

The Whole Grain Stamp



GETTING WHOLE GRAINS TO 3

January 18-20, 2006, Orlando

THE WHOLE GRAINS COUNCIL AND ITS WHOLE GRAIN STAMP PROGRAM

According to a recent survey conducted by the Whole Grains Council and Knorr®-Lipton®, “ability to find or locate whole grain products in the store” is cited by 40% of adults as a challenge to their efforts to consume more whole grains.

In early 2005, the Whole Grains Council launched its Whole Grain Stamp program, creating an eye-catching black and gold stamp-shaped graphic to make it easy for consumers to find, buy and consume whole grain products.

This section explains how the Whole Grain Stamp program was developed, and reports on its success in moving the consumer needle.

The Whole Grains Council

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All About the Whole Grain Stamp

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Development of the Whole Grain Stamp Program

- Reprint of a chapter from the forthcoming book *Whole Grains and Health*

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WHOLE GRAINS COUNCIL

MISSION, GOALS AND PROGRAMS

In April 2002 a group of concerned millers, manufacturers, scientists and chefs gathered in San Diego at a Whole Grains Summit organized by Oldways Preservation Trust. Responding to a challenge issued by Oldways President K. Dun Gifford, they decided to band together to promote increased consumption of whole grains. Jointly with Oldways, they organized the Whole Grains Council to develop and are carry out a consumer education campaign and to enlist others to join in this important effort.

Oldways and the Whole Grains Council set these goals:

- To reach scientific consensus on the definition of “whole grain” and on the health benefits of whole grains, and to advocate additional research about whole grains and health.
- To educate consumers about the benefits of whole grains and to help them find, buy and cook whole grains.
- To help grain-product companies, retailers and restaurants meet the needs of health-conscious consumers with appealing products.
- To serve as a conduit between science, industry and consumers.

Since then, the Whole Grains Council has:

- Grown from 9 members to over 100, including industry leaders.
- Created a website at www.wholegrainscouncil.org.
- Achieved consensus on a consumer-friendly definition of whole grains, which is now widely accepted in the industry.
- Held conferences in November 2004 and January 2006 focused on moving consumers to greater whole grain consumption.
- Managed a continuing campaign to educate the media and the public about the health benefits and delicious tastes of whole grains.
- Launched the Whole Grain Stamp, creating an eye-catching packaging symbol that helps consumers select and buy whole grain products.

In 2006 and 2007 we will continue to create and manage innovative program that promote increased consumption of whole grains. These programs will be designed to bring whole grains to all the places Americans eat. A few examples of planned programs:

Schools We will continue to collect information from schools which have successfully added whole grains to their menus, and will create an area of the WGC website where they can share their stories with others just starting the journey. We will create another web page for our members to post information about the whole grain products they have available to schools.

Restaurants We will publicize restaurants who serve whole grains and make it easier for consumers to find them. An area of our website will list national chain restaurants offering whole grain options.

Supermarkets We are in ongoing discussions with several national grocery chains, gathering information on the WGC resources that would best help them educate consumers about whole grains. We plan to create a kit of graphics and whole grain references for supermarkets.

WHOLE GRAINS COUNCIL

TIMELINE OF DEVELOPMENT

- July 2001 Invitations mailed for 2002 Whole Grains Summit Conference in San Diego.
- April 2002 Whole Grains Summit in San Diego; Oldways issues Whole Grains Challenge. Challenge accepted, committee of K.D. Gifford, M. Orlando and J. Dahlberg formed.
- January 2003 Oldways' 10th Anniversary Mediterranean Diet conference in Boston devotes a half-day to whole grain science and health; foundation is laid for Scientific Advisory Committee.
- July 2003 First meeting of Whole Grains Council in Chicago at IFT meeting; leadership and initial goals decided.
- October 2003 Whole Grain Stamp concept circulated to Whole Grains Council members.
- May 2004 Second meeting of the Whole Grains Council members and Board -- agreement on a definition of "whole grains;" conceptual agreement on "consumer-oriented" Whole Grain Stamp.
- July 2004 Whole Grains Council completes its first full year of operation with 25 Founding Members.
- November 2004 Whole Grains Second Summit Conference in New Orleans; Whole Grain Stamp system and design unveiled to members and media.
- January 2005 Guidelines for use of Whole Grain Stamp issued; Stamp unveiled to public and made available to members for use on products.
- February 2005 First grain food products carrying Whole Grain Stamp appear in stores.
- March 2005 16 WGC members display Whole Grain Stamp info and products with the Stamp at Expo West in Anaheim.
- August 2005 Number of whole grain food products bearing the Stamp reaches 250.
- November 2005 Whole Grains Council reaches milestone of 100 members.
- January 2006 Whole Grains Council Third Summit Conference in Orlando.

AN OVERVIEW OF THE WHOLE GRAIN STAMP PROGRAM

The 2005 Dietary Guidelines for Americans call on everyone to eat at least three servings of whole grains daily. However, many consumers are unsure what's a whole grain product and what isn't.

Now Americans can look for the Whole Grain Stamp, an eye-catching gold and black graphic that identifies foods containing a half or a full "Guidelines" serving of whole grains per labeled serving.

Good Source
A half serving
of whole grains



At least 8g
whole grain per
labeled serving

Excellent Source
A full serving
of whole grains



At least 16g
whole grain per
labeled serving

100% Excellent Source
A full serving
of whole grains



At least 16g whole grain
per labeled serving
AND no refined grain

How Do Products Qualify?

Any product – from breads to breakfast bars, cereals to side dishes, crackers to cakes, and pizza to pasta – can use the Whole Grain Stamp. Companies follow three steps:

- 1) They check their formulations to see which products are eligible to use the Stamp. Products must contain at least 8g of whole grain ingredients per serving to use the "Good Source" Stamp and at least 16g of whole grain for the "Excellent Source" Stamp.
- 2) They join the Whole Grains Council at www.wholegrainscouncil.org.
- 3) They receive graphic files and guidance from the Council to help them quickly add the Whole Grain Stamp to the packaging of their qualified products.

Members submit product compliance information on each proposed product to the WGC. Once members have joined the Council, there are no additional per-package royalty fees associated with Stamp usage, and companies are also eligible to participate in all other programs of the WGC.

Trust the Stamp

Whole Grains Council members began adding the Stamps to their packaging in February 2005. By the end of 2005, over 500 products qualified to use the Stamp.

An intensive media campaign is teaching Americans to "Trust the Stamp." In 2005, information about the Whole Grain Stamp appeared on Oprah and the Today Show, in magazines as diverse as Cooking Light, Parade, and Vogue and in newspapers across the nation, from the Washington Post to the San Jose Mercury News. The campaign will continue in 2006.

