

The whole grain foods claim is consistent with and complements the fruits and vegetables/cancer claim. Experts have consistently cited diets rich in fruits and vegetables and whole grains as beneficial in preventing cancer. The existing fruits and vegetables claim separates fruits and vegetables specifically from the

[70] *Id.*
[71] 21 C.F. R. §101.73.
[72] 21 C.F.R. § 101.75.
[73] 21 C.F.R. § 101.76.
[74] 21 C.F.R. § 101.77.
[75] 21 C.F.R. § 101.78.
[76] 21 C.F.R. § 101.81.

fruits/vegetables/grains claim, focusing consumer attention solely on fruits and vegetables and making clear that consumers should choose fruits and vegetables. Thus, the whole grain foods claim will impress upon consumers that whole grains themselves are an important component of the diet and that consumption of fruits and vegetables alone does not eliminate the need to consume whole grain foods.

The whole grain foods claim is also consistent with, and complementary of, the fiber-containing grain products, fruits,- and vegetables/cancer claim and the fruits, vegetables, and grains containing fiber/CHD claim. The existing claims reference grains generally, but do not reference whole grains specifically. The whole grain foods claim emphasizes the importance of whole grain foods, because whole grains confer special benefits beyond those conferred by all grains. Authoritative bodies recognize the need for whole grain foods specifically, and recommend that whole grain foods comprise a portion of the recommended grain foods consumed each day.[77]

The whole grain foods claim will allow consumers to focus on the benefits of whole grain foods in the diet. A consumer study conducted by General Mills showed the benefits of the proposed claim in increasing consumer awareness of whole grain foods.[78] Consumers viewed either one of the already-existing "fruits, vegetables, and grain products" claims, or a claim referencing "whole grain cereals and other plant foods." Consumers were then asked for unaided recall of the message conveyed. More than twice as many consumers mentioned "whole grains" as unaided recall from the "whole grain cereals and other plant foods" claim than from the other two claims. Clearly, the proposed claim would draw more consumer attention to the benefit of whole grain foods than that drawn by already-existing claims.

The whole grain foods claim complements the fiber-containing food health claims and the above soluble fiber from whole oats claim,[79] because it incorporates whole grain

[77] *See, e.g*, NUTRITION AND YOUR HEALTH, *supra* note 1, at 25.
[78] See Attachment 6.
[79] 21 C.F.R. § 101.81.

foods rather than grain products containing fiber. "Whole grain foods" is not only broader than "fiber", but has different connotations from fiber. "Whole grain foods" will likely appeal to more consumers than the term fiber. Consumers associate fiber with bran, unfavorable taste, and laxation. Thus, consumers might not choose to consume fiber for fear of unfavorable effects, and might recognize a need for fiber only if they suffer from gastrointestinal ailments. However, by using the broader term "whole grain foods", consumers will recognize a type of food that provides substantial health benefits to the general population beyond fiber.

Although fiber is one component of whole grain foods that may contribute to reducing the risk of CHD and some cancers, the effects of whole grain foods on these diseases do not likely result from the fiber content alone.[80] FDA itself has stated that fiber is not the only component of whole grains that affects serum lipids and thus, CHD ("ß-glucan soluble fiber is the primary, but not the only, component in whole oats that affects serum lipids").[81] Furthermore, FDA denied a dietary fiber/cancer health claim because FDA recognized that scientific evidence does not indicate conclusively that fiber itself reduces cancer risks.[82] However, FDA permits claims for certain foods containing fiber because FDA acknowledges that a low fat diet rich in these foods reduces cancer risks.[83]

Like with fiber-containing foods, scientists do not know the exact mechanisms of

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[80] NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, CARCINOGENS AND ANTICARCINOGENS IN THE HUMAN DIET, 1993, at 83 (stating that the beneficial effects of whole grains may be due to lignan precursors and other phytoestrogens); UNITED STATES DEPARTMENT OF AGRICULTURE AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, EATING RIGHT WITH THE DIETARY GUIDELINES, 1992 (stating that "some of the benefit from a high fiber diet may be from the food that provides the fiber, not from the fiber alone"); COMMITTEE ON DIET AND HEALTH, FOOD NUTRITION BOARD, COMMISSION ON LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK, National Academy Press, Washington D.C., 1989, at 8 (stating that certain diets, including those rich in whole-grain cereals, lowering the occurrence of heart disease and certain cancers may be explained by the high levels of complex carbohydrates, vitamins, minerals, trace elements, and nonnutritive constituents).
[81] 62 Fed. Reg. 3584, 3585 (January 23, 1997).
[82] 58 Fed. Reg. 2537 (January 6, 1993).
[83] *Id.*

the beneficial effects of whole grain foods. However, studies suggest that fiber alone does not cause the beneficial effects of whole grains on certain cancers and CHD.[84] Thus, this authoritative statement claim is both different from, and broader than, existing health claims for fiber products in that it addresses a low fat diet containing whole grain foods and other plant foods. This authoritative statement claim is not inconsistent with, and properly complements, the fiber-containing foods claims and other already-approved health claims.

