



FEB 3 2006

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Jeff Dahlberg
Chairman
The Whole Grains Council
Oldways Preservation Trust
266 Beacon Street
Boston, Massachusetts 02116

Dear Mr. Dahlberg:

This is in response to your letter to Margaret O'K. Glavin, dated December 28, 2005, concerning the Food and Drug Administration's (FDA) denial of a citizen petition to define "excellent source," "good source," and "made with" as descriptors for the whole grain content of foods. Your letter stated that the Whole Grains Council feels strongly about the following four points: (1) The view that "whole grains equal fiber" is outdated; (2) a full serving of whole grains does not naturally contain 5 g of fiber; (3) statements such as "2g of whole grain" will mislead consumers; and (4) consumers are best served by consistent government policy.

As you are aware, FDA denied the citizen petition mentioned in your letter (Docket No. 2004P-0223) on November 8, 2005. The denial letter noted that there are important questions for the agency to resolve related to the classification of certain label statements on foods, including those for whole grains. We agree that many whole grain foods do not contain sufficient fiber to make a fiber claim and we are aware that scientific evidence has suggested that the health benefits of whole grains are based on more than their fiber content. However, the agency first needs to decide the appropriate classification of certain types of label statements, such as those in the denied citizen petition, before proposing such statements.

All statements on food labels must be truthful and not misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act). Information on the entire label must be taken into consideration on a case by case basis to determine whether a label is false or misleading. We currently do not have evidence to demonstrate that factual statements about whole grains, such as "2g of whole grain," are misleading to consumers.

We agree that consumers are best served by consistent government policy. We have had discussions with USDA and are working with them to ensure consistency on our whole grain policies.

You provided an attachment to your letter that explained your whole grain stamp program. However, the stamps use the terms "good source" and "excellent source" and the program

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defines these terms similar to that set forth in the denied citizen petition. We wish to point out that food labels bearing these stamps could be misbranded under sections 403(a) and 403(r).

As you know, the Center for Food Safety and Applied Nutrition (CFSAN) publishes annually its list of program priorities for the year. For FY 2005, CFSAN listed "Develop strategy to initiate rulemaking on claims for whole grains" as a "B" item. Activities on the "B-list" are those we plan to make significant progress on, but which we may not complete before the end of the fiscal year. We are working on 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. We wish to assure you that we are actively working on this initiative.

We hope this is helpful.

Sincerely yours,



Shellee Anderson


Special Assistant

Food Labeling and Standards Staff

Center for Food Safety and

Applied Nutrition

WHOLE GRAINS COUNCIL



Whole Grains at Every Meal

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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Panera Bread
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Rudi's Organic Bakery
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Snyder's of Hanover
David Thomas
Sorghum Partners
Anne Banville
USA Rice Federation

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www.wholegrainscouncil.org

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

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:

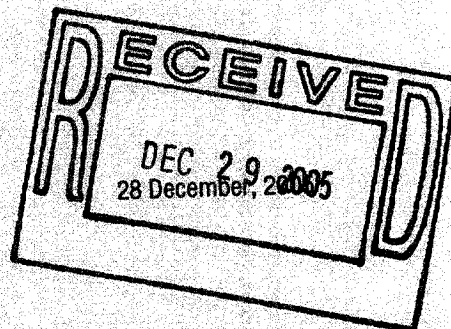
"Whole grain cereals are also sources of phytochemicals, such as phytate and phytoestrogens, which may independently impact CHD." (p. 369)

"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 multi-plicity 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 – that are 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,



