

11 May 2006

Division of Dockets Management
(HFA - 305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061.
College Park, MD 20852

Re: Federal Register, Vol. 71, No. 33, Docket No. 2006D-0066

This is responding to the announcement in the Federal Register, vol. 71, No. 33, Friday, February 17, 2006 regarding Draft Guidance for Industry and FDA staff: Whole Grains Label Statements: Availability.

I am a member of the Advisory Committee on Public Policy of the Society for Nutrition Education (SNE). I was the principal author of the comments made by SNE during the process of development of the Dietary Guidelines for 2005 and MyPyramid. In my capacity as Foods and Nutrition Specialist I develop programs in nutrition education for the University of Puerto Rico. As part of my job I have been trying to teach the public how to identify whole grain products that conform to intent of the 2005 Dietary Guidelines and My Pyramid. It is not an easy job.

A food guide, by definition, attempts to supply the nutrients that are needed based on non-enriched, non-fortified foods. That is the point of developing such a guide.

Both in MyPyramid and the Dietary Guidelines for Americans 2005, it is emphasized that the foods recommended are in their form of lowest fat and sugar. The concept of discretionary calories was added by the DGAC to emphasize how little added sugar and fat can be included and still retain a diet with high nutritional value.

In the discussion of whole grains the point is emphasized that as an entity they seem to have properties that are beneficial beyond their known nutrient content, i.e. the whole is greater than the parts.

The discretionary calories in the food patterns that form the basis for the recommendations of MyPyramid range from 154 for small children (1,000 kcal pattern) to 334 for those who need 3,200 kcal per day. The amount in 2,000 kcal is 208 kcal.

At the end of this letter I have included descriptions from labels found in the supermarket. They include a whole grain bread (with added nutrients), a whole wheat bread, a breakfast cereal with "whole grains" prominently displayed on the label and aimed at children, and another breakfast cereal, with "whole grains" prominently on the label that is aimed at adults. The calories from sugars in these products range from 12 to 45 kcal per portion, with one of the cereals aimed at children having 44 kcal from sugar per portion. The fortification of these products runs from none to 100% for selected nutrients. For cereals it is unlikely that a person eats only "one portion", frequently less than one cup of cereal.

None of these differences are clear from the information stated on the front of the box or label. One has to read the nutrition facts panel, and do some simple math (sugar content * 4) to get the facts that I have presented.

It is my understanding that it is the intent of the FDA to clarify this situation so that a person can read the front of the label and know what is in the package. With that in mind I think that the definition of whole grains has to address the issue of the sugar content and the fortification status of the product. If not, the public cannot discern what whole grain foods that are harmonious with the guidelines as issued. Whi this in mind I propose the following definitions:

- Whole grain: A product that maintains the principal anatomical components – the starchy endosperm, germ and bran –in the same relative proportions as they exist in the intact caryopsis. Such products do not have added nutrients that do not occur in the whole grain, and the amount of added sugars or other sweeteners is limited to no more than 3 grams per 100 kcal.
- Made with whole grains: A product in which 51% or more of the grains in the product, by weight, are whole grains and the other grains present are enriched but not fortified with other nutrients. The label “made with whole grains” would not apply to products that contain more than 5 grams of sugar per 1 ounce equivalent of the product.
- For all products that include whole grains whether they qualify for the label of “whole grain” or “made with whole grain” the label should also state the grams of whole grain present in the product and the amount recommended. For example, “[Name of product] provides at least x grams of whole grain in each serving. At least 48 grams of whole grain is recommended daily.”

In conclusion we recommend that the FDA consider two levels of labeling for whole grain products: “whole grain” and “made with whole grain”. In addition we recommend that the label of any food that contains whole grains include a statement as to the grams of whole grains present compared with the amount recommended in the reference 2,000 kcal diet..

Thank you for your consideration of this matter.

Sincerely,

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Examples of bread and cereal labels found in Supermarkets

Breads:

Healthy Choice, “100% whole grain”:

Ingredient list: whole wheat flour, water, crushed wheat, wheat gluten, high fructose corn syrup, raisin juice concentrate, contains 2% or less of the following: honey, molasses, yeast, cultured whey, maltodextrin, salt, canola oil, dough conditions (soy lecithin, mono and diglycerides, guar gum, ascorbic acid), malted barley flour, yeast nutrients (ammonium sulfate), calcium sulfate (calcium), niacin, iron, (ferrous sulfate), thiamine monitrate (Vitamin B1), riboflavin (vitamin B2), folic acid. No artificial preservatives added.

Nutrition facts: Calories per serving: 80 (1 slice, 38 gm).

