



A nonprofit education organization
dedicated to increased consumption of
whole grains to provide better health for
all consumers

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March 22, 2012

Re: Docket No. FDA-2011-N-0320

OMB control # 0910-New: Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages.

Office of Information and Regulatory Affairs
OMB

Attn: FDA Desk Officer,

We are writing in response to the Food and Drug Administration's (FDA) planned Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages, on behalf of Oldways Preservation and Exchange Trust, Inc. ("Oldways"), a 501(c)(3) non-profit organization that created and operates the Whole Grains Council. As the world's leading educational organization promoting whole grains, Oldways and its Whole Grains Council applaud the FDA and the Center for Food Safety and Applied Nutrition (CFSAN) for its sustained efforts to support clarity and understanding on whole grain labels.

We share the goal of better whole grain labeling. For several years our Whole Grain Stamp has been a major force in replacing unsubstantiated, vague and interpretive claims with a simple descriptive statement of whole grain content in grams, as permitted in FDA's 2006 Draft Guidance on Whole Grain Label Statements. Because of its widely accepted success in helping consumers find products offering a significant amount* of whole grain, the Whole Grain Stamp is now used on more than 6,600 products in 35 countries.

We would like to express our concerns regarding the Whole Grain Stamp, a registered certification mark of Oldways, and its misuse as proposed in the current draft of the Study. Oldways believes that such use will constitute infringement and dilution under U.S. trademark law. Two versions of the Whole Grain Stamp have been registered as certification marks with the United States Patent and Trademark Office, Registration Nos. 3,934,580 and 3,934,582. The Whole Grain Stamp can only be used with the express prior approval of Oldways, on products containing 8 grams or more of whole grain content. Pairing it with ingredient lists and Nutrition Facts Panels that do not reflect this amount of whole grain content, as planned in the Study, would also be false and misleading.

In addition to these trademark issues, misuse of the Whole Grain Stamp could have two major negative impacts that we believe are inconsistent with CFSAN's intent and goals for the Study. As we have detailed in the attached material, we believe use of the Whole Grain Stamp in the proposed manner will result in erroneous and misleading survey data, with damaging results for federal policy and public health. Moreover, we are concerned

* 8 grams is a significant amount of whole grain according to the USDA FSIS Statement of Interim Policy Guidance (October 2005), the IOM report School Meals: Building Blocks for Healthy Children (October 2009), and the 2010 Dietary Guidelines for Americans (January 2011).

that this misuse will risk further confusing consumers, and undermining the intent of the Study as well as the FDA's continuing work to improve consumers' nutrition and dietary choices.

We feel confident that these are not CFSAN's intentions for the Study, and encourage FDA to consider broadening the Study's scope beyond its current focus on misleading claims, to also collect data on how consumers understand and use the three methods of identifying whole grains recommended in the 2010 Dietary Guidelines for Americans (p. 37):

- 1) Look for 100% whole grain foods.
- 2) Look for foods where 51% of the total weight is whole grain (i.e. that qualify for the FDA Whole Grain Health Claim)
- 3) Look for foods with at least 8 grams of whole grains.

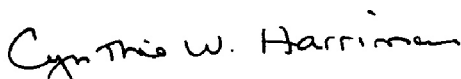
The Whole Grain Stamp, with its clearly defined and enforced standards, supports two of these three government-recommended methods, and could be part of such a broadened scope. We have also attached information on the standards of the Whole Grain Stamp certification mark, and a review of the whole grain content of products that bear the Whole Grain Stamp.

We hope that Dr. Schneeman, Dr. Poos and others on their team would be willing to meet with us to discuss our concerns. We would be happy to work with you to suggest and approve ideas for incorporating the Whole Grain Stamp into this Study in meaningful ways, as well as to hear your suggestions for ways that Oldways and the Whole Grains Council can continue to support the good work of CFSAN. Please let us know if we can answer any questions, and thank you for the opportunity to contribute to the success of the proposed Study.

Best regards,



Sara Baer-Sinnott, President



Cynthia W. Harriman, Director of Food & Nutrition Strategies

Study Methodology Misrepresents the Whole Grain Stamp

Oldways and the Whole Grains Council are deeply concerned with the FDA's proposed misuse of the Whole Grain Stamp in the Agency's planned Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages.

The methodology of the Study involves randomly pairing different labels with one of two different ingredient lists. Version 1 of the ingredient list shows a whole grain ingredient in the first position. Version 2 shows the first whole grain ingredient in the fourth position (breakfast bar), the seventh position (bread) or the eighth position (tortilla chips).

