



February 3, 2012

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg:

The Center for Science in the Public Interest (CSPI) is encouraged by the responses that the Food and Drug Administration (FDA) has received to the 17 warning letters that it sent to companies in February 2010 regarding a variety of food labeling violations. CSPI's review found that about 75 percent of those companies have corrected their labeling.¹ Because issuing warning letters to companies whose products displayed misleading labels resulted in provoking timely adherence to FDA regulations, CSPI urges FDA to target additional violations, particularly those that have a significant impact on public health, by using this successful strategy. Accordingly, we are submitting this letter as a recommendation that FDA focus its resources on what we believe to be one of the most common types of deceptive labeling — misleading whole grain claims.

We remind FDA that this is not a new issue. In 1993, then-Commissioner David Kessler² assured us that FDA would act on CSPI's 1993 whole wheat petition,³ saying that the agency would take action on whole wheat claims.⁴

¹ Gerber, one of the companies, that received a warning letter regarding its usage of nutrient content claims on products for children under 2 years of age, has only made partial changes. Gerber Graduates Puffs no longer say "good source of iron, zinc, and vitamin E." However there still are "Nutra Protect" blocks on the principal display panel with the symbols for zinc, iron and vitamin E. Gerber has changed its 2nd Food Carrots label from stating "no added sugar" to "no added salt." In addition, Gerber changed the word "healthy" to "as healthy as fresh" but the label still claims that the product is a good source of vitamin A.

² Dr. Kessler currently serves on CSPI's Board of Directors.

³ CSPI Petition to Prohibit Misbranding of Whole Wheat Products and to Promulgate Food Labeling Regulations Concerning Products Made with Whole Wheat, Docket No. 93P-0227 (Jun. 25, 1993). That petition is still pending.

In February 2006, FDA issued a draft guidance on the issue of whole grain label statements ("2006 Draft Guidance).⁵ CSPI filed comments to the 2006 Draft Guidance.⁶ In those comments, CSPI urged FDA to (a) require labels with whole grain claims (or whole-grain-like claims such as "multigrain," "12 grain," or "harvest grain") to disclose the percentage of grain that is whole or (b) at least prohibit misleading claims such as "good source of whole grain" and "made with whole grain."

On December 2, 2010, we described our concerns about whole-grain labeling issues at length in a presentation to then-Regulatory Affairs Director Roberta Wagner and other FDA staff. At that time we set forth a conceptual framework for evaluating product claims. We expanded on those discussions in a meeting with Ms. Wagner and other FDA staff on March 11, 2011.

We were thus pleased to see a Notice in the May 26, 2011, Federal Register announcing FDA's intent to conduct an experimental study on "Consumer Responses to Whole Grain Labeling Statements on Food Packaging."⁷ FDA and CSPI agree, "that consumers may have difficulties in understanding the meaning of whole grains or recognizing whole-grain foods."⁸ We also agree, "that consumer product perceptions and purchase decisions can be influenced by labeling statements."⁹ We commend FDA for researching the whole grains issue and hope that this action is the first of several steps FDA will take to regulate misleading whole grain claims.¹⁰

We believe that in 2012 FDA should make it a priority to stop misleading claims involving whole grains.

CSPI recognizes that FDA faces time and resource constraints. Therefore this letter is more focused than our comprehensive report entitled *Food Labeling Chaos: The Case for Reform*, which we provided to you at the end of 2009.¹¹ That report addressed a wide variety of issues, some of which FDA is already tackling (e.g., improving the Nutrition Facts panel and standardizing front-of-pack nutrition labeling).

⁴ Letter from Dr. David Kessler, FDA Commissioner, to Michael Jacobson, Ph.D., Exec. Dir. CSPI (Nov. 1, 1993). See Attachment 1 (enclosures omitted).

⁵ www.regulations.gov/#!/documentDetail;D=FDA-2006-D-0298-0001 (last visited Dec. 29, 2011). Comments on the draft guidance have been submitted as recently as December 2010. FDA has not issued a final Guidance.

⁶ CSPI's comment on the 2006 Draft Guidance is Attachment 3.

⁷ <http://www.regulations.gov/#!/documentDetail;D=FDA-2011-N-0320-0001> (last visited Dec. 16, 2011).

⁸ *Id.*

⁹ *Id.*

¹⁰ CSPI conducted its own survey of consumer perceptions about whole grains, discussed in more detail below.