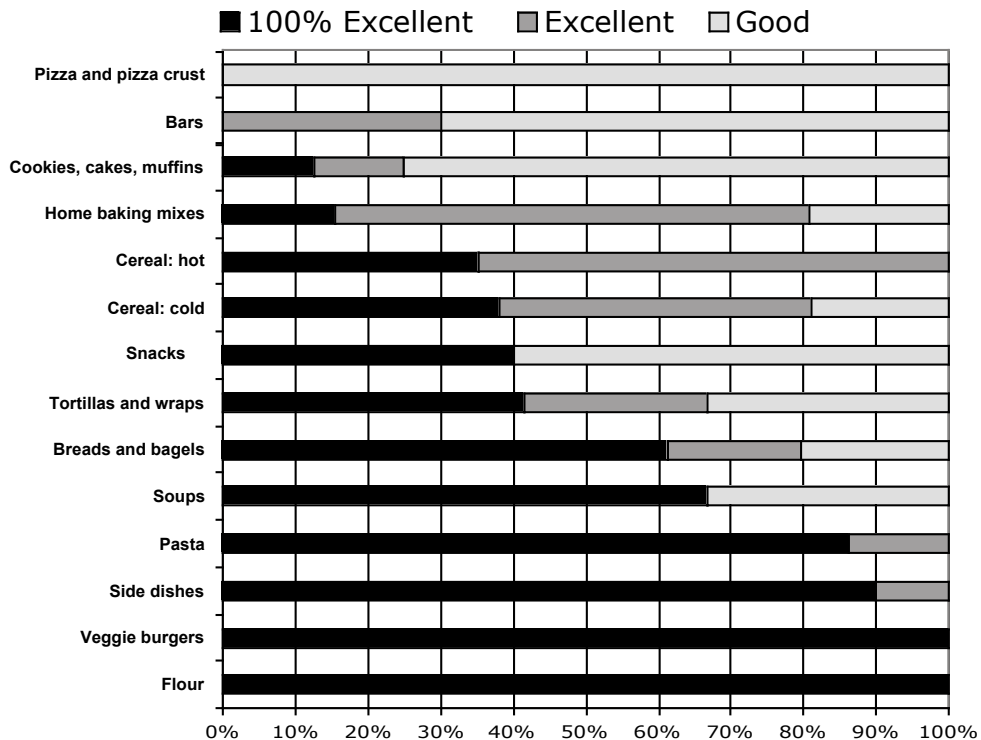
THE WHOLE GRAIN STAMP NOW IN STORES EVERYWHERE

As of January 6, 2006, 49 companies had begun using Whole Grain Stamps on 561 different products (including 30 to be announced in the first quarter of 2006). These products cover a wide range of foods, at all three levels of whole grain content.

Products Using the Whole Grain Stamp By Food Group	Food Group	# of Products
	Breads and bagels	187
	Cereal: hot	108
	Side dishes (rice, other grains)	70
	Cereal: cold	58
	Home baking mixes	26
	Flour	22
	Pasta	22
	Snacks (pretzels, crackers, etc.)	20
	Tortillas and wraps	11
	Bars: granola & breakfast (not ready for announcement)	10
	Cookies, cakes, muffins	8
	Pizza and pizza crust	6
	Soups	3
	Veggie burgers	1

Products Using the Whole Grain Stamp By Stamp Level	Stamp Level	# of Products
	100% Excellent Source	295
	Excellent Source	176
	Good Source	90

Percent of each Food Group using each Stamp Level



COMPANIES USING THE WHOLE GRAIN STAMP

<u>Company</u>	<u>Food Groups</u>
American Italian Pasta Company	Pasta (Muellers, Heartland, Golden Grain)
Alpine Valley Bread Co.	Breads
Alvarado Street Bakery	Breads
American Rice	Rice
Arrowhead Mills	Cereal
Aunt Millies / Perfection Bakeries	Bread
Barbara's Bakery **	Cereal, bars
Bob's Red Mill **	Cereal, flour, grains, baking mixes, popcorn
Bread Basket	Bread
Bruegger's Bagels	Bagel, wrap
Café Valley Bakery	Cake
Canada Bread	Bread
Dr. Kracker **	Crackers
Farm to Market Bread Co.	Bread
Farmer Direct Foods	Flour
Frontier Soups	Soups
Fullbloom Baking Co.	Muffins
Gardenburger	Veggie burgers
General Mills	Bars (Cascadian Farm)
Grain Miller/Country Choice **	Cereal, bars, cookies
Great Harvest Bread Co.**	Bread
Indian Harvest Specialtifooods	Grains
Kashi Company	Cereal
King Arthur Flour **	Cereal, baking mixes
La Tortilla Factory	Tortillas
Lotus Foods	Rice
Martin's Supermarket	Bread
Mary's Gone Crackers	Crackers
McCann's	Cereal
Mestemacher Bread **	Bread
Natural Ovens **	Bread
Nature's Path **	Cereal, baking mixes, pasta (Lifestream)
Purity Vita Spelt	Pasta
Quaker/Near East **	Cereal, side dishes
Racconto	Pasta, bread sticks
Riviana Foods**	Rice
Rizzuto Foods	Pizza crust
Roman Meal Company	Bread
Rubschlager Baking Co.**	Bread
Rudi's Organic Bakery	Bread
Schwan Foods	Pizza (Tony's)
Snyder's of Hanover	Pretzels, Tortilla Chips
Sturm Foods**	Cereal
Sunnyland Mills	Bulgur, grano
Traditional Bread	Bread
Uncle Ben's / Masterfoods USA	Rice side dishes

(plus two more companies not ready to publicly announce their registered products)

** These are "double digit" stamp companies, with more than 10 products registered.

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DEVELOPMENT OF THE WHOLE GRAIN STAMP PROGRAM

An urgent consumer need spawns a universal packaging symbol

By Jeff Dahlberg, Research Director, National Grain Sorghum Producers and Chair, The Whole Grains Council; K. Dun Gifford, President, Oldways Preservation Trust; Cynthia W. Harriman, Director of Food & Nutrition Strategies, Oldways Preservation Trust

When the legendary Ancel Keys wrote *Eat Well, Stay Well* in 1959, nutritionists were just beginning to suspect that whole grains might offer health advantages over enriched flour. Keys wrote,

Enriched flours have added thiamine as well as riboflavin, niacin, and iron, approaching whole-wheat flour in these respects. But other ingredients are removed from the wheat when it is refined; possibly enriched white flour is not actually the full nutritional equivalent of the natural grain.¹

Yet over the next four decades, even as the evidence for eating whole grains was solidly documented by nutrition scientists, consumers made only miniscule increases toward eating more whole grains. According to USDA disappearance data, whole grains constituted 0.5% of our calorie intake in 1972, and 1.4% of intake in 1999.²

Knowledgeable experts attributed this, in large part, to consumers' difficulty in identifying whole grain products. Even those people who were convinced of the benefits of whole grains found themselves confused and overwhelmed by misleading packaging claims in the bread and cereal aisles and throughout supermarkets.

Formation of the Whole Grains Council and Initial Goals

In April of 2002, Oldways Preservation Trust, a non-profit known for its effective work in translating nutrition science into consumer-friendly health-promotion tools, held a Whole Grains Summit in San Diego. At this event, Oldways issued a whole grains

challenge to consumers: "For one week, eat whole grains each morning, as cereal, as toast or as a roll" then "notice whether you still crave your mid-morning coffee-break snack."

Also at this conference, scientists, chefs and industry leaders joined together to explore the idea of helping consumers more readily identify whole grains, through a universal packaging symbol. This call was echoed a year later in the *Proceedings of the Nutrition Society* by leading grain researchers collaborating in an article entitled "Whole Grain Health Claims in the USA and other Efforts to Increase Whole-Grain Consumption." The authors stated,

There is a need to develop a 'consumer-friendly' whole grain definition so that consumers can easily identify what is a whole-grain product. In addition, a universal on-package whole grain identifier would be useful, such as a seal, logo, or insignia to readily signify wholegrain products. It cannot be hoped to successfully educate, market and increase whole-grain consumption until consumers can identify wholegrain foods.³

By mid-summer of 2003, Oldways had organized a consortium called The Whole Grains Council to carry on the work started at the San Diego summit.

