

APPENDIX C

**2003 Whole Grains Health Claim Notification
(Kraft Foods)**



Kraft Foods

Sheryl A. Marcouiller
Senior Food Law Counsel
Kraft Foods North America, Inc.

<mailto:Julie.Schrimpf@cfsan.fda.gov>

Julie Schrimpf, PhD, RD
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Pkwy (HFS-830)
College Park, MD 20740-3835

November 26, 2003

Dear Ms. Schrimpf:

On August 8th, Kraft Foods North America, Inc. (Kraft) notified the Food and Drug Administration (FDA) that the company plans to use the food label to educate consumers about the well-established relationship between the consumption of whole grain foods and reduced risk of coronary heart disease. As required by section 403(r)(3)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 343(r)(3)(C), Kraft provided to FDA the authoritative statement of the Food and Nutrition Board of the National Research Council upon which the label claim will be based, along with additional detailed supporting scientific literature. FDA subsequently advised Kraft that the required notice was received on August 11th and the notification period would expire on December 9th. With this letter, we are including a petition revised to incorporate recent discussions with FDA, as confirmed in my letter dated November 3rd and in response to your subsequent request for a fully amended petition to facilitate display on the agency's web site.

The exact wording of the claim will be as follows: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may reduce the risk of heart disease." The claim will be used on foods that contain at least 51% whole grain (using dietary fiber as a marker); meet the regulatory definitions for "low saturated fat" and "low cholesterol"; bear quantitative trans fat labeling; contain less than 6.5 grams total fat and less than or equal to 0.5 grams trans fat per reference amount customarily consumed (following standard rounding rules); and meet all general requirements for health claims in 21 C.F.R. 101.14.

Respectfully submitted,

Sheryl A. Marcouiller
Senior Food Law Counsel

**Notification for a Health Claim
Based on an Authoritative Statement:
Whole Grain Foods and Heart Disease**

DATE: 08/8/2003; revised 11/25/2003

SUBMITTED BY: Jean E. Spence
Senior Vice President
Research and Development
Kraft Foods North America, Inc.
Three Lakes Drive
Northfield, IL 60093-2753

SUBMITTED TO: Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

TABLE OF CONTENTS

| | <u>Page</u> |
|---|-------------|
| I. INTRODUCTION..... | 5 |
| II. BACKGROUND—THE <i>DIET AND HEALTH</i> REPORT | 6 |
| III. AUTHORITATIVE STATEMENT..... | 8 |
| A. <i>Diet and Health</i> | 8 |
| B. Health Claims Based on <i>Diet and Health</i> | 9 |
| C. Total fat intake as addressed in <i>Diet and Health</i> | 11 |
| IV. EXACT WORDING OF THE PROPOSED CLAIM | 12 |
| V. STATUTORY BASIS FOR THE CLAIM | 12 |
| A. Requirements for health claims based on authoritative statements..... | 13 |
| B. Authoritative status of the <i>Diet and Health</i> statement..... | 15 |
| C. Form and Content of Claim | 16 |
| VI. NATURE OF THE FOOD ELIGIBLE TO BEAR THE CLAIM | 17 |
| A. Whole grain content..... | 17 |
| B. Fat and Cholesterol Content..... | 17 |
| 1. Physical nature of whole grain foods | 19 |
| 2. Low saturated fat criterion—effect on total fat..... | 19 |
| C. Trans fat criterion and labeling | 20 |
| D. Product categories..... | 20 |
| VII. REVIEW OF SCIENTIFIC LITERATURE REGARDING THE RELATIONSHIP BETWEEN WHOLE GRAINS AND CHD | 21 |
| A. Literature Review..... | 21 |
| 1. Literature published before <i>Diet and Health</i> | 21 |