## VII. Conclusion

For many years, significant scientific agreement has supported the proposition that consuming a low fat diet rich in whole grain foods and other plant foods may help reduce the risk of CHD and certain cancers. The NRC, a scientific body qualified to make an authoritative statement under FDAMA, published an authoritative statement about this relationship in its *Diet and Health* report. *Diet and Health* represents a deliberative review of the scientific evidence on diet and disease relationships. Current literature shows that significant scientific agreement on this relationship continues to exist today.

Despite repeated recommendations by scientists and government bodies to consume more whole grain foods, consumption of whole grain foods remains low. The proposed authoritative statement claim for whole grain foods will raise consumer awareness of whole grain foods and their benefits. The claim will encourage consumer adherence to dietary recommendations and thus, will further important government goals and policies to enhance public health.

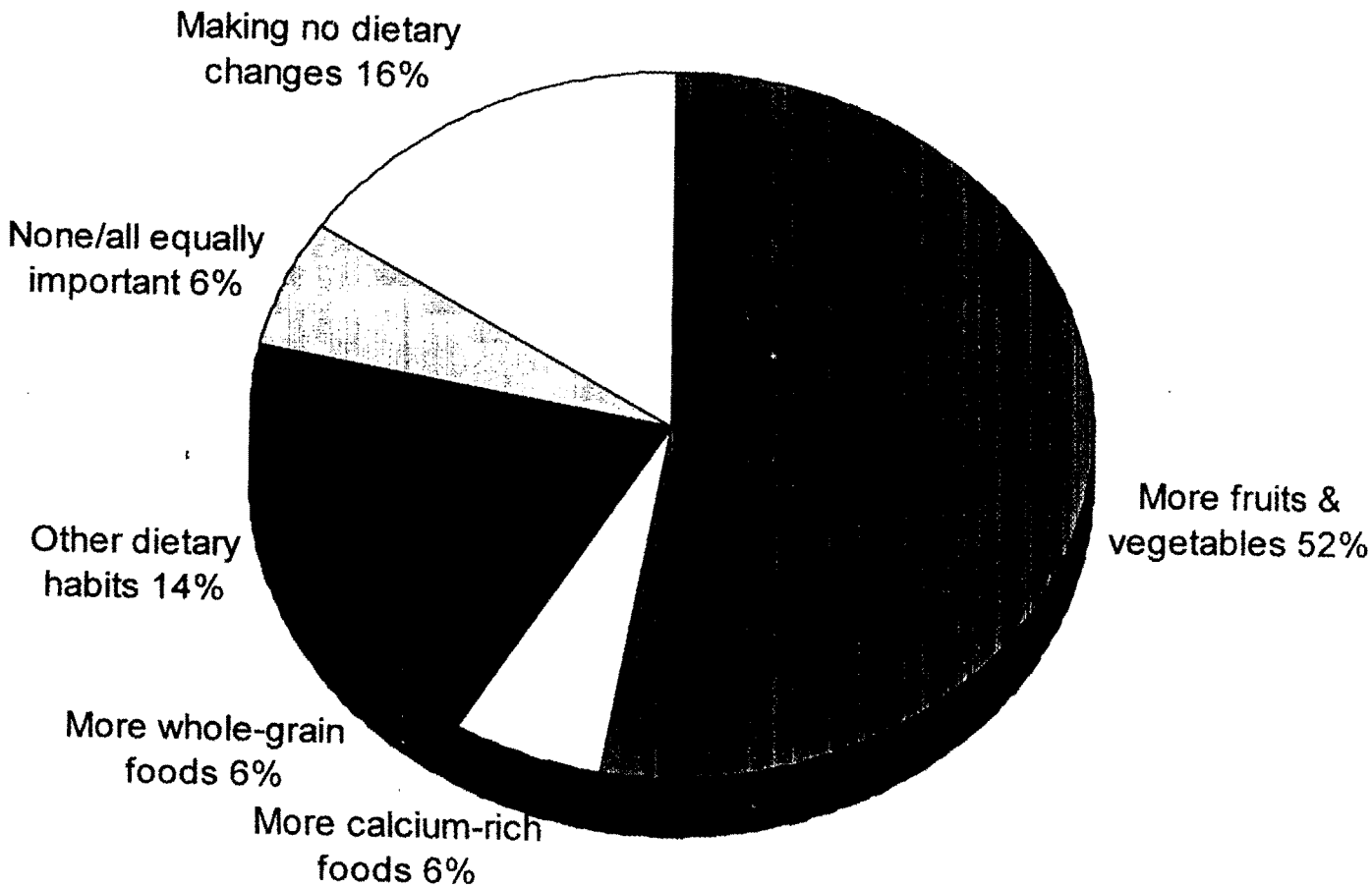
Respectfully submitted,

General Mills, Inc.