In July of that year, the group held its first formal meeting and in the course of the following twelve months, assembled a strong group of twenty-five founding members – large companies and small ones; ingredient suppliers and packaged-goods producers; private corporations and commodity associations. These twenty-five industry pioneers were:

Founding Members of the Whole Grains Council:

American Institute of Baking
Barbara's Bakery
Campbell Soup
Fleischmann's Yeast
General Mills
King Arthur Flour
Lotus Foods
National Grain Sorghum Producers
Nature's Path
Panera Bread
Rudi's Organic Bakery
Sorghum Partners
USA Rice Federation

Arrowhead Mills
Bob's Red Mill
Farmer Direct Foods
Frito-Lay
Hodgson Mill
Lesaffre Yeast
Montana Flour & Grains / Kamut Assn.
Natural Ovens
Oldways Preservation Trust
Roman Meal Company
Snyder's of Hanover
Sunnyland Mills

Consensus on a Consumer-Friendly Definition of Whole Grains

The Whole Grains Council set as its first two goals (a) establishing a consumer-friendly consensus definition of whole grains, and (b) creating a universal packaging symbol for foods delivering a dietarily-significant amount of whole grains. Neither goal could exist without the other. It's not possible to denote foods containing whole grains without defining "whole grains" – and it's an empty gesture to define whole grains but then provide no mechanism for consumers to take action in finding them.

Through the end of 2003 and the first months of 2004, the Whole Grains Council worked on both these goals. Through a careful process of industry collaboration, the Council crafted a whole grains definition based on the AACC's widely-accepted definition, but adapted it to be understandable to consumers rather than scientists alone – in short, to meet the goal of being consumer-friendly. The end result, which was posted for feedback on the AACC website and later endorsed at a Whole Grains Council meeting in Chicago in May 2004, reads:

Whole grains or foods made from them contain all the essential parts and naturally-occurring nutrients of the entire grain seed. If the grain has been processed (e.g., cracked, crushed, rolled, extruded, lightly pearled and/or cooked), the food product should deliver approximately the same rich balance of nutrients that are found in the original grain seed.

Examples of generally accepted whole grain foods and flours are:

*Amaranth, Barley (lightly pearled), Brown and Colored Rice, Buckwheat, Bulgur, Corn and Whole Cornmeal, Emmer, Farro, Grano (lightly pearled wheat), Kamut® grain, Millet, Oatmeal and Whole Oats, Popcorn, Quinoa, Sorghum, Spelt, Triticale, Whole Rye, Whole or Cracked Wheat, Wheat Berries, and Wild Rice.*⁴

The Need for a Whole Grains Packaging Symbol

While work was going forward on the definition, the Council forged ahead in creating the whole grains packaging symbol so urgently needed by consumers. Aware that the final result would need widespread support across all segments of the industry and from government to be successful, the Whole Grains Council explored many options.

After consultation and discussion, the Council determined that the packaging symbol should have these attributes:

- 1) It should identify products with dietarily significant levels of whole grains, while differentiating between various levels of whole grain content, to help consumers make a gradual transition to the nuttier, fuller taste of whole grains.
- 2) It should clearly say "whole grain" with its graphics – even to those not familiar with the symbol – and be simple but eye-catching.
- 3) It should be easy for manufacturers to put on packaging – economical to print, and reproducible through all common printing methods.

The first point was especially important. Although the FDA had already authorized whole grain health claims for foods,⁵ these packaging claims have several limitations:

- To be eligible for the claims, foods must contain at least 51% whole grain ingredients by weight. Since moisture is factored into total weight, foods like bread – which averages 40% moisture – can only reach this standard with great difficulty.
- Eligibility is determined by a “fiber proxy.” Only foods containing 11% fiber, the amount found in wheat, can use the claim. This means that a bag of brown rice cannot carry the whole grains health claim, as rice contains only 3.5% fiber by weight. Other whole grains, such as millet (8.5% fiber), quinoa (5.9% fiber) and whole cornmeal (7.3% fiber) would also not qualify.
- A words-only health claim, without a graphic symbol, is not easy for consumers to recognize as they rush down cluttered grocery aisles.

The Whole Grains Council felt strongly that increased consumption of whole grains would happen only if packaging could highlight foods in *all* food categories, made from *all* varieties of whole grains.

It was also important to the Council that its symbol encourage “transition foods” – foods that may not be made entirely with whole grains but that

nonetheless contribute significantly to consumers’ diets. Just as consumers moved gradually from whole milk to skim milk by choosing 2% and 1% milk in turn, most consumers can best start their transition from refined grains to whole grains by having clear choices for foods that are made in part – but not entirely – with whole grains. In doing so, however, they need to be assured that their choices contain meaningful amounts of whole grains.

Consumer, Industry and Government Input

For a year, starting in October 2003, the Whole Grains Council mocked up rough graphics to refine a successful system of content levels. Portland-based Koopman-Ostbo Inc. offered early graphic support, and once a system was adopted by the members, in October 2004, graphic artist Susan Godel translated the Council’s concept into a finished, professional design.

Early concepts – shown in rough cartoon form in Figure 1 on this page – featured percents, stars, and gauges to differentiate between levels of whole grain content. Several options were explored before the Council settled on the best approach.



Figure 1. Early concepts for a universal whole grain packaging symbol took many different approaches, before the “Stamp” design was finally chosen.

Consumer Interviews

In January and February of 2004, the Council carried out consumer interviews in three geographic areas of the country (New Hampshire, Minnesota and California) to get broad-based input on what would constitute a successful seal. In almost 500 interviews with supermarket shoppers, the majority reacted positively to mockups of the symbol on a cracker box, with comments like these:

- *The symbol looks like it is official so I would trust it.*
- *I've been eating a lot of whole grains lately so this product would catch my attention.*
- *I don't really know much about whole grains but the crackers look good so I just might try it.*

- *It looks like a good product and the label makes me think the crackers are healthy foods.*
- *I'd be more likely to buy that – I've been trying to eat whole grains. They're better for my heart.*
- *A logo would be a faster way to find whole grain products.*

This research indicated that an attractive, easy-to-understand symbol would attract both current consumers of whole grains and those that were not yet eating whole grains. With this largely-positive feedback from “the trenches,” the Council continued to work with members to fine-tune the development of its whole grain packaging symbol.

At this point, one important element was missing in the symbol’s development. Although the Council had firm direction from consumers and

from its members, it did not yet have guidance from the U.S. government. At the January 28-29 meeting of the Dietary Guidelines Advisory Committee, in Washington, DC, Joanne Slavin, PhD, a scientific advisor to the Whole Grains Council, testified on the health benefits of whole grains and on the need for a consistent and universal whole grain packaging seal. A transcript of the meeting⁶ reports:

Dr. Slavin stressed that it is important to help consumers understand what whole grains are and where they can be found. The best way to find whole grain products is to read the ingredients label. A whole grains seal or a whole grain health claim on the package can be helpful, but different companies use them in different ways.