| | | |
|-------|--|-----------|
| a. | Literature cited in <i>Diet and Health</i> | 21 |
| b. | Literature not cited in <i>Diet and Health</i> | 25 |
| 2. | New scientific evidence corroborating conclusions set forth in <i>Diet and Health</i> | 26 |
| a. | Observational studies | 26 |
| b. | Intervention studies | 36 |
| c. | Review papers..... | 40 |
| B. | Summary of Literature | 43 |
| VIII. | ADDITIONAL EVIDENCE IN SUPPORT OF THE CLAIM | 47 |
| A. | Recommendations regarding fat intake | 47 |
| 1. | Current nutrition science | 48 |
| 2. | Nutrition public policy | 48 |
| a. | The Dietary Guidelines for Americans | 49 |
| b. | The National Institutes of Health | 49 |
| c. | The National Academy of Sciences/Food and Nutrition Board | 50 |
| 3. | Regulatory precedent..... | 51 |
| B. | Whole grains as a public health priority | 52 |
| 1. | Recommendations for whole grain intake | 52 |
| a. | The Dietary Guidelines for Americans | 53 |
| b. | The Food Guide Pyramid for Young Children..... | 53 |
| c. | Healthy People 2010 | 54 |
| d. | The American Cancer Society | 55 |
| e. | The American Diabetes Association..... | 55 |
| f. | The American Dietetic Association..... | 55 |

| | | |
|-----|---|----|
| g. | The American Heart Association | 56 |
| 2. | Inadequate whole grain consumption in the United States | 56 |
| 3. | Barriers to whole grain consumption | 57 |
| IX. | SUMMARY AND CONCLUSIONS | 58 |
| X. | LITERATURE CITATIONS..... | 60 |
| XI. | APPENDICES | |
| A. | Authoritative Statement | |
| B. | Whole Grain Foods Authoritative Statement Claim Notification 1999 | |
| C. | Survey of whole grain and non-whole grain products | |
| D. | Label Examples for Cereal and Cracker Products | |

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

Whole Grain Foods and Heart Disease

I. INTRODUCTION

Kraft Foods North America, Inc. (Kraft) is planning to use the food label to educate consumers about the well-established relationship between the consumption of whole grain foods and reduced risk of coronary heart disease (CHD). As required by section 403(r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 343(r)(3)(C), Kraft is notifying the Food and Drug Administration (FDA) that the company intends to make a health claim based upon an authoritative statement of the Food and Nutrition Board (FNB) of the National Research Council (NRC), the working arm of the National Academy of Sciences (NAS). The exact wording of the proposed claim is as follows: “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 contain a minimum of 51% whole grains (using dietary fiber as a marker), meet the regulatory definitions for “low saturated fat” and “low cholesterol,” bear quantitative trans fat labeling in the Nutrition Facts box, contain less than 6.5 grams total fat and 0.5 grams or less trans fat per reference amount customarily consumed (RACC) (following standard rounding rules), and meet all general requirements for health claims in 21 C.F.R. § 101.14. In particular, the claim will appear on foods such as whole grain cereals, crackers, breads, and whole grain based snack mixes and bars.

The proposed claim is based upon the following authoritative statement made in the classic report *Diet and Health: Implications for Reducing Chronic Disease Risk*¹ (“*Diet and Health*”):

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). Although this statement was published in 1989, the relationship between whole grain foods and reduced risk of CHD, in the context of a diet low in saturated fat and cholesterol, remains substantiated by a balanced review of the current scientific literature.

II. BACKGROUND—THE *DIET AND HEALTH* REPORT

The *Diet and Health* report reflects a comprehensive review and analysis of scientific literature addressing diet and the spectrum of major chronic diseases. The report presents the findings of the Committee on *Diet and Health* (the “Committee”), a 19-member interdisciplinary committee established by the FNB to explore the relationship between chronic disease risk and foods, food groups, food components, and dietary patterns. Widely considered a major work in the field of nutrition, the report remains respected and relevant today. It has been used as a basis for two authoritative statement health claims authorized pursuant to FDAMA notifications: in 1999, it was cited as a basis for a health claim concerning whole grain foods and reduced risk of CHD; in 2000, it provided a basis for a health claim addressing the relationship between potassium, blood pressure, and reduced risk of stroke.

¹ National Research Council, *Diet and Health: Implications for Reducing Chronic Disease Risk*, at 8 (National Academy Press 1989).

Kraft has carefully reviewed the conclusions set forth in the *Diet and Health* report concerning the beneficial relationship between whole grain foods and reduced risk of CHD. In addition to the information and findings set forth in the text of *Diet and Health*, our review considered the studies evaluated by the Committee on *Diet and Health* and cited in the report, more recent studies addressing whole grain foods and CHD, current recommendations concerning whole grain consumption, current recommendations and science concerning total fat intake, regulatory precedent including the currently authorized whole grain claim,² and other information relevant to the development of an authoritative statement health claim addressing whole grain foods and CHD.