[84] *See* Section VI.C. above for the potential mechanisms that may contribute to the beneficial effects of whole grain foods.

ATTACHMENT 1

# Dietary habit which is most important




Market Facts Inc., Chicago, IL 1998

3

# Qualifying Whole Grain Products*
## Cereals

| Product | RACC Serving (grams) | Whole Grain (grams) | Fiber (grams) |
|---|---|---|---|
| **GMI** | | | |
| Wheat Chex | 55 | 46 | 4.9 |
| Crispy Wheaties & Raisins | 55 | 35 | 3.8 |
| Oatmeal Crisp with Raisins | 55 | 33 | 3.3 |
| Cheerios | 30 | 28 | 2.8 |
| Wheaties | 30 | 27 | 3.4 |
| Whole Grain Total | 30 | 26 | 3.0 |
| Oatmeal Crisp with Apple | 55 | 21 | 2.9 |
| Multigrain Cheerios Plus | 30 | 18 | 1.8 |
| **Kellogg's** | | | |
| Healthy Choice Toasted Brown Sugar Squares | 55 | 49 | 5.3 |
| Raisin Squares | 55 | 41 | 4.4 |
| Frosted Mini Wheats Bite Size | 55 | 40 | 4.3 |
| Frosted Mini Wheats | 55 | 40 | 4.3 |
| Nutrigrain Almond Raisin | 55 | 39 | |
| Apple Cinnamon Squares | 55 | 37 | 4.0 |
| Low Fat Granola w/o Raisins | 55 | 32 | 3.2 |
| Healthy Choice Almond Crunch w/ Raisins | 55 | 32 | 3.4 |
| Nutrigrain Golden Wheat | 30 | 30 | 3.2 |
| **Post** | | | |
| Spoon Size Shredded Wheat | 55 | 54 | 5.8 |
| Shredded Wheat | 55 | 54 | 5.8 |
| Shredded Wheat & Bran | 55 | 54** | 5.8 |
| Fruit & Fibre Peaches /Raisins/ Almonds | 55 | 29** | 3.1 |
| Grape Nuts Flakes | 30 | 26 | 2.8 |
| Grape Nuts | 55 | 41 | 4.4 |
| Frosted Shredded Wheat – Bite Size | 55 | 24 | 2.6 |
| Raisin Bran | 55 | 20** | 2.2 |
| **Quaker** | | | |
| Shredded Wheat | 55 | 54 | 5.8 |
| Oatmeal Squares | 55 | 44 | 4.3 |
| Oatmeal, Regular (Hot) | 40 | 40 | 4.0 |
| Toasted Oatmeal Honey Nut | 55 | 36 | 3.6 |
| Natural Low Fat Granola with Raisins | 55 | 33 | 3.6 |
| Life | 30 | 18 | 1.8 |
| Cinnamon Life | 30 | 18 | 1.9 |
| **Malt-O-Meal** | | | |
| Toasty-O's | 30 | 28 | 2.8 |

*Based on USDA Food Guide Pyramid Research.

**These levels may be over estimated as they include the bran as well as whole grain.

# Qualifying Whole Grain Products*
## Breads, Snacks, Grains

| Product | RACC Serving (grams) | Whole Grain (grams) | Fiber (grams) |
|---|---|---|---|
| **Breads, Rolls** | | | |
| Whole Wheat Bread (56% WG) | 50 | 28 | 3.0 |
| Whole Wheat Pita | 50 | 34 | 3.7 |
| Whole Wheat English Muffin | 55 | 33 | 3.5 |
| Whole Wheat Bagel | 55 | 31 | 3.3 |
| Whole Wheat Roll | 50 | 29 | 3.1 |
| Whole Wheat Biscuit | 55 | 29 | 3.1 |
| **Snacks / Crackers** | | | |
| Whole Wheat Cracker (i.e.,Triscuits) | 30 | 27 | 2.9 |
| Whole wheat blend crackers (e.g. Wheat Thins) | 30 | --- | 2.0 |
| Tortilla Chips, baked | 30 | 23 | 2.2 |
| Popcorn, low fat (popped) | 30 | 27 | 4.3 |
| **Grains (Pasta, Rice, etc.)** | | | |
| Whole Wheat Tortilla | 55 | 33 | 3.5 |
| Whole Wheat Macaroni, Prepared (55gm.dry) | 140 | 32 | 3.4 |
| Whole Wheat Spaghetti, Prepared (55gm.dry) | 140 | 32 | 3.4 |
| Whole Wheat Noodles, Prepared (55gm.dry) | 140 | 28 | 3.0 |
| Wild Rice, Prepared (45gm.dry) | 140 | 34 | 2.5 |
| Brown Rice, Prepared (45 gm. dry) | 140 | 24 | 2.0-2.5 |
| Bulgur, Prepared (45gm.dry) | 140 | 33 | >3.0 |

*Based on USDA Food Guide Pyramid Research.