In May 2004, General Mills, which had recently joined the Whole Grains Council to further the group's efforts, filed a Citizen's Petition with the FDA for establishment of descriptor claims for whole grains. This petition (Docket 2004P-0223)⁷ proposed an industry standardization of packaging descriptors for whole grain content as follows:

Excellent source of whole grain:

The terms "excellent," "rich in," or "high in" whole grain(s) may be used on the label and in labeling of foods provided that the food contains 16g or more of whole grain per labeled serving.

Good source of whole grain:

The terms "good source," "contains," or "provides" whole grain(s) may be used on the label and on the labeling of foods provided that the food contains 8g to 15g of whole grain per labeled serving.

Made with whole grain:

The term "made with" whole grain(s) may be used on the label and on the labeling of foods provided that the food contains at least 8g of whole grain per labeled serving.

The filing of this petition codified a defacto industry standard that would complement the existing whole grain health claims with consumer-friendly descriptor claims. The Whole Grains Council leadership conferred with its members and decided to align itself with this potential standard, as long as this standard was in line with government guidance expected soon.

A few months after the filing of the General Mills Citizen's Petition, in August of 2004, the Dietary Guidelines Advisory Committee released its report summarizing the science that would be used to formulate the 2005 Dietary Guidelines. The report's conclusion on the subject of whole grains was:

Consuming at least three servings of whole grains per day can reduce the risk of diabetes and coronary heart disease and may help with weight maintenance. Thus, daily intake of three or more servings of whole grains per day is recommended, preferably by substituting whole grains for refined grains.⁸

Previously, the USDA had defined a "grain serving" as "the grams of grain product containing 16 grams of flour."⁹ Therefore, a recommendation for 3 servings or more of whole grains would mean consumption of 48g or more of whole grain content.

In addition to setting "three or more whole grains a day" as the goal for most Americans, the Dietary Guidelines Advisory Committee report also endorsed the importance of recognizing consumption of "transition foods" – those containing both whole and enriched grains.

In practice, when a person selects a mixed grain bread or cereal, he gets *both* a whole grain portion and an enriched grain portion. Because of the desirable baking properties of enriched flour, these mixed grain products are often appealing to consumers who do not choose to eat 100 percent whole grains. ... While many are not entirely whole grains, they provide some whole grains in the diets of those who might not otherwise select any. The proposed Pyramid food patterns suggest that half of all grain servings be whole grains. This approach allows these mixed products to fit readily into a person's food choices.¹⁰

Now that the USDA had clearly indicated its goals for whole grain consumption, the Whole Grains Council was able to confirm that the descriptors outlined by General Mills' Citizen's Petition would support and complement USDA efforts and definitions. The Council finalized its decision to create a symbol identifying foods containing a half serving (8g) and a full serving (16g) of whole grains.

On November 14, 2004 the Council previewed the actual graphics of the Whole Grain Stamp to the public and the press at the "Whole Grains Go Mainstream" conference held in New Orleans by Oldways Preservation Trust, the Council's parent organization. That same day, the Council's Board of

Directors met with Dr. Eric Hentges, Director of USDA’s Center for Nutrition Policy and Promotion. In his capacity as manager of the Dietary Guidelines update process, Dr. Hentges expressed his support for a symbol that could be an important tool in helping consumers increase consumption of whole grains. He reviewed the Whole Grain Stamp and urged the Council to make clear to consumers that any food bearing the 100% Stamp must also provide a full serving of whole grain (Excellent Source). The following day, a meeting of the Council’s members formally approved the new Stamp program.

The Whole Grain Stamp is Unveiled, with Three Versions

Two months later, on January 12, the 2005 Dietary Guidelines for Americans were released. The Guidelines, as widely expected in the wake of the Advisory Committee Report, called for all Americans to “con-

sume 3 or more ounce-equivalents of whole grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products. In general, at least half the grains should come from whole grains.”¹¹

US Code, Title 7, Section 5341 requires that the Dietary Guidelines “shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.”¹² A week after the Guidelines’ introduction – with the knowledge that official government policy now required a many-fold increase in whole grains consumption – the Whole Grains Council unveiled its Whole Grain Stamp program to the public and authorized its members to begin the process of placing the Stamps on qualifying foods.

The Whole Grain Stamp has three levels, as shown in Figure 2:

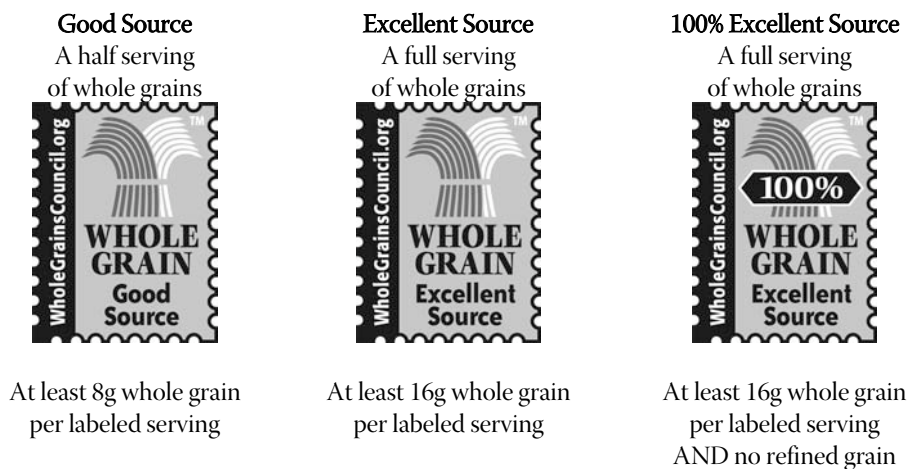


Figure 2. The Whole Grain Stamp program, from the Whole Grains Council, clearly marks products that contribute a significant amount of whole grain to Americans’ diets.

The three levels of the Stamp make it easy for consumers to translate the Dietary Guidelines into action: Eat three foods labeled “Excellent Source” or six foods labeled “Good Source” to reach the minimum of three whole grain servings a day – or a total of 48g of whole grain content. The 100% Excellent Stamp offers the added option of eating only foods where all the grain is whole grain – a choice that is important to selected consumers. With the Whole Grain Stamps, all Americans can find the type of whole grain foods that meet their needs.

Within six weeks, two members of the Council – Great Harvest Bread Company and Bruegger’s Ba-

gels – began using the Whole Grain Stamp at their bakery-café across the country. As the two chains between them had over 450 locations in almost every state of the union, the Stamp quickly came to consumers’ attention. By springtime, the Stamp began appearing on packaged goods from early adopters like Bob’s Red Mill and Kashi cereals.

As word of the Whole Grain Stamps spread through the grain-foods industry, membership in the Whole Grains Council rose steeply. From 33 members at the time of the Stamp program’s introduction in late January, the group grew to 54 by the end of March, then to 78 by July 1. At the end of the

summer of 2005, membership included 93 of America's leading companies and grain organizations.

By this time, over half of these companies were already using the Stamps, and had collectively registered over 400 products with the Council's compliance system. Consumers were beginning to notice the Stamp in supermarkets around the country, and the Whole Grains Council was carrying out an aggressive education campaign to explain the significance of the Whole Grain Stamps.