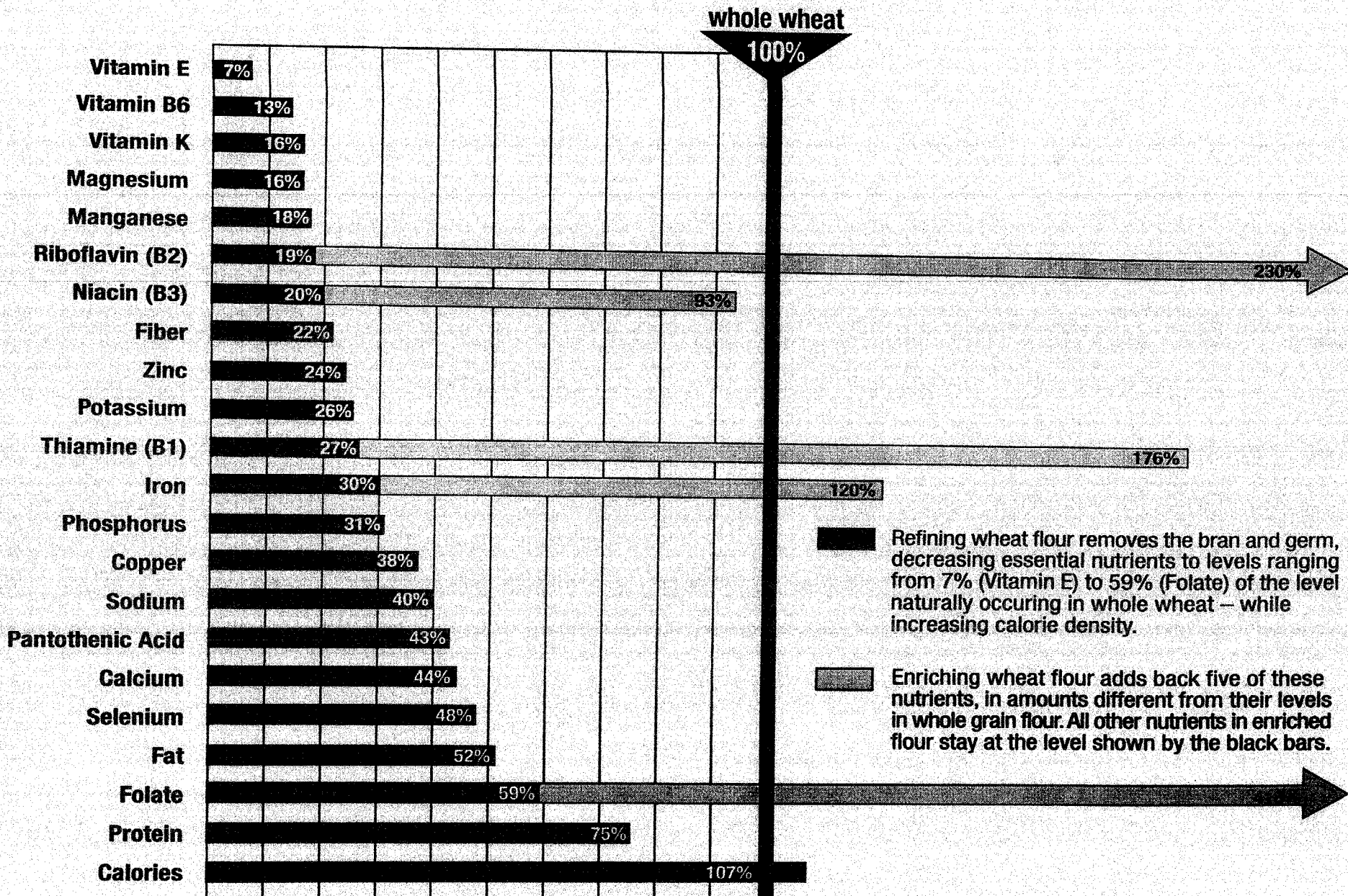
Jeff Dahlberg
Chairman, the Whole Grains Council

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

Nutrients in Wheat Flour: Refined, Whole and Enriched

When whole wheat flour equals 100%, this chart compares nutrients in refined flour, without and with enrichment.



The Whole Grain Stamp Program

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

Officers & Directors

Jeff Dahlberg, Chairman
Nat'l Grain Sorghum Producers*
Mike Orlando, Immediate Past Chair
Sunnyland Mills*
Robert Brown, Vice Chair
Frito-Lay*
Mary Jane Hominda, Vice Chair
Roman Meal Company*
David Neuman, Vice Chair
Nature's Path*
K. Dun Gifford, Secretary-Treasurer
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Arrowhead Mills
Lorraine Hood
Barbara's Bakery
Dennis Gilliam
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Kouassi Kouakou
Campbell Soup
Kent Symms
Farmer Direct Foods
Keith Dierberg
Fleischmann's Yeast
Susan Crockett
General Mills
Paul Kirby
Hodgson Mill
André Giles
Kamut Association
Montana Flour & Grains
Dave Anderson
King Arthur Flour
Glenn Vance
Lesaffre Yeast Corporation
Caryl Levine
Lotus Foods
Paul Stitt
Natural Ovens
Gordon Albright
Panera Bread
Betsy Jarvis
Rudi's Organic Bakery
Robert Gould
Snyder's of Hanover
David Thomas
Sorghum Partners
Anne Barville
USA Rice Federation

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 is 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 serving or a full 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

Whole Grains Council members began adding the Stamps to their packaging in February 2005. By mid-2005, a wide range of breads, cereals, crackers, soups and other products bearing the Whole Grain Stamp appeared on retail shelves and in restaurants, bakeries and cafés.