¹¹ Bruce Silverglade and Ilene Ringel Heller, *Food Labeling Chaos: The Case for Reform* (CSPI 2009), available at www.cspinet.org/new/pdf/food_labeling_chaos_report.pdf (last visited Dec. 16, 2011).

To assist FDA in that regard, we will discuss whole grain deceptions and recommend specific FDA action to remedy the problem areas. Deceptive claims involving whole grains vary in their exact nature. This letter, therefore, first describes the various types of deception and then makes recommendations for stopping those deceptions.¹²

The specific types of deception are:

1. The terms "wheat" and "whole grain" are widely misused.
2. The phrase "made with" whole wheat (or whole grain) often means "very little" whole grain.
3. The Whole Grain Stamp is misleading.
4. "Multigrain" products are usually not 100 percent whole grain and sometimes contain no whole grain at all.
5. "Stone ground" claims are deceptive unless the grain is truly stone ground and the amount of whole grain is substantial.
6. "Whole grain" slogans on product lines are deceptive unless the amount of whole grain in individual products is clearly disclosed.

1. The Terms "Wheat" and "Whole Grain" Are Widely Misused.

When consumers see the terms "wheat" and "whole grain" on food labels, we suspect they view them as claims that a product is entirely whole wheat or that it contains substantial amounts of whole wheat or other kinds of beneficial whole grains.

The 2006 Draft Guidance says that "a 'whole grain' statement . . . could be construed as meaning that the product is '100 percent whole grain.'"¹³ Consumer confusion is in large part due to that fact that unfortunately, "the FDA had not defined any claims concerning the grain content of foods," nor has it set "standards of identity for whole grains per se."¹⁴ This inaction opens the door for misleading whole grain claims. In its comment on the 2006 Draft Guidance, the Federal Trade Commission agrees that, "general, unqualified whole grain claims are likely to convey that all or nearly all of the grain in the product is whole grain."¹⁵ The number of comments in response to the 2006 Draft Guidance, which sought guidance on the labeling of products that contain a blend of whole and refined grains, demonstrates that many companies would like the FDA to clarify this issue.¹⁶

¹² This letter expands on CSPI's comments to the 2006 Draft Guidance.

¹³ 2006 Draft Guidance at question 7.

¹⁴ *Id.* at questions 7 and 9. The FDA *has* set standards of identity for whole wheat bread, rolls, and buns (21 C.F.R. § 136.180) and whole wheat macaroni products (21 C.F.R. § 139.138).

¹⁵ Federal Trade Commission comment on the 2006 Draft Guidance at 12.

¹⁶ See for example, AACC International's comment on the 2006 Draft Guidance at 4; Independent Baker's Association's comment on the 2006 Draft Guidance at 2.

A national public opinion survey (conducted over the Internet so that participants could view labels) that CSPI commissioned revealed that consumers overestimated the amount of whole wheat in a product when shown product packages that emphasized the word "wheat," including when "wheat" was accompanied by depictions of dark-colored crackers, heads of wheat, or the term "stone ground."¹⁷

Bread labeled as "wheat bread" when the first ingredient is ordinary white or non-whole wheat flour is particularly deceptive and does not meet standards of identity for bread. Standards of identity are intended to "promote honesty and fair dealing in the interest of consumers."¹⁸

The standard of identity for bread made completely from whole wheat is "whole wheat bread."¹⁹ The standard of identity for bread made with "flour" (also known as "white flour," "wheat flour" and "plain flour")²⁰ is "bread" or "white bread."²¹ If enriched flour is used, where vitamins and minerals are added, the standard of identity is "enriched bread."²² Thus, there is no standard of identity for bread that is not 100-percent whole wheat.²³ It is neither "white bread," "enriched bread," nor "wheat bread."

However, the use of "wheat bread" as a product name is becoming ubiquitous. Even sandwich shops, such as Subway, give consumers a choice between white bread and something called "9-Grain wheat bread," which consumers may assume is largely whole wheat. However, Subway's 9-Grain Wheat bread is primarily white flour.²⁴

¹⁷ CSPI commissioned the Opinion Research Corporation to study a demographically representative U.S. sample of 1,049 adults, 18 and older (conducted January 6-7, 2011). Participants viewed the principal display panels of nine products and stated which of the following statements best applied to each product:

- a) All the grain is whole grain.
- b) At least half the grain is whole grain.
- c) Less than half the grain is whole grain.
- d) There is little or no whole grain.
- e) Other _____.

We refer to the results of this study several times in this letter. Relevant portions of the study are contained in Attachment 2.

¹⁸ FDCA § 401, 21 U.S.C. § 341.