Salty Snack / Tortilla Chips. The label shows an 8g Whole Grain Stamp, and a serving size of 28g. This means that whole grains make up 28.6% of the weight of this product. Yet the V2 Ingredient List shows the first whole grain ingredient in the eight position.

INGREDIENTS: YELLOW CORN FLOUR, MALTODEXTRIN, SOYBEAN OIL, CHICORY ROOT FIBER, POLYDEXTROSE, ONION POWER [SIC], GARLIC POWDER, **WHOLE CORN**, CITRIC ACID, NATURAL AND ARTIFICIAL FLAVORS, BUTTERMILK, ARTIFICIAL COLOR, SALT, SPICES, WHEY PROTEIN CONCENTRATE, MONOSODIUM GLUTAMATE.

It's mathematically impossible for seven other ingredients to each weigh more than an ingredient that makes up 28.6% of a product. Therefore, this label implies that the product does not actually contain 8g of whole grain, and depicts the Whole Grain Stamp as untruthful and misleading.

Even consumers who are not mathematically inclined would know that a product that had a whole grain only after the onion powder and garlic powder would contain very little grain. Products showing the Whole Grain Stamp must contain 8g or more of whole grain, an amount which has been defined by USDA/FSIS, IOM, and the 2010 Dietary Guidelines as a significant amount of whole grain.¹

Bread. The label shows an 8g Whole Grain Stamp, and a serving size of 38g. This means that whole grains make up 21.05% of the weight of this product. Yet the V2 Ingredient List shows the first whole grain ingredient in the seventh position, with additional whole grain ingredients in the eighth, thirteenth and fourteenth positions.

INGREDIENTS: WHEAT FLOUR, MALTED BARLEY FLOUR, WATER, YEAST, SUGAR, SOYBEAN OIL, **WHOLE WHEAT FLOUR, WHOLE GRAIN WHEAT**, SUNFLOWER SEEDS, HONEY, WHEAT STARCH, SALT, **WHOLE GRAIN BARLEY, WHOLE GRAIN RYE**, SOY FLOUR, CULTURED WHEAT FLOUR, WHEAT GLUTEN.

¹ 8 grams is a significant amount of whole grain: USDA FSIS Statement of Interim Policy Guidance (October 2005) states (page 3), "A significant amount of whole grain would be at least a one-half ounce equivalent of whole grain ingredient, i.e., at least grams of dry whole grain ingredient...". The IOM report School Meals: Building Blocks for Healthy Children (October 2009) states (page 125), "...the goal of the criterion is to ensure that foods qualify as whole grain-rich if they contain at least 8 g of whole grains..." And the 2010 Dietary Guidelines for Americans states (page 37) that "Another example [of foods that help meet the whole grain requirement] is foods with at least 8 grams of whole grains per ounce-equivalent."

Even consumers who have never made bread have seen tiny packets of yeast in the store and would intuitively understand that if whole grains were less than the amount of yeast, they would not constitute 21% of the product. (According to nationally-respected bread expert Peter Reinhart², yeast typically makes up 0.5%-1% of the finished weight of bread, and sugar and oil typically make up less than 4% of total weight each.)

In this case, four whole grain ingredients add up to 21% of the total weight. As with the salty snacks, it's mathematically impossible to create an FDA-compliant label with this ingredient list and 8g of whole grain.

The weight of bread typically is composed of about:

55%	Grain	21g in a 38g serving
35-40%	Water	13-15g in a 38g serving
5-10%	Other ingredients	2-4g in a 38g serving

If we assume the first two whole grain ingredients are in larger amounts than the last two, to make up the stated 8g of whole grain, this product would contain

13g	wheat flour
—	malted barley flour ³
13g	water (taking the lower, conservative end)
—	yeast
—	sugar
—	soybean oil
3g	whole wheat flour
3g	whole grain wheat
—	sunflower seeds
—	honey
—	wheat starch
—	salt
2g	whole grain barley
2g	whole grain rye
—	soy flour, cultured wheat flour, wheat gluten, combined

The other 11 ingredients can only add up to about 4g between them – something that's not possible with the ingredients in this order.

A real bread label with 21% whole grain content looks very different. We reviewed our database of products using the Whole Grain Stamp and found that, in sandwich breads where 21% or less of the total weight is whole grain, the first whole grain ingredient comes no later than the third ingredient:

Position of first whole grain	Proportion of labels
1 st ingredient	8%
2 nd ingredient	32%
3 rd ingredient	60%

² Peter Reinhart, one of the world's leading authorities on bread, is baking instructor at Johnson & Wales University and author of several award-winning books on bread baking. Information by email, March 2012.