This media campaign began with newspaper articles in early spring, with extensive coverage of the Stamp program in publications including *USA Today*, the *Washington Post*, the *San Jose Mercury News*, the *Dallas Morning News* and the *San Francisco Chronicle*. In March, the Whole Grain Stamps were featured on the Today show, and in early May, an hour-long segment of the Oprah Winfrey show explained the importance of whole grains and fiber, and praised the introduction of the Stamps, advising viewers, "If you still aren't sure which of your favorite foods are really made with whole grains, look soon for these stamps on products. They're going to help take out the guesswork." As the year wore on, information about the Whole Grain Stamp program also appeared in leading magazines including *Cooking Light*, *Prevention*, and *Time* magazines.

Good Source and Excellent Source Become an Industry Standard

At the same time that the logo of the Whole Grain Stamp was becoming widely established in 2005, several other companies augmented and complemented this growing standard by tagging their products as Good Source of Whole Grains (for products with 8g or more of whole grains per serving) and Excellent Source of Whole Grains (for products with 16g of whole grains per serving) – but using their own brand-oriented graphics. General Mills cereals, Kraft cookies and crackers (under the Nabisco brand) and cereals (under the Post brand) and Pepperidge Farm crackers were among the many products reinforcing and supporting the prevailing Good Source/Excellent Source standard in this way.

This significant and virtually unprecedented industry cooperation ensured that consumers would receive a clear message about whole grains – in stark

contrast to the confusion that existed before the food industry closed ranks around a common standard. Through the efforts of the Whole Grains Council and its Stamp program, consumers are finding it much easier to increase their consumption of whole grains.

References

- ¹ *Eat Well and Stay Well*, by Ancel and Margaret Keys, Doubleday & Co., 1959.
- ² Food Consumption USDA/ERS Disappearance Data, Jacobs – as reported by Julie Miller Jones at the Whole Grains Go Mainstream conference, November 2004.
- ³ Marquart, Wiemer, Jones and Jacob, *Proceedings of the Nutrition Society* (2003), 62, 151-160.
- ⁴ www.wholegrainscouncil.org/ConsumerDef.html.
- ⁵ For full details, see www.cfsan.fda.gov/~dms/flgrain2.html
- ⁶ Transcript at www.health.gov/dietaryguidelines/dga2005/minutes01_2829_2004.htm.
- ⁷ Petition at www.fda.gov/ohrms/dockets/dockets/04p0223/04p0223.htm
- ⁸ 2005 Dietary Guidelines Advisory Committee Report, Part D (Science Base), Section 5 (Carbohydrates) available at www.health.gov/dietaryguidelines/dga2005/report/PDF/D5_Carbs.pdf.
- ⁹ Documentation: Pyramid Servings Database, 3.2.2.1 (page 3-13) available at www.ba.ars.usda.gov/cnrg/services/section2.pdf.
- ¹⁰ 2005 Dietary Guidelines Advisory Committee Report, Appendix G2, page 16-17.
- ¹¹ The 2005 Dietary Guidelines, at www.healthierus.gov/dietaryguidelines/.
- ¹² US Code, Title 7, Section 5341 is available at <http://uscode.house.gov>.

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WHOLE GRAINS – REGULATORY STATUS

The Whole Grain Stamp is a voluntary industry program designed by a non-profit educational organization to support the 2005 Dietary Guidelines. It is not an official government program. Certain other whole grain claims and wording are specifically sanctioned by the U.S. government.

In most cases, the FDA has jurisdiction over packaging claims and wording, although the USDA claims jurisdiction over some elements of packaging on foods containing meat and poultry. FDA and USDA are working toward harmonizing their sometimes-conflicting rules and guidelines for food and nutrition labeling. Until they achieve that goal – a process that will take years – the government has officially blessed the whole grain claims below.

Whole Grain Health Claims – FDA

FDA authorizes content statements such as “contains X grams of whole grain” and “100% whole grain.” It also allows two claims allowed under the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA):

	Whole Grains Health Claim (low fat)	Whole Grains Health Claim (moderate fat)
Date	As of July 1999	As of December 2003
Claim wording	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	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.
Foods that qualify*	Foods that contain 51 percent or more whole grain ingredient(s) by weight and <ul style="list-style-type: none"> • contain at least 11% fiber • are low in fat (≤ 3g) 	Foods that contain 51 percent or more whole grain ingredient(s) by weight and <ul style="list-style-type: none"> • contain at least 11% fiber • are low in saturated fat (≤ 1g) • are low in cholesterol (≤ 20 mg) • contain less than 6.5g total fat • contain 0.5g or less trans fat

* All qualified foods assume RACC amount. RACC is Reference Amount Customarily Consumed per eating occasion, an amount set in FDA regulations for all categories of foods. A full list of RACCs can be found in 21 CFR 101.12 at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=101.12

USDA FSIS Interim Policy Guidance

The Food Safety and Inspection Service (FSIS) of the USDA has jurisdiction over packaging on foods containing meat and poultry. On October 14, 2005 FSIS issued an interim statement saying that it “does not object to foods being characterized as whole grain –”

- if at least 51% of the grain components are whole grain. [Note that this differs from the FDA’s requirement that 51% of total weight of *all* ingredients, including water, must be whole grain.]
- as long as the food contains at least 8g of dry whole grain ingredients.

Interestingly, FSIS states it does *not* allow statements such as “contains X grams of whole grains” – while FDA specifically states it *does* allow such statements.

The Whole Grains Council is working with USDA and FDA to be a positive force for reconciling the conflicting regulations around whole grain labeling, so that consumers can easily find, buy and enjoy whole grain products.

FDA DELAYS RULING ON WHOLE GRAINS

The General Mills Citizen Petition

On May 10, 2004 General Mills (GMI) filed a Citizen Petition¹ with the FDA, asking the FDA “to establish the descriptive claims ‘excellent source,’ ‘good source,’ and ‘made with’ for whole grain content under the Agency’s authority to prevent false and misleading food labeling statements.” The petition describes Good Source as containing 8-15g of whole grain, and Excellent Source as containing 16g or more of whole grain.

FDA’s Dilemma

To rule on the merits of this petition, the FDA would have to establish new precedents – precedents required to be compatible with other similar claims that might arise in the future. How will a ruling on whole grains affect future rulings on the health benefits of soy? Chocolate? Fish? Several of the broad issues to be resolved include these:

A. What kind of claim is appropriate?

The FDA routinely authorizes *nutrient claims* such as “high in calcium” but has, to date, limited such claims to “nutrients and dietary substances with an established daily value.” Whole grains are widely agreed to be a substance, but have no established daily value (Dietary Guidelines aren’t considered daily values!).

The FDA also authorizes *health claims* that “describe a relationship between a food...and reducing risk of a disease or health-related condition.” But GMI’s proposed descriptors don’t make any health claim.

So where do whole grains fit in? In its petition, GMI proposed that whole grains be regulated as “descriptive claims” (a third category FDA has used in the past) rather than as the usual “nutrient claims” or “health claims.” FDA has not yet ruled.

B. Is whole grain a “category” or a “substance?”

As stated above, FDA claims can be made for “dietary substances” but they cannot be made for categories of foods (such as soup, crackers, or pizza). General Mills argued that whole grains are a substance, because certain health benefits are common to all whole grains. FDA has not yet ruled.