¹⁹ 21 C.F.R. § 136.180(b).

²⁰ 21 C.F.R. § 137.105(a).

²¹ 21 C.F.R. § 136.110(e)(1).

²² 21 C.F.R. § 136.115(b).

²³ 2006 Draft Guidance at question 9.

²⁴ Subway, US Product Ingredients (Revised Nov. 2010), available at <http://www.subway.com/Nutrition/Files/usProdIngredients.pdf> (last visited Dec. 16, 2011).

Our survey shows that 61% of consumers believe that at least half of the grains in the Hostess Brands Home Pride Butter Top Wheat Bread (see label below) are whole. However, the product has more enriched wheat flour, water, sweetener, and yeast than whole wheat flour.



Numerous brands of "wheat" crackers or "whole grain" crackers are made primarily with refined grain. CSPI's survey shows that 57% of consumers think that at least half of the grain in Lance Whole Grain Crackers (see label below) is whole. But those crackers contain more enriched white flour and vegetable oil in the crackers than whole wheat flour.



Similarly, our survey shows that 55% of consumers think that at least half the grain is whole in Old London Melba Snacks Roasted Garlic Whole Grain Crackers (see label below), despite the fact that the Principal Display Panel prominently states "5g WHOLE GRAIN." This response demonstrates that consumers are not able to evaluate the amount of whole grains relative to the amount of refined grains. Judging from the NFP and ingredient list, this product probably has three times as much white flour as whole grain flour. Five grams is a very modest amount of whole grain in a serving of these crackers.²⁵



The misleading elements of many labels are well illustrated by the examples above. In many cases, CSPI was unable to determine the amounts or percentages of whole grains in products because the label failed to provide sufficient information to do so. If existing labels prove opaque to CSPI's experienced label decoders, then ordinary harried consumers in the store are likely to experience even more difficulty.

Whole grain deception is not a new issue. FDA addressed exaggerated whole wheat claims in the 1990s by sending warning letters to several companies.²⁶ Then-Commissioner David Kessler assured us that FDA would act on CSPI's 1993 whole wheat petition²⁷ and stated that "FDA will continue to take . . . [additional whole wheat]

²⁵ USDA, Food Safety and Inspection Service, Statement of Interim Policy Guidance, *Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grain Claims* (Oct. 14, 2005), www.fsis.usda.gov/OPPDE/larc/Claims/Food_Guide_MYPyramid_Policy.pdf (last visited Dec. 16, 2011).

²⁶ Warning Letter from Raymond Mlecko, Dist. Dir. to Brian Chadbourne, Pres. Keebler Co. (Apr. 26, 1993); Warning letter from Matthew Lewis, Dist. Dir. Newark Dist. Office to Arthur G. Murray, Pres. Sunshine Biscuits (Apr. 1, 1992).

²⁷ CSPI Petition to Prohibit Misbranding of Whole Wheat Products and to Promulgate Food Labeling Regulations Concerning Products Made with Whole Wheat, Docket No. 93P-0227 (Jun. 25, 1993).

actions when necessary.”²⁸ Despite that commitment, similar deceptive whole grains claims have proliferated.

2. The Phrase “Made With” Whole Wheat (or Whole Grain) Often Means “Made With Very Little” Whole Grain.

Many products claiming to be “made with” whole wheat (or whole grain) have ordinary white flour as their primary ingredient. Our survey shows that many consumers overestimate the amount of whole grain in these products. For example, 59% of participants who viewed a box of Kellogg’s Eggo Waffles (see label below) thought that at least half of the grains are whole. However, whole wheat flour is only the third ingredient. There is more water and ordinary white flour than whole grain.



In order to bolster the “made with” claim, some manufacturers use several other tricks to imply a higher-than-actual content of whole grain. For instance, pictures of dark-colored bread or crackers appear on product labels because many consumers associate a dark color with healthful whole grain.²⁹ Similarly, manufacturers feature heads of wheat on product labels. They may also use color additives such as annatto, beta-carotene, caramel, or turmeric to darken a baked good made primarily from white flour.

Using caramel coloring or other ingredients to help simulate the “whole grain” or “wheat” color is deceptive. The FDA should prohibit coloring for that use or, at the very least, require the front labels to declare that the product is “artificially colored.”³⁰

²⁸ Letter from Dr. David Kessler, FDA Commissioner, to Michael Jacobson, Ph.D., Exec. Dir. CSPI (Nov. 1, 1993).