Total fat, 1 gm.	2%	Sodium, 170 mg.	6%
Saturated fat, 0 gm.	0%	Total Carbohydrate, 18 gm.	6 %
Polyunsaturated fat, 0 gm.		Dietary fiber, 3 gm.	12%
Monounsaturated fat, 0 gm.		Sugars, 3 gm	
Cholesterol, 0 mg.	0%	Protein, 3 gm	

Vitamin A	0%	Niacin	15%
Vitamin C	0%	Magnesium	6%
Calcium	15%	Phosphorus	6%
Iron	15%	Zinc	4%
Thiamine	15%	Copper	4%
Riboflavin	15%	Folic acid	15%

= enriched whole grain bread (iron, thiamine, riboflavin, niacin, folic acid) and fortified with calcium. This means that the proportion between the nutrients has been altered. The implication is that the body is receiving too much of some and, in comparison, not enough of others. (Please note the number of nutrients at 15%, and these are the ones mentioned on the label as being added).

Nature’s Own: “100 % whole wheat”

Ingredient list: whole wheat flour, water, brown sugar, yeast, wheat gluten. Contains 2% or less of each of the following: honey, salt, vegetable oil, conditioners (sodium stearoyl lactylate, calcium stearoyl-2-lactylate, monoglycerides, calcium iodate, calcium peroxide, datem), cultured whey, vinegar, calcium sulfate, monocalcium phosphate, yeast food (ammonium sulfate).

Nutrition facts: Calories per serving: 50 (26 gm o 0.9 onzas)

Total fat, 1 gm.	2%	Sodium, 115 mg.	5%
Saturated fat, 0 gm.	0%	Total Carbohydrate, 10 gm.	3 %
Polyunsaturated fat, 0 gm.		Dietary fiber, 2 gm.	8%
Monounsaturated fat, 0 gm.		Sugars, 1 gm	

Cholesterol, 0 mg.	0%	Protein, 4 gm	
Vitamin A	0%	Niacin	10%
Vitamin C	0%	Magnesium	N/A
Calcium	4%	Phosphorus	N/A
Iron	2%	Zinc	N/A
Thiamin	6%	Copper	N/A
Riboflavin	6%	Folic acid	4%

= whole wheat bread, not enriched or fortified. (Please note that the percent of the nutrients varies on the label. The differences in terms of dietary fiber and carbohydrates are caused by the difference in the size of a slice).

Note: both breads have 3 grams of sugar or less per portion.

Cereales:

Quick oats:

Ingredient list: 100 % rolled oats

Nutrition facts: Calorías por porción: 140 (½ cup, 39 gm, dry).

Total fat, 3 gm.	5%	Sodium, 0 mg.	0%
Saturated fat, 0.5 gm.	3%	Total Carbohydrate, 26 gm.	11%
Polyunsaturated fat, 0 gm.		Dietary fiber, 4 gm.	16%
Monounsaturated fat, 0 gm.		Soluble fiber, 2 gm.	
		Sugars	N/A
Cholesterol, 0 mg.	N/A	Protein, 5 gm	

Not a significant source of cholesterol, sugars, vitamin A, vitamin C and calcium. (Iron and other nutrients are not listed because the law permits their listing, but does not mandate it).

For children:

Lucky charms (General Mills): Announced on the front of the box: “ Whole Grain”

Ingredient list: oat flour, marshmallows (sugar, modified corn starch, corn syrup, dextrose, gelatin, calcium carbonate, yellow 5&6, blue 1, red 40, artificial flavor), sugar, corn syrup, corn starch, salt, calcium carbonate, color added, trisodium phosphate, zinc and iron (mineral nutrients), vitamin C (sodium ascorbate), A B vitamin (nicinamide). Artificial flavor, vitamin B6 (pyridoxine hydrochloride), vitamin B2 (Riboflavin), vitamin B1 (Thiamin mononitrate), vitamin A (palmitate), A B vitamin (folic acid), Vitamin B12, Vitamin D, wheat starch, vitamin E (mixed tocopherols) added to preserve freshness.

Nutrition facts: Calories per serving: 120 (1 cup, 30 gm.).

Total fat, 1 gm.	1%	Sodium, 170 mg.	6%
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Saturated fat, 0 gm.	0%	Total Carbohydrate, 25 gm.	10%
Trans fat, 0 gms.		Dietary fiber, 1 gm.	4%
Polyunsaturated fat, 0.5 gm.		Sugars, 13 gm	
Monounsaturated fat, 0.5 gm.		Other carbohydrates, 11 gm.	
Cholesterol, 0 mg.	0%	Protein, 2 gm	

Vitamin A	10%	Niacin	25%
Vitamin C	25%	Vitamin B6	25%
Calcium	10%	Folic Acid	25%
Iron	45%	Vitamin B12	25%
Vitamin D	10%	Phosphorus	N/A
Thiamin	25%	Magnesium	N/A
Riboflavin	25%	Zinc	10%

This product has 44 kcal of sugar in a 120 kcal portion. (i.e. 37% sugar)

Hunny B's (Kellogg's Disney)

List of ingredients: Corn meal, graham flour, brown sugar, sugar, salt, high fructose corn syrup, calcium carbonate, wheat starch, honey, baking soda, caramel color, artificial cream flavor, iron, sodium ascorbate and ascorbic acid (vitamin C), niacinamide, red #40, yellow #5, zinc oxide, blue #1, pyridoxine hydrochloride (Vitamin B6), yellow #6, riboflavin (vitamin B2), thiamin hydrochloride (vitamin B1), vitamin A palmitate, BHT (preservative), folic acid, turmeric color, vitamin D, vitamin B12.