On the basis of this review, Kraft concluded that *Diet and Health* supports the use of a health claim communicating the relationship between whole grains and CHD on a wide variety of whole grain foods. In particular, a review of the report and supporting literature demonstrates that consistency with *Diet and Health* does not require that the proposed claim be restricted to whole grain foods that meet the definition of “low fat” in 21 C.F.R. § 101.62. The “low fat” constraint was incorporated into the 1999 notification, but is not required by the report or underlying scientific evidence. Moreover, consumption of the whole grain foods that are the subject of this notification is entirely compatible with a healthful diet consistent with the recommendations of public health experts. Additionally, the whole grain and saturated fat criteria specified in this notification, along with the quantitative restrictions on total fat and trans fat content, will restrict the total fat content of products bearing the claim, ensuring that products bearing the proposed claim will contain moderate levels of total fat considerably lower than the disqualifying level for total fat. When framed as proposed, the claim gives appropriate emphasis to the benefit of consuming whole grain foods that are low in saturated fat and cholesterol without unduly limiting communication focused on whole grains to foods that are “low” in total fat content.

² Whole Grain Foods Authoritative Statement Claim Notification, docket no. 99P-2209 (Mar. 10, 1999); Letter from S. Pape to C. Lewis (July 6, 1999).

III. AUTHORITATIVE STATEMENT

A. *Diet and Health*

The authoritative statement upon which the proposed whole grain health claim is based appears in the executive summary of the *Diet and Health* report. The executive summary, which reflects the Committee's major conclusions and their bases, contains the Committee's finding 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). Immediately following this statement, the FNB offered possible explanations for the anticipated health benefits of plant-based foods, including whole grains:

Although the mechanisms underlying these effects are not fully understood, the inverse association with coronary heart disease may be largely explained by the usually low saturated fatty acid and cholesterol content of such diets. Such diets are also low in total fat, which is directly associated with the risk of certain cancers, but rich in complex carbohydrates (starches and fiber) and certain vitamins, minerals, trace elements, and nonnutritive constituents, and these factors probably also confer protection against certain cancers and coronary heart disease.

(*Diet and Health*, at 8). On the subject of total fat, the FNB stated (*Diet and Health*, at 7) that “[t]here is clear evidence that the total amounts and types of fats and other lipids in the diet influence the risk of atherosclerotic cardiovascular disease and, to a less well-established extent, certain forms of cancer and possibly obesity.” The FNB explained that a reduction in total fat consumption would be expected to promote health by facilitating concomitant reductions in intake of saturated fatty acids:

Intake of total fat *per se*, independent of the relative content of the different types of fatty acids, is not associated with high blood cholesterol levels and coronary heart disease. A reduction in total

fat consumption, however, facilitates reduction of saturated fatty acid intake; hence, in addition to reducing the risk of certain cancers, and possibly obesity, it is a rational part of a program aimed at reducing the risk of coronary heart disease.

(*Diet and Health*, at 7). The Committee on Diet and Health recommended that total fat intake be reduced to 30% or less of calories, with less than 10% of total calories derived from saturated fat. (*Diet and Health*, at 13). In offering this recommendation, the Committee again emphasized the need to limit saturated fat and cholesterol (*Diet and Health*, at 13):

A large and convincing body of evidence from studies in human and laboratory animals shows that diets low in saturated fatty acids and cholesterol are associated with low risks and rates of atherosclerotic cardiovascular diseases. High-fat diets are also linked to a high incidence of some types of cancer and, probably, obesity. Thus, reducing total fat and saturated fatty acid intake is likely to lower the rates of these chronic diseases. Fat intake should be reduced by curtailing the major sources of dietary fats rather than by eliminating whole categories of food. For example, by substituting fish, poultry without skin, lean meats, and low- or nonfat dairy products for high-fat foods, one can lower total fat and saturated fatty acid intake while ensuring an adequate intake of iron and calcium—two nutrients of special importance to women. Dietary fat can also be reduced by limiting intake of fried foods, baked goods containing high levels of fat, and spreads and dressings containing fats and oils.

B. Health Claims Based on *Diet and Health*

In 1999, the FNB's authoritative statement concerning whole grains was used to support the following health claim:

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.