³ Malted barley flour is created by sprouting whole barley kernels, creating a mash and then drying it. Depending on further processing, the resulting product may or may not be a whole grain, so we are leaving the malted barley flour out of the whole grains equation here. In any event, malted barley flour is limited to 0.75% of both wheat flour and whole wheat flour by their respective federal Standards of Identity.

This is not surprising. When a bread is made with roughly equal amounts of refined and whole grains, it's not uncommon for water (35 - 40% of total weight) to be the first ingredient, followed by either refined grain or whole grain (under 30% each).

Therefore, this label implies that the product does not actually contain 8g of whole grain, and depicts the Whole Grain Stamp as untruthful and misleading. As defined since the program's inception in 2005, products showing the Whole Grain Stamp must contain 8g or more of whole grain. This level has been defined by USDA/FSIS, IOM, and the 2010 Dietary Guidelines as a significant amount of whole grain.

Breakfast Bar. The label shows an 8g Whole Grain Stamp, and a serving size of 40g. This means that whole grains make up 20% of the weight of this product. The lower-whole-grain Ingredient List (V1 in this case) shows the first whole grain ingredient in the fourth position, with an additional whole grain ingredient in the fifth position.

INGREDIENTS: SOY PROTEIN ISOLATE, CORN SYRUP, SOYBEAN OIL, **WHOLE GRAIN ROLLED OATS, WHOLE WHEAT FLOUR,** CHICORY ROOT FIBER, POYDEXTROSE, MALTODEXTRIN, PALM KERNEL AND PALM OIL, ARTIFICIAL FLAVOR.

In this case, the order of ingredients seems less misleading at a quick glance. Discerning consumers, however, would notice that the Nutrition Facts Panel lists only 4g of fat, while listing three oils: soybean oil, palm kernel oil and palm oil. (We'll ignore the additional fat content of other ingredients, to keep things simple.) If the two whole grain ingredients add up to 8g together, the first must be at least 4g. Yet it comes after the soybean oil, which must be less than 4g.

Therefore, this label implies that the product does not actually contain 8g of whole grain, and depicts the Whole Grain Stamp as untruthful and misleading.

Impact of Misuse of the Whole Grain Stamp

With the proposed methodology, we feel that FDA's infringement of the Whole Grain Stamp certification mark will have three major negative impacts:

1) It will result in skewed data that can lead to skewed policies.

Respondents in the Experimental Study are asked to answer several questions based on the label they are shown. Misuse of the Whole Grain Stamp could undermine the reliability of collected data. Question B5, for example, asks consumers to rate the claim shown on a scale of "Not trustworthy at all" to "Very trustworthy." Consumers shown the Whole Grain Stamp paired with an impossible Nutrition Facts Panel and Ingredients List may answer "Not trustworthy at all" simply based on FDA's misuse of the Stamp.

(We question overall the use of unrealistic label and ingredients examples in this Study. Although the Federal Register notice says that "All label images will be mock-ups resembling food labels that may be found in the marketplace," the bread label, especially, bears little resemblance to a real bread label, further confounding the variables that may enter into consumers' responses.)

2) It will risk further confusing consumers.

For seven years, the Whole Grain Stamp has been a reliable and trusted way for consumers to identify products offering a significant amount of whole grain. If consumers were to see FDA misrepresenting the Whole Grain Stamp, their confidence and justified

certainty in the Stamp would be undermined, pushing back the hard-won increases in whole grain consumption for which the Whole Grain Stamp has been in part responsible.

3) It violates the standards of the Whole Grain Stamp program.

The Whole Grain Stamp is a valued registered certification mark of Oldways and the Whole Grains Council. Use of this symbol in a way that is not in line with the clearly defined standards of the Stamp Program, and is not prior-approved by Oldways and the Whole Grains Council, would constitute trademark infringement and dilution.

In summary, as described in our cover letter, we would welcome the opportunity to work with FDA on appropriate ways to include the Whole Grain Stamp in the FDA's planned Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages.