Nutrition facts: Calories per serving: 110 (1 cup, 29 gm).

Total fat, 0.5 gm.	1%	Sodium, 280 mg.	15%
Saturated fat, 0 gm.	0%	Total Carbohydrate, 24 gm.	10%
trans fat, 0 gm.		Dietary fiber, 1 gm.	5%
		Sugars, 6 gm	
Cholesterol, 0 mg.	0%	Other carbohydrates, 17 gm.	
		Protein, 2 gm	

Vitamin A	10%	Niacin	25%
Vitamin C	25%	Vitamin B6	25%
Calcium	10%	Folic Acid	25%
Iron	45%	Vitamin B12	25%
Vitamin D	10%	Phosphorus	N/A
Thiamin	25%	Magnesium	N/A
Riboflavin	25%	Zinc	10%

This product provides 24 kcal of sugar in a 110 kcal portion. (i.e. 22% sugar)

For adults:

Special K, Vanilla Almond (Kellogg's)

Ingredient list: rice, whole grain wheat, sugar, honey coated sliced almonds (dry roasted almonds, sugar, honey, water maltodextrin, salt), high fructose corn syrup, salt, malt flavoring, ascorbic acid (vitamin C), natural and artificial flavors, reduced iron,

niacinamide, pyridoxine hydrochloride (vitamin B6), riboflavin (vitamin B2),k thiamin hydrochloride (vitamin B1), vitamin A palmitate, BHT (preservative), folic acid, vitamin D and Vitamin B12.

Nutrition facts: Calories per serving: 110 (3/4 cup, 30 gm).

Total fat, 1.5 gm.	2%	Sodium, 160 mg.	7%
Saturated fat, 0 gm.	0%	Total Carbohydrate, 25 gm.	8%
Trans fat, 0 gm.		Dietary fiber, 1 gm.	6%
		Sugars, 9 gm	
Cholesterol, 0 mg.	0%	Protein, 2 gm	

Vitamin A	15%	Niacin	35%
Vitamin C	35%	Vitamin B6	35%
Calcium	0%	Folic Acid	35%
Iron	45%	Vitamin B12	35%
Vitamin D	10%	Phosphorus	N/A
Thiamin	35%	Magnesium	N/A
Riboflavin	35%	Zinc	N/A

This product provides 45 calories of sugar in a 110 calories serving (i.e. 41% sugar).

Whole Grain Total (General Mills). Announced on the front of the box: “ Whole Grain”. It also says: “excellent source of whole grain”, but does not indicate the quantity.

Ingredient list: Whole grain wheat, sugar, calcium carbonate, whole grain brown rice, corn syrup, salt, corn bran, lactose, distilled monoglycerides, vitamin C (sodium ascorbate), zinc and iron (mineral ingredients), vitamin E, (tocopheryl acetate), A B vitamin (niacinamide), a B vitamin (calcium pantothenate), annatto extract color, vitamin B6 (pyridoxine hydrochloride), vitamin B2 (riboflavin), vitamin B1 (thiamin mononitrate), a B vitamin (folic acid), vitamin A (palmitate), vitamin B12, vitamin D. Freshness preserved by BHT.

Nutrition facts: Calorías por porción: 110 (3/4 taza, 30 gm.).

Total fat, 1 gm.	1%	Sodium, 190 mg.	8%
Saturated fat, 0 gm.	0%	Potassium, 90 mg.	3%
Trans fat, 0 gm.		Total Carbohydrate, 23 gm.	8%
Polyunsaturated fat, 0 gm.		Dietary fiber, 3 gm.	10%
Monounsaturated fat, 0 gm.		Sugars, 5 gm	
Cholesterol, 0 mg.	0%	Protein, 2 gm	

Vitamin A	10%	Niacin	100%
Vitamin C	100%	Vitamin B6	100%
Calcium	100%	Folic Acid	100%
Iron	100%	Vitamin B12	100%
Vitamin D	10%	Pantothenic acid	100%
Vitamin E	100%	Phosphorus	8%

Thiamin	100%	Magnesium	6%
Riboflavin	100%	Zinc	100%
		Copper	4%

This product provides 20 kcal of sugar in 110 calorie portion (i.e. 18% sugar). While some nutrients are provided at 100% levels, others are 4 to 8 percent. Whole grains, because of the quantity eaten, should be a significant source of magnesium, i.e. in six portions one would get 1/3 of the magnesium required during the day.