C. Is there a daily value for whole grains? Should there be one?

The FDA routinely functions in a world of micro- and macronutrients, advising Americans on vitamins, minerals, fats, fibers and carbs. All of these have recommended daily values. But people eat foods, not nutrients – and the recommendations of the Dietary Guidelines don’t count as daily values (DVs). The FDA has no established DV for whole grains and might potentially argue that DVs should be limited to nutrients. Does whole grain need a DV in order to use the “Good Source” and “Excellent Source” descriptors? If so, what would that DV be? FDA has not yet ruled.

D. How can whole grain content be analyzed and proven?

The amount of calcium or Vitamin A in a product can be analyzed. But science has not yet established an easy way to “test” for whole grain content. Failing a foolproof test, the FDA has historically allowed whole grain content to be measured by “fiber proxy.” Since each whole grain has a specific fiber content, measuring fiber is one way to measure the presence of specific whole grains. However, adding extra bran (not a whole grain when it’s missing the germ and endosperm) can skew such a test. Because FDA allowed analysis by “fiber proxy” on the two existing whole grain health claims, GMI proposed continuing to use this method until and unless a better method arises. FDA has not yet ruled.

E. Must an excellent source of whole grain be an excellent source of fiber?

In 1993, FDA ruled that any claim that a product contains whole grain “implies that the product is a good source of dietary fiber. Such a claim would therefore be misleading if the product did not contain sufficient fiber... [to meet] the definition for ‘good source of dietary fiber.’ ”

Since that time (and in fact previous to that ruling) repeated studies have consistently shown that the benefits of whole grains derive from more than just fiber. The Dietary Guidelines, in fact, cite this reality.

FDA should acknowledge that science has made this 1993 rule obsolete. In fact, virtually no grains reach the good or excellent source of fiber level in normal Dietary Guidelines-recommended serving sizes. This old rule, however, is still on FDA’s books, and needs to be updated. FDA has not yet ruled.

FDA’s Letter to General Mills

On November 8, 2005 – nearly a year and a half after receiving GMI’s petition, the FDA responded, saying it would deny GMI’s petition “because the agency first needs to decide the appropriate classification for such statements under its authority...” In its letter², FDA mentioned many of the issues above as barriers to its immediate action. However, the FDA letter went on to say,

The agency acknowledges the need for action on this topic. The recommendations from the recent “Dietary Guidelines for Americans” 2005 demonstrate that consumers can benefit from increased consumption of whole grains. We are reviewing options for public input on how to classify certain statements about food, including dietary guidance statements. Our review includes possible approaches on how to provide useful information to the public on whole grains. In addition, we are considering the development of guidance on what we consider the term “whole grains” to include.

The Position of the Whole Grains Council

The Whole Grains Council continues to urge the FDA to move forward as quickly as possible with the action promised above, and pledges to do whatever it can to support FDA in its efforts. The WGC filed a letter with the FDA on December 28, 2005, with our views on some of the above issues. (Copy follows.)

We note that the FDA has not yet acted on the merits on GMI’s petition, and when it does, it may yet rule in favor of the substance of this petition. However, we recognize that definitive action may take FDA months or, more likely, years; we note that the organic industry was self-regulating for a dozen years before government guidelines for organic packaging symbols were finalized.

For the benefit of the American public and our members, the Whole Grains Council will continue to support implementation of the Dietary Guidelines by encouraging consumers to Trust the Stamp.

1. The original GMI petition can be viewed at www.fda.gov/ohrms/dockets/dockets/04p0223/04p-0223-cp00001-toc.htm
2. FDA’s November 8, 2005 letter to GMI can be found at www.fda.gov/ohrms/dockets/dockets/04p0223/04p-0223-pdn0001-vol5.pdf.

A consortium of industry, scientists, chefs and Oldways to increase consumption of whole grains to provide better health for all consumers

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Margaret O'K. Glavin
Associate Commissioner for Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

28 December, 2005

Re: Docket No. 2004P-0223/CP1

Dear Ms. Glavin,

On November 8, 2005, the FDA notified General Mills ("GMI") that the FDA could not at this time approve GMI's May 2004 Citizen's Petition "because the agency first needs to decide the appropriate classification of certain label statements before considering whether to publish a proposed rule for such statements." The Whole Grains Council ("WGC") notes that the FDA did not rule on the merits of the petition, but instead deferred a determination pending further study.

The WGC applauds FDA's acknowledgement of the need for rulemaking action on the topic of whole grains. As a non-profit consortium including more than 100 grain industry companies and many leading scientists, we urge the FDA to recognize that the ultimate national goal is to encourage increased consumption of whole grains in ways consistent with a balanced diet. The WGC stands ready to assist the FDA in any way possible as that agency moves with all speed to help American consumers identify and consume more healthy whole grain products.

In this context, we wish to put before the FDA our concerns about certain suggestions in the FDA's response to the GMI petition. The WGC feels strongly about the following four points:

1) The view that "whole grains equals fiber" is outdated.

In January 1993, when FDA finalized its rule for nutrient content claims (58 FR 2302 at 2374), FDA suggested that whole grain was synonymous with fiber. Even then, this view did not comport with the scientific consensus set forth in the IOM's authoritative 1989 *Diet and Health* report. The Committee on Diet and Health stated that "there was no conclusive evidence that it is dietary fiber rather than the other components of vegetables, fruits and cereal products that reduces the risk of [certain] diseases." (p.9) In the dozen years since 1993, numerous peer-reviewed studies have shown that whole grains contain many other substances, in addition to fiber, that contribute to the health benefits of whole grains.

The Institute of Medicine recognized this more recent research in its 2005 volume titled *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* in these two statements:

"Whole grain cereals are also sources of phytochemicals, such as phytate and phytoestrogens, which may independently impact CHD." (p. 369)

"There are many constituents of whole grains, in addition to Dietary Fiber, that may reduce the risk of CHD (Slavin et al., 1997; Thompson, 1994)." (p. 387)

The 2005 *Dietary Guidelines for Americans* further reinforces this point, when it details the elements *in addition to fiber* that are lost when grain is refined:

"In the grain-refining process, most of the bran and some of the germ is removed, resulting in the loss of dietary fiber (also known as cereal fiber), vitamins, minerals, lignans, phytoestrogens, phenolic compounds, and phytic acid." (p. 25)

On the basis of these long-standing federal policy statements about the multiplicity of benefits accruing from regular consumption of whole grains, we urge the FDA to revise its earlier fiber-centric view of whole grains. (Attachment 1 with this letter illustrates some of the many nutrients – besides fiber – present in whole wheat but much diminished in refined wheat. Other grains are comparable.)

2) A full serving of whole grains does not naturally contain 5g of fiber.

While fiber is an important contributor to health, continuing to require that foods labeled “Excellent Source of Whole Grain” must also be an “Excellent Source of Fiber” or “High in Fiber” would create surprising – and undesirable – unintended consequences.

USDA has defined a “grain serving” as “the grams of grain product containing 16 grams of flour.” (*Pyramid Servings Database, 3.2.2.1 (p. 3-13) at www.ba.ars.usda.gov/cnrg/services/section2.pdf.*) Yet, as Table 1 below illustrates, **no whole grain**, when served in USDA-size servings, could be considered an Excellent Source (5g) of fiber – and only two (barley and bulgur) could be a Good Source (2.5g) of fiber – without fortification with extra bran or other fiber sources. Fortification, however, is generally discouraged in qualifying for FDA packaging claims, creating a Catch 22 for producers and consumers.