²⁹ See U.S. Dept. of Health and Human Services, U.S. Dept. of Agriculture, *Eating healthier and feeling better using the Nutrition Facts Label*, available at <http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM275412.pdf> (last visited Dec. 16, 2011) (“Whole grain foods can’t always be identified by color or name, such as multi-grain or wheat.”).

³⁰ CSPI Petition to Require Front of Package Disclosure of Food Color Additives, Docket No. FDA-2011-P-0886-001/CP (Dec. 8, 2011). That petition is pending.

Manufacturers also prey on consumers who dislike brown-colored bread by producing "made with whole grain" white breads. CSPI threatened to sue Sara Lee over its labels for "Soft and Smooth Made with Whole Grain White Bread," which has 70 percent ordinary flour and only 30 percent "whole grain white flour." As part of a settlement agreement,³¹ Sara Lee agreed to make clear that its product is only 30 percent whole grain.

3. The Whole Grain Stamp is Misleading.

The Whole Grain Council created the Whole Grain Stamp in 2005.³² It now appears on over 6,000 products.³³ In order to use the stamp, companies must be members of the Whole Grain Council and pay annual membership dues that range from \$1,000 - \$9,000. Dues are assessed on a sliding scale according to the size of the company's sales.³⁴ To qualify for the basic Whole Grain Stamp, the product must contain at least 8 grams of whole grain per serving.³⁵

The first problem with the Whole Grain Stamp is that the qualifying level of 8 grams of whole grain may constitute only a small percentage of the grain in a product, and the label does not indicate what percent of the grains are whole and what percent are refined.³⁶

The percentage is critical because the U.S. Dietary Guidelines has advised the public to "make at least half of your grains whole." Advising consumers that a product

³¹ CSPI Press Release, *Sara Lee to Make Clear its "Made with Whole Grain White Bread" is 30 Percent Whole Grain* (Jul. 21, 2008), available at www.cspinet.org/new/200807212.html (last visited Dec. 16, 2011); Settlement Agreement Letter between CSPI and Sara Lee Corp. and CSPI (Jul. 21, 2008), available at www.cspinet.org/new/pdf/sara_lee_settlement-letter-072108.pdf (last visited Dec. 16, 2011).

³² Identifying Whole Grain Products, available at www.wholegrainscouncil.org/whole-grains-101/identifying-whole-grain-products (last visited Dec. 16, 2011).

³³ About Us, available at www.wholegrainscouncil.org/about-us (last visited Dec. 16, 2011).

³⁴ Join the Whole Grains Council, available at www.wholegrainscouncil.org/get-involved/join-the-whole-grains-council (last visited Dec. 16, 2011).

³⁵ Stamp FAQ – Manufacturers, available at www.wholegrainscouncil.org/whole-grain-stamp/stamp-faq-manufacturers (last visited Dec. 16, 2011). Note, however, that there are no restrictions regarding the fat, sugar, sodium, or calorie content of the product on which the Whole Grain Stamp appears. The use of a whole grain stamp or listing of amount of whole grain is analogous to a nutrient-content claim, which is, in some instances, required to be accompanied with disclosure of high levels of fat, cholesterol or sodium. 21 C.F.R. § 101.13 (h)(1).

³⁶ Although the 2006 Draft Guidance (at question 10) says that manufacturers can make factual statements about the number of grams in a product, it also says that such statements cannot be misleading and cannot imply a particular level of the ingredient (such as "excellent source"). The Whole Grain Stamp is both misleading and implies a high level of whole grains.

has X grams of whole grain does not enable them to determine whether a particular product contains more whole grain than refined grain. For instance, a two-ounce serving of pasta with 8 grams of whole grains may also contain 48 grams of refined grains.

In the absence of percentage information or a direct statement as to how many grams are whole grains and how many grams are refined grains, the presence of the 8-gram Whole Grain Stamp may encourage consumers to inadvertently eat excessive amounts of refined grains. Many consumers who purchase pasta containing only 8 grams of whole grains (and 48 grams of refined grain) might erroneously believe that they are following advice to "make at least half of your grains whole," when only 14 percent of the pasta's grains are whole. Furthermore, some consumers might assume that since their pasta is whole grain, they could also eat a refined grain roll (or bread, cereal, cookie, etc.) and still be following the advice to make half of their grains whole.

A second problem with the Whole Grain Stamp is that the Whole Grain Stamp can be featured on products high in sodium, trans and saturated fat, or sugar, such as a highly sweetened product like Lucky Charms (see side panel excerpt below). Because consumers associate the Whole Grain Stamp with healthier choices,³⁷ this kind of labeling is misleading and creates consumer confusion — and thus deception — analogous to the widely criticized and now defunct Smart Choices Program.