The notification proposing this health claim (the "1999 whole grains notification") presented evidence that the proposed authoritative statement continued to be supported by the evolving body of science. The notification characterized the available science as reflecting significant scientific agreement regarding the ability of a low fat diet rich in whole grain foods to reduce the risk of CHD and

certain cancers. The notification has been interpreted to require that foods eligible to bear the notified claim must be “low” in fat, saturated fat, and cholesterol, as defined by FDA.

The 1999 whole grain notification also included a specification for whole grain content, defining “whole grain foods” for purposes of the proposed health claim as foods with 51% or more whole grain ingredient(s) by weight per Reference Amount Customarily Consumed (RACC). Such foods provide a minimum of 16 grams of whole grain, which is the equivalent whole grain food serving under the Food Guide Pyramid.

It was proposed that dietary fiber be used as a marker to identify whole grain foods for the purpose of assessing compliance with the claim. A formula³ based on the fiber content of whole wheat (the most prevalent grain in the U.S. diet) was proposed to calculate the minimum amount of fiber necessary for foods with different RACCs to qualify for the claim. The result of this calculation for different RACCs is provided in Table 1.

Table 1
Minimum Fiber Content to Qualify for the Whole Grain Health Claim
for Different Reference Amounts Customarily Consumed

| RACC (g) | Minimum fiber content (g) |
|---------------------|--|
| 30 | 1.7 |
| 45 | 2.5 |
| 50 | 2.8 |
| 55 | 3.0 |

³Dietary fiber necessary to qualify for the claim = (11 grams dietary fiber per 100 grams whole wheat x 51% x RACC)/100.

C. Total fat intake as addressed in *Diet and Health*

Although the claim proposed in the 1999 notification expressly referenced low fat diets, and the notification required foods bearing the claim to be “low fat” as defined by FDA, neither the *Diet and Health* report nor more recent science mandates such an approach. The *Diet and Health* report reflects significant scientific agreement that diets low in saturated fat and cholesterol are associated with a reduced risk of CHD. The Committee on Diet and Health did suggest that diets high in total fat may increase CHD risk, primarily because such diets may also be high in saturated fat. The emphasis placed in *Diet and Health* on saturated fat and cholesterol supports a similar emphasis and approach in claims pertaining to CHD risk. The continued relevance of this approach is confirmed by recent literature and dietary recommendations, which are discussed in detail in Parts VII and VIII below.

Although saturated fat and cholesterol are predominant concerns identified in *Diet and Health*, it is appropriate to consider total fat intake in fashioning a claim addressing CHD risk. There should be some assurance that foods bearing such claims do not promote excessive or otherwise unreasonable consumption of fat. There is, however, no basis for concluding that a food that does not meet the technical definition of “low fat” in 21 C.F.R. 101.62(b)(2) cannot be part of a diet that contains an appropriate amount of total fat. The Committee on Diet and Health suggested that high fat foods should be limited, but did not recommend the elimination of foods that may contain moderate levels of fat.

A flexible approach to total fat content is particularly warranted in the case of whole grains, for which a beneficial effect has been demonstrated. The beneficial effect of whole grains independent of fat intake was evident in studies considered in the preparation of *Diet and Health* and is corroborated by more recent science. The available literature supports a conclusion that the total fat content, *per se*, of diets rich in fiber or whole grain foods is unrelated to CHD, and provides no

persuasive evidence that whole grain foods that are low in saturated fat and cholesterol, but not necessarily low in total fat, are any less effective in reducing the risk of CHD than their low-fat counterparts. A balanced review of 40 studies with original data on the effect of whole grain foods or dietary fiber (a marker for whole grains) on the risk or incidence of CHD is provided below in Part VII.

IV. EXACT WORDING OF THE PROPOSED CLAIM

Kraft intends to make the following authoritative statement claim on the label and/or labeling of certain whole grain food products:

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 similar to the currently authorized whole grains health claim except that the claim is succinctly worded to focus upon the relationship between heart disease and diets rich in whole grains and low in saturated fat and cholesterol. As noted previously, this focus is fully consistent with *Diet and Health* and is further supported by substantial amounts of additional data and recommendations that have become available since *Diet and Health* was published. The supportive data and other information are discussed in detail in Parts VII and VIII of this notification.