Table 1: No Grain Qualifies as “High in Fiber” in USDA-size Servings

Grain	Percent fiber	Fiber in One USDA Serving	Grain needed to yield 5g fiber
Whole Wheat	12.2%	2.0 g	41 g
Oats/oatmeal	10.6%	1.7 g	47 g
Whole-grain corn	7.3%	1.2 g	69 g
Popcorn	14.5%	2.3 g	35 g
Brown rice	3.5%	0.6 g	143 g
Whole rye	14.6%	2.3 g	34 g
Whole Barley	17.3%	2.8 g	29 g
Wild rice	6.2%	1.0 g	81 g
Buckwheat	10.0%	1.6 g	50 g
Triticale	14.6%	2.3 g	34 g
Bulgur	18.3%	2.9 g	27 g
Millet	8.5%	1.4 g	59 g
Quinoa	5.9%	0.9 g	85 g
Sorghum	6.3%	1.0 g	79 g

List of grains from Dietary Guidelines for Americans 2005, Table 7 “Whole Grains Available in the United States.” All values for fiber content from SR18 USDA National Nutrient Database for Standard Reference.

As Table 1 further shows, whole grains vary in fiber content, and anywhere from 27g to 143g of whole grain would be needed to reach the “high fiber” level. Served as finished foods at the table, the amounts in Table 1 would result in very large portions (and accompanying calories) for many grains – 4 cups of popcorn, 3 slices of whole wheat bread, or 8 cups of brown rice, for instance – to reach the “high fiber” level.

Allowing whole grains to be brought to the attention of consumers only if they are unnaturally high in fiber or served in large quantities inimical to good health does not meet this goal. It would be better to properly educate consumers that whole grains and fiber are linked but not interchangeable.

3) Statements such as “2g of whole grain” will mislead consumers.

The November 8 FDA letter to General Mills advises that manufacturers are currently permitted to use “factual statements on foods labels such as ‘10 grams of whole grains’... providing that such statements are not false or misleading.”

The WGC is concerned that such statements will create extensive consumer confusion on this very important subject of whole grains. We can envision packages with banners saying “Now with 2g of whole grain” which will lead many consumers to believe that 2g of whole grain is a dietarily significant amount, when it is not. The WGC believes that whole grain content should only be highlighted when it reaches levels of 8g or more – the equivalent of half a Dietary Guidelines serving.

We were pleased to see that FSIS, in an October 14, 2005 interim policy guidance statement, agreed with this assessment. It now allows statements about whole grains on foods with a “significant amount of whole grain component,” and defines “significant” as follows:

“A significant amount of whole grain would be at least a one-half ounce-equivalent of whole grain ingredient, i.e., at least 8 grams of dry whole grain ingredient...”

(FSIS: Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grain Claims, October 14, 2005)

4) Consumers are best served by consistent government policy.

The WGC strongly recommends that USDA, HHS and FDA work together to present a unified approach that supports implementation of the policies of the Dietary Guidelines. US Code, Title 7, Section 5341 requires that the Dietary Guidelines “shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.”

Consequently, we urge that the FDA act in concert with HHS and USDA in these specifics:

A. Serving Size

Since the Dietary Guidelines consider 16g of whole grain content (or an “ounce-equivalent” of multi-ingredient food) to constitute a serving, FDA must adopt this position in its rulings regarding labeling for whole grains.

B. Transition Foods

We urge FDA to support a labeling system that helps Americans locate and consume “transition foods” – foods in which refined grains and whole grains are combined.

In addition to recommending “three or more whole grains a day” as the goal for Americans adults (and most children), the Dietary Guidelines Advisory Committee also endorsed the importance of recognizing consumption of such transition foods:

“In practice, when a person selects a mixed grain bread or cereal, he gets *both* a whole grain portion and an enriched grain portion. Because of the desirable baking properties of enriched flour, these mixed grain products are often appealing to consumers who do not choose to eat 100 percent whole grains. . . . While many are not entirely whole grains, they provide some whole grains in the diets of those who might not otherwise select any. The proposed Pyramid food patterns suggest that half of all grain servings be whole grains. This approach allows these mixed products to fit readily into a person’s food choices.” (2005 Dietary Guidelines Advisory Committee Report, Appendix G2, page 16-17)

We understand that consideration of rules on whole grains takes the FDA into new territory, because whole grains are a substance and not a nutrient such as calcium or magnesium. We recognize that the FDA proceeds with deliberation before setting precedents that might impact other areas of federal dietary policy, and we thank FDA for turning its resources to this important area with all due deliberation.

Position of the Whole Grains Council

The Whole Grains Council and its 100-plus industry members believe that its **Whole Grain Stamp** program, which helps consumers quickly and easily identify products containing a half-serving or full serving of whole grains, best supports fulfillment of the Dietary Guidelines and existing government policy. (See Attachment 2 for an overview of the WGC Stamp Program.)

The “Good Source” and “Excellent Source” designations used on our Whole Grain Stamps are familiar to consumers and have already helped Americans to eat more whole grains – the goal that FDA, HHS, USDA and the WGC are all working together to achieve.

Sincerely yours,



Jeff Dahlberg
Chairman, the Whole Grains Council

cc: Dr. Andrew C. von Eschenbach, Acting Commissioner, FDA
Dr. Barbara Schneeman, Director, Office of Nutritional Products, Labeling & Dietary Supplements, FDA
Felicia Satchell, Staff Director, Office of Food Labeling Standards & Compliance, FDA
K. Dun Gifford, President, Oldways Preservation Trust

Attachments: (1) Comparison of nutrients in whole wheat, refined wheat and enriched wheat
(2) Whole Grain Stamp program overview

Whole Grains Council sees stamp program still moving forward

December 1, 2005) • by Josh Sosland

BOSTON The denial of a petition to the Food and Drug Administration seeking definitions for terms like "excellent source" of whole grain does not necessarily mean the end of the whole grains stamp program.

Even before the F.D.A. action, food companies making such statements were doing so without having been granted the authority.

"We didn't have F.D.A. approval before, so really nothing has changed in that regard," said Cynthia Harriman, director of food and nutrition strategies, Whole Grains Council/Oldways Preservation Trust.

Since late 2004, the W.G.C., a consortium from industry, science, culinary specialists and Oldways Preservation Trust, has been recruiting food companies join the group and to incorporate a whole grains stamp on their food packages. The organization is committed to increasing consumption of whole grains. The W.G.C. believes the whole grain stamps or seals will help consumers identify which food products contain whole grains.

Ms. Harriman said all its members already had signed an agreement stating that they understand the stamps are not F.D.A. approved. She also indicated that the W.G.C. has sent e-mail to each of its members informing them of the F.D.A.'s decision. The response to date has been positive, she said, adding that companies likely will contact counsel before making final decisions about whether to continue using the seal.

Peter Barton Hutt, an expert in matters relating to the F.D.A., said the agency's move should not stop food companies from making claims about whole grains content.

"The F.D.A. can't really even make up its mind whether a claim about whole grain is or is not a nutrient descriptor," said Mr. Hutt, a partner in the Washington law firm of Covington and Burling. "They tentatively come down on the side that it probably is. My suggestion with regard to that, is that if I were in the industry, I would continue to use the claim. I thought the General Mills petition made a strong case that it is not a fiber claim, and it is not a nutrient claim. So I would ignore the F.D.A. since they are very tentative in their position.