A consumer-education campaign on the Stamp program is underway, which has included the Today Show (March 28) and Oprah (May 3), along with ongoing coverage in major newspapers and magazines including *Parade*, *Cooking Light*, *Prevention*, *the Washington Post*, *Time magazine* and more.

Any company that is a member of the Whole Grains Council and has qualifying whole grain products is eligible to use the Stamp. Council members include most major grain-products producers, along with a diverse group of smaller companies across the industry spectrum.

The goals of the Whole Grains Council include making the Stamp universal, so that consumers can quickly and easily recognize the wide range of delicious whole grain options offered in their favorite supermarkets and restaurants. In 2006-2007 the Council is also working on new campaigns to bring more whole grains to schools and restaurants.

At the end of 2005, the Whole Grains Council included 103 members (see list on following page). Over half of these companies had already begun to use the Stamp, while most of the others were in the process of implementing this useful consumer tool. Over 450 qualifying products have been registered with the Council for the right to use the Whole Grain Stamp on packaging, with more being added each week.

Questions about the Whole Grains Council can be addressed to Cynthia Harriman, Oldways Preservation Trust, 617-896-4820 or Cynthia@oldwayspt.org.

Whole Grains Council Members as of December 28, 2005
(a complete list is on our website)

Oldways Preservation Trust

Abel & Schafer
Alpine Valley Bakery
Alvarado St. Bakery
American Institute of Baking
American Italian Pasta Co.
American Rice, Inc.
Arrowhead Mills
Aunt Millie's / Perfection Bakeries
Bagel Boy
Bakery Barn
Barbara's Bakery
Bionaturae / Euro-USA Trading Co.
BLIMPIE International
Bob's Red Mill
Bread Basket
Bruegger's Bagels
Café Valley
Canada Bread
Cargill / Horizon Milling
CereformUSA
Damascus Bakery
Del Mar Nutrition
Dr. Kracker
Earth's Best / Hain-Celestial
Enjoy Life Natural Brands
Farmer Direct Foods
Farm to Market Bread
Flatout Bread
Fleischer's Bagels
Fleischmann's Yeast
Food for Life Baking Co.
Frito-Lay
Frontier Soups
Fullbloom Baking Co.
Gardenburger

General Mills

Gia Russa / Starletta Organics
Giusto's Specialty Foods
Gold Medal Bakery
Grain Millers / Country Choice
Great Harvest Bread Co.
Harbar Corporation
Harvest Time Bread
Health Valley / Hain-Celestial
Hodgson Mill
Indian Harvest Specialty Foods
Interstate Bakeries
Jessica's Brick Oven
Kamut Assn / Montana Flour & Grains
Kashi
Kavli International AS
Kellogg
King Arthur Flour
La Bonita Olé
La Brea Bakery
La Tortilla Factory
Lesaffre Yeast
Lotus Foods
Martin's Supermarkets
Mary's Gone Crackers
McCann's
Mestemacher Bread
Mission Foods
National Barley Foods Council
National Sorghum Producers
National Rice Company
Natural Ovens
Nature's Path
Northern Gold Foods Ltd.
Nu-World Amaranth

Panera Bread

Prodotti Mediterranei
Purity Foods
Quaker Oats
Raccorto
Ricera
Rice-Tec
Rich Products
Riviana Foods
Rizzuto Foods
Roman Meal Company
Rubschlagel Baking
Rudi's Organic Bakery
Schwan Food Co.
Snyder's of Hanover
Sorghum Partners
Sturgis Foods
Sturm Foods
Sunnyland Mills
Sunrich
Sunwest Foods
The Baker
Tia Rosa / Bimbo Bakeries
Tortilla King / Mama Lupe's
Traditional Breads
Tumaro's Gourmet Tortillas
Uncle Ben's / Masterfoods USA
Unilever
USA Rice Federation
Van's International
Vermont Bread
Western Bagel
Zen Bakery