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# In-Store Concept Test

***Marketing Roundtables Inc. Minneapolis, MN December 1998***

## Methodology

A concept test was conducted among consumers in Minneapolis grocery stores. They were each presented one of three concepts (**code 10, code 20, or code 30).** The concept was removed, and they were asked to describe in their own words what was the main or most important message the statement was telling them.

The following claims each appeared on a board picturing four cereal boxes:

***Code 10 (FDA)*** – "Diets high in fiber-containing grain products, fruits and vegetables, and low in fat may reduce the risk of some cancers, a disease associated with many factors."

***Code 20 (FDA)*** – "Diets rich in fiber-containing grain products, fruits and vegetables and low in saturated fat and cholesterol may reduce the risk of heart disease, a disease associated with many factors."

***Code 30 (Authoritative)*** – "Diets rich in whole grain cereals and other plant foods may reduce the risk of coronary heart disease and certain cancers."

**Code 10 and Code 20** are current FDA-approved claims. **Code 30** represents the authoritative statement from the NAS Diet and Health Report (NAS, 1989).

## Results

The table below sets forth the percentages of consumers mentioning whole grain as part of their message recall.

| | Whole Grain |
|---|---|
| Code 10 (FDA) n=50 | 6% |
| Code 20 (FDA) n=50 | 12% |
| Code 30 (Authoritative) n=50 | 26% |

## Conclusion

The proposed claim (NAS, 1989), **code 30**, succeeded in more than doubling consumer recall of whole grain as part of the message.

PATTON BOGGS LLP
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July 6, 1999

VIA FACSIMILE AND REGULAR MAIL

Ms. Christine Lewis (HFS-451)
Deputy Director
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: *General Mills, Inc.; Whole Grain Foods Authoritative Statement Claim Notification*

Dear Ms. Lewis:

On behalf of General Mills, Inc. ("General Mills"), I make the following supplements to the "Whole Grain Foods Authoritative Statement Claim Notification," submitted by Patton Boggs LLP, on behalf of General Mills, on March 10, 1999. These amendments are made without prejudicing the 120-day notification period set forth in section 303 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA").[1]

## 1. Difference from Existing Claims

The notification is amended to include the following statement on page 27, immediately following the last paragraph of section VII, "Consistency with Currently Authorized Health Claims," and preceding section VIII, "Conclusion":

"The whole grain foods claim is not equivalent to any authorized health claims, including those for fiber. The whole grain foods claim refers to 'diets rich in whole grain foods and other plant foods,' as opposed to fiber-containing foods. Rather than fiber being a food component referred to in the claim as necessary for the beneficial relationship, the whole

[1] Pub. L. No. 105-115 (November, 21, 1997).



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PATTON BOGGS LLP
ATTORNEYS AT LAW



grain claim recognizes the explicit wording, and intended meaning, of the authoritative statement: whole grain foods themselves have a beneficial effect that cannot be attributed to fiber, or any other single component of the foods. Furthermore, because diets that satisfy the whole grain claim, do not necessarily satisfy the fiber claims, and vice versa, the claims are clearly mutually exclusive. Thus, the proposed whole grain foods claim satisfies FDAMA's requirements because it is appropriately based on an authoritative statement, and is not equivalent to an already-authorized health claim."

## 2. Model Claim

The model claim set forth on page 10 of the notification is amended to read:

*Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.*[2]

The amended model claim includes the concept that a diet should be low in saturated fat and cholesterol (as well as low in total fat and rich in whole grain foods and other plant foods) in order to have the potentially beneficial effects on heart disease risk.

## 3. Confidentiality

General Mills does not object to the Food and Drug Administration making public the March 10, 1999, notification, and this letter, on July 8, 1999, the day the 120-day notification period set forth in FDAMA expires and the claim takes effect.

Sincerely,

Stuart M. Pape
Counsel, General Mills, Inc.

SMP/Sro449573

[2] The claim would not need to refer to "saturated fat and cholesterol" if the disease endpoint in the claim were only "certain cancers."