"Its clear that they are months and maybe years from making a decision. It reminds me very much of their failure to take any kind of action with regard to the carbohydrate craze until it was too late and even then

they still haven't taken any action. This will not get resolved for Lord knows how long. That's why my position to the industry is that they continue to use these claims and should not wait what will be months or years while F.D.A. thinks about it."

Ms. Harriman said industry's efforts to reinforce the Dietary Guidelines have been crucial in gains made during the past year in whole grains intake.

"We now have 100 members, which represents an unprecedented effort to help consumers and to help industry," Ms. Harriman said. "We simply were not willing to sit back and wait.

"The most important thing about the stamps is we feel they support the Dietary Guidelines." She added that she doesn't believe the F.D.A. (and other federal agencies) is following through on their mission of supporting the guidelines in every regard.

She mentioned she was particularly concerned about the petition's reference to the 1993 ruling regarding whole grains and fiber. She noted that to make the connection between fiber and whole grains is to discount all of the research that has taken place over the past 10 years that proves the health benefits of whole grains versus enriched grains are not limited to fiber. But she added that she remains optimistic that the government will follow through on its plans to issue rule making in the next several months. She stressed that whatever the decision is, it must be in tune with the guidelines.

Ms. Harriman also expressed concern about F.D.A.'s support of label statements such as "contains 10 grams of whole grains" ... She warned that such labels will confuse consumers who have no context whether "2 grams of whole grains" or "10 grams of whole grains" is beneficial to their health.

The Legal Times recently named Peter Hutt as one of the 11 Leading Food & Drug lawyers in Washington DC. In describing Mr. Hutt's reputation as a standout in the field, the Legal Times observed that he "has done it all" and "is renowned for the breadth and depth of his expertise in virtually every area of food and drug law." Hutt, a former chief counsel of the FDA, is viewed by many as "the dean of the food-and-drug bar," according to the Legal Times.



Claims That Can Be Made for Conventional Foods and Dietary Supplements

Claims that can be used on food and dietary supplement labels fall into three categories: health claims, nutrient content claims, and structure/function claims. The responsibility for ensuring the validity of these claims rests with the manufacturer, FDA, or, in the case of advertising, with the Federal Trade Commission.

I. Health Claims

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition.

There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or dietary supplement: 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted in health claim petitions; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences; such claims may be used after submission of a health claim notification to FDA; and 3) the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. Such health claims must be qualified to assure accuracy and non-misleading presentation to consumers.

The differences between these three methods of oversight for health claims are summarized below. Appendix C of *The Food Labeling Guide* contains a summary of those health claims that have been approved for use on food and dietary supplement labels: www.cfsan.fda.gov/~dms/flg-6c.html.

A "health claim" by definition has two essential components: (1) a substance (whether a food, food component, or dietary ingredient) and (2) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in health are considered to be dietary guidance rather than health claims, provided that the context

of the statement does not suggest that a specific substance is the subject. Dietary guidance statements used on food labels must be truthful and non-misleading. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health related condition. Unlike health claims, dietary guidance statements and structure/function claims are not subject to FDA review and authorization. There are some regulatory requirements associated with the use of structure/function claims; see

www.cfsan.fda.gov/~dms/labstruc.html.

NLEA Authorized Health Claims. The Nutrition Labeling and Education Act (NLEA) of 1990, the Dietary Supplement Act of 1992, and the Dietary Supplement Health and Education Act of 1994 (DSHEA), provide for health claims used on labels that characterize a relationship between a food, a food component, dietary ingredient, or dietary supplement and risk of a disease (for example, "diets high in calcium may reduce the risk of osteoporosis"), provided the claims meet certain criteria and are authorized by an FDA regulation. FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine that the nutrient/disease relationship is well established. For an explanation of the significant scientific agreement standard, see:

www.cfsan.fda.gov/~dms/ssaguide.html.

Health Claims Based on Authoritative Statements. The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim on foods to be authorized. FDAMA allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an "authoritative statement"

from a scientific body of the U.S. Government or the National Academy of Sciences. FDA has prepared a guide on how a firm can make use of authoritative statement-based health claims. This guide can be found at: www.cfsan.fda.gov/~dms/hclmguid.html. FDAMA does not include dietary supplements in the provisions for health claims based on authoritative statements. Consequently, this method of oversight for health claims cannot be used for dietary supplements at this time. Examples of health claims based on authoritative statements may also be found at: www.cfsan.fda.gov/~dms/flg-6c.html.

Qualified Health Claims. FDA's 2003 *Consumer Health Information for Better Nutrition Initiative* provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited. Both conventional foods and dietary supplements may use qualified health claims. FDA uses its enforcement discretion for qualified health claims after evaluating and ranking the quality and strength of the totality of the scientific evidence. Although FDA's "enforcement discretion" letters are issued to the petitioner requesting the qualified health claim, the qualified claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter. FDA has prepared a guide on interim procedures for qualified health claims and on the ranking of the strength of evidence supporting a qualified claim, see: www.cfsan.fda.gov/~dms/hclmgui3.html. Qualified health claim petitions that are submitted to FDA will be available for public review and comment. A [listing of petitions open for public comment](#) is at the FDA Dockets Management website. A summary of the qualified health claims authorized by FDA may be found at: www.cfsan.fda.gov/~dms/qhc-sum.html. For more information on Qualified Health Claims, see www.cfsan.fda.gov/~dms/lab-qhc.html.

II. Nutrient Content Claims

The Nutrition Labeling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient or dietary substance

in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not "characterize" the nutrient level may be used to describe any amount of a nutrient present. However, a statement such as "only 200 mg of sodium" characterizes the level of sodium as being low and would therefore need to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement that it does not comply with the claim. Most nutrient content claim regulations apply only to those nutrients or dietary substances that have an established daily value:

www.cfsan.fda.gov/~dms/flg-7a.html. The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as *high* or *low*, are used consistently for all types of food products and are thus meaningful to consumers. *Healthy* has been defined by a regulation as an implied nutrient content claim that characterizes a food that has "healthy" levels of total fat, saturated fat, cholesterol and sodium. Percentage claims for dietary supplements are another category of nutrient content claims. These claims are used to describe a percentage level of a dietary ingredient for which there is no established Daily Value. Examples include simple percentage statements such as "40% omega-3 fatty acids, 10 mg per capsule," and comparative percentage claims, e.g., "twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)." (See 21 CFR 101.13(q)(3)(ii):

www.cfsan.fda.gov/~lrd/cf101-13.html.) A summary of the rules for use of nutrient content claims can be found in Chapter VI of The Food Labeling Guide: www.cfsan.fda.gov/~dms/flg-toc.html. Examples of nutrient content claims can be found in Appendices A and B of The Food Labeling Guide: www.cfsan.fda.gov/~dms/flg-6a.html and www.cfsan.fda.gov/~dms/flg-6b.html.

III. Structure/Function Claims

Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory procedures for such claims for dietary supplement labels. Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or

function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-approved by FDA but must be truthful and not misleading. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or

prevent any disease," because only a drug can legally make such a claim. Further information regarding structure/function claims can be found in FDA's January 9, 2002 Structure/Function Claims Small Entity Compliance Guide:

www.cfsan.fda.gov/~dms/scfmguid.html. Manufacturers of dietary supplements that make structure/function claims on labels or in labeling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claim.

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