Please see following pages for



A. Standards of the Whole Grain Stamp Program

B. Statistics on whole grain content of products using the Whole Grain Stamp

FACT SHEET: Standards of the Whole Grain Stamp Program

Two Variations of the Whole Grain Stamp

In the U.S. the Whole Grain Stamp has two principal options⁴, as shown below:

The 100% Stamp	The Basic Stamp
	
<p>For products where ALL of the grain is whole grain.</p>	<p>Product may contain some extra bran, germ, or refined flour.</p>
<p>Minimum: 16g (16 grams) whole grain per serving. (a full serving of whole grain)</p>	<p>Minimum: 8g (8 grams) whole grain per serving. (one half serving of whole grain)</p>

Gram Number Changes to Reflect Whole Grain Content

While 16g and 8g are the minimum requirements for the 100% and Basic Stamps, respectively, these are not the only numbers used on the Stamp. The gram number changes to reflect the whole grain content of each individual product, as shown in the image below:



All products using the Whole Grain Stamp must receive individual review and prior approval, since the Stamp is a registered certification mark.

⁴ FSIS Version: Products containing meat or poultry and subject to USDA / FSIS review have slightly different standards, as agreed with FSIS in August 2006. To use the Basic Whole Grain Stamp, products subject to FSIS review must contain at least 8g of whole grain ingredients per labeled serving and per RACC. At least 51% of the grains in the product must be whole grains.

Descriptive and not Interpretive; no Percentages

The Whole Grain Stamp was designed to support FDA's 2006 Draft Guidance for Whole Grain Labeling, which says that "Manufacturers can make factual statements about whole grains on the label of their products, such as "10 grams of whole grains" ... provided that the statements are not false or misleading..." As such, the identification of grain content in the Whole Grain Stamp is intended to be descriptive rather than interpretive; the Whole Grain Stamp does not attempt to make a judgement about the overall healthfulness of a product, unlike marks such as the defunct Smart Choices.

We incorporated this gram-based approach after discussing alternatives in a meeting with FDA in March of 2006. Another possible alternative discussed with FDA – using the Whole Grain Stamp to document the percent of grain that is whole grain – did not turn out to be possible, since percent declarations on food labels must be expressed as a percent of total weight of *all* ingredients, not of a subset such as grain ingredients.⁵

We decided against this approach as misleading to consumers. For example, a loaf of bread where fifty-one percent of the grain is whole grain might be labeled "Contains 28% whole grain!" since grain typically makes up only about 55% of the total weight of bread. (51% of 55 = 28%) Most consumers would be thoroughly confused by this statement.

⁵ See 21 CFR 102.5(b) "The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids). In its February 2006 Draft Guidance on Whole Grain Labeling, FDA makes one exception, for the labeling of products where all the grain is whole grain, saying "We recommend that products labeled with "100 percent whole grain" not contain grain ingredients other than those the agency considers to be whole grains."

FACT SHEET: Usage of the Whole Grain Stamp

The Whole Grain Stamp is currently used on more than 6,600 products in 35 countries.

31% use the 100% Stamp
69% use the Basic Stamp

Absolute level of whole grain content. Although eligibility for the Whole Grain Stamp starts at a level of 8g per serving of whole grain content, most products contain significantly more than the minimum. In fact, almost two-thirds contain twice the minimum or more:

19% 32 grams or more
45% 16-31 grams
26% 9-15 grams
10% 8 grams

Percent of total weight that is whole grain. Products using the Whole Grain Stamp contain a high percentage of their total weight as whole grain. In 42% of products, the whole grain content comprises at least 51% of the total weight of the grain, a key requirement for the FDA Whole Grain Health Claim.

Percent of grain that is whole grain. Products using the Whole Grain Stamp also contain a high percentage of their grain as whole grain. Whole Grains Council data do not capture this proportion directly. However, this can be derived based on knowledge of category-specific information for common food categories:

Category	Typical % of total weight that is grain ⁶	WG Stamp % of total weight that is whole grain	WG Stamp % of grain that is whole grain
Pasta	100%	82%	82%
RTE cereal	70%	53%	76%
Hot cereal	100%	73%	73%
Bread / Rolls	55%	38%	69%
Crackers	85%	59%	69%
Pizza	23%	13%	57%
Waffles / Pancakes	50%	25%	50%
Bagels / English muffins	50%	22%	44%

Summary. Overall, the Whole Grain Stamp helps consumers quickly and easily identify products containing significant amounts of whole grain.

⁶ Typical percents from the article "Gradual Incorporation of Whole-Grain Flour into Grain-Based Products," by Len Marquart, Hing Wan Chan, Mary Orsted, Kristen Schmitz, Elizabeth Arndt and David Jacobs Jr. *Cereal Foods World*, May-June 2006, Vol. 51, No. 3.