³⁷ The Rudd Center for Food Policy & Obesity at Yale University surveyed parents with children between the ages of 2–11 years, 50% believed that Lucky Charms with a whole grains claim contained more whole grains than other brands of children's cereal and 38% believed the cereal was healthy because it contained whole grains.
www.yaleruddcenter.org/resources/upload/docs/what/advertising/Nutrition-RelatedClaims_PHN_12.11.pdf, at 4.

4. "Multigrain" Products are Usually Not 100 Percent Whole Grain and Sometimes Contain No Whole Grain at all.

"Multigrain" claims may deceive consumers into believing that a product has more whole grains than it really does. Such claims are material to the purchasing decision. Consumers may think that a product labeled as "multi-grain" or a similar term means that the product contains a substantial amount of whole grains.³⁸ Other consumers might think that a product containing more than one grain is a healthier one, but do not realize that the number of different grains is not nearly as important as the percent of grains that is whole. Also, it is often difficult for consumers to determine if particular grains are whole simply by reading the ingredient list. For example, Barilla Plus Rotini Multigrain Pasta lists barley, spelt, and oats, which are not always whole grains.³⁹ When CSPI called Barilla, we were told that there is no whole grain in this product.⁴⁰ It is impossible for a consumer to learn this by reading the label.



As our survey shows, some consumers equate "multigrain" with high whole grain content when that is not the case. For example, 42% of consumers think that at

³⁸ CSPI Petition to Prohibit Misbranding of Whole Wheat products and to Promulgate Food Labeling Regulations Concerning Products Made with Whole Wheat, Docket No. 93P-0227 Jun. 25, 1993). That petition is still pending.

³⁹ 2006 Draft Guidance at question 5 (regarding barley).

⁴⁰ Telephone conversations between Barilla Consumer Relations, and Erika Knudsen, CSPI (Feb. 1, 2011) and Emily Gilbert, CSPI (Dec. 28, 2011). Ironically, in its comment in response to the 2006 Draft Guidance, Barilla urged FDA to prohibit the misleading use of "whole grain blend" and "whole wheat blend." Barilla America Inc.'s comment on the 2006 Draft Guidance at 3.

least half of the grain in Nabisco's Saltine Crackers with Multigrain (see label below) is whole. On the contrary, these crackers have more white flour and soybean oil than whole grain.



5. "Stone Ground" Claims are Deceptive Unless the Grain is Truly Stone Ground and the Amount of Whole Grain is Substantial.

Use of the term "stone ground" implies that the product is less refined and, therefore, more healthful. However, the amount of grain that is truly stone ground and whole may be minimal. According to a *USA Today* exposé, "Stone ground is just a marketing phrase," and much of the "stone ground" flour is not even ground between stones.⁴¹

A survey conducted for Hodgson Mills, which petitioned FDA unsuccessfully for a standard of identity for stone ground wheat flour, shows that:

- 72 percent of respondents seek foods with lower levels of refinement,
- 69 percent believe that stone grinding results in a different level of refinement, and
- 95 percent believe that the level of refinement affects the value of the product.⁴²

Stone ground claims deceive consumers into believing that a product contains whole grains when it does not. Our survey shows that 63% of consumers think that at least half of the wheat in Nabisco's Wheatsworth Stone Ground Wheat Crackers (see label below) is whole. In fact, the crackers contain more ordinary white flour, soybean oil, and wheat germ than whole wheat flour. Additionally, Nabisco adds caramel color

⁴¹ Elizabeth Weise, *The hard truth about stone-ground*, USA Today, Mar. 14, 2006, at 6D. www.usatoday.com/news/health/2006-03-13-stone-ground-flour_x.htm (last visited Dec. 14, 2011).

⁴² Hodgson Mills Petition for Reconsideration, Docket No. 01P-0290/CP1 (Jan. 20, 2003). www.fda.gov/ohrms/dockets/dailys/03/Jan03/013003/8004c7b8.pdf (last visited Dec. 14, 2011).

to the product and depicts a head of wheat on the PDP to reinforce the perception that the product is largely whole wheat.



6. "Whole Grain" Slogans on Product Lines are Deceptive Unless the Amount of Whole Grain in Individual Products is Clearly Disclosed.

Slogans such as General Mills' "Whole Grain Guaranteed" are deceptive when manufacturers use them on labels for products that are not 100 percent whole grain.