V. STATUTORY BASIS FOR THE CLAIM

Section 303 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (21 U.S.C. § 343(r)(3)) authorizes food manufacturers to make health claims without prior FDA approval provided certain conditions are met. In enacting the FDAMA notification scheme for health and nutrient content claims, Congress intended to provide “streamlined procedures” for the dissemination of scientifically sound nutrition information to the public (H.R. Rep. No. 105-399, at

98 (1997)). The ultimate legislative goal, well-served by the present notification, was to ensure a flexible regulatory mechanism by which well-established diet and health information reaches consumers. This objective is in line with FDA's recently announced Consumer Health Information for Better Nutrition initiative.

A. Requirements for health claims based on authoritative statements

The FFDCa, as amended by FDAMA, specifically authorizes the use of health claims based on authoritative statements when the following criteria 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 further provides that the statement “shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.”

In 1998, FDA issued a document providing guidance on the types of claims that qualify as FDAMA authoritative statements and the procedures that should be followed for submitting a health claim notification (Guidance for Industry (June 11, 1998)). In this guidance document, FDA identified six criteria for FDAMA claims, four of which are based on the plain language of the statute and the last two of which are based on FDA's interpretation of the statute and its legislative history. According to the FDA guidance document, an authoritative statement:

- 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 FDA guidance document further stated that the agency interprets FDAMA as requiring health claims to be supported by significant scientific agreement—the

same standard that is required for health claim regulations.⁴ Separately, FDA has also advised that a health claim based on an authoritative statement must not be 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 FFDCFA. (63 Fed. Reg. 34101, 34102 (June 22, 1998)).

B. Authoritative status of the *Diet and Health* statement

The *Diet and Health* statement upon which the proposed whole grains health claim is based qualifies as an “authoritative statement” under section 403(r)(3)(C) of the FFDCFA, as amended by FDAMA. The statement concerns the relationship between whole grain foods and CHD, a serious and chronic disease that is associated with dietary habits over a lifetime. It is based upon a deliberative review of the literature by an expert Committee established by the FNB and the NRC, which in turn are affiliated with the NAS, an agency that is identified in FDAMA as an authoritative body that may be the source of authoritative statements. Because the statement appears in the executive summary of a major report of the NRC (the working arm of the NAS), it is reasonably characterized as reflecting consensus within an authoritative body. Indeed, in its review of the 1999 whole grains notification, FDA determined this precise statement to be an authoritative statement upon which a health claim may be based.

⁴ The 1998 guidance represented FDA’s current thinking, as of the date of its issuance, on the procedures to be followed for notifying the agency of a health claim or nutrient content claim based on an authoritative statement of a scientific body. As posted on the internet (<http://www.cfsan.fda.gov/~dms/hclmguid.html#foot1>), the guidance contains a link that references more recent information on food labeling. Among the significant developments in recent years are judicial decisions concerning the role of the First Amendment in shaping government regulation of commercial speech, including health-related claims, and completion of the report of the agency’s Task Force on Consumer Health Information for Better Nutrition, along with the associated guidance documents. See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); 68 Fed. Reg. 41387 (July 11, 2003).

The statement also is “currently in effect,” as required by FDAMA. Since the 1999 whole grains notification, multiple papers, studies, and dietary recommendations have corroborated the conclusions set forth in *Diet and Health* concerning the relationship between CHD and diets rich in whole grains and low in saturated fat and cholesterol. These papers, studies, and recommendations are discussed fully in Parts VII and VIII of this notification.

C. Form and Content of Claim

In addition to establishing criteria for authoritative statements, FDAMA also sets forth criteria that proposed claims based on authoritative statements must meet. The form and content of the proposed whole grain health claim satisfy these criteria. In particular, the form and content of the proposed claim (1) provide an accurate representation of the authoritative statement; (2) are truthful and not misleading, consistent with sections 403(a) and 201(n) of the Act; (3) enable the public to comprehend the information and to understand its significance in the context of the total daily diet; and (4) are supported by significant scientific agreement concerning diets rich in whole grains and low in saturated fat and cholesterol.

Additionally, the proposed claim is distinct from, and not equivalent to, any health claim the agency has authorized by regulation, including FDA-approved health claims addressing the relationship between CHD risk and soy protein, plant sterol and stanol esters, or certain types of fiber-containing foods. Significantly, the proposed health claim is distinct from approved claims concerning fiber-containing foods because whole grain foods as such have been shown to confer beneficial health effects. The anticipated benefits of whole grains are not attributed to fiber, *per se*, or any other isolated component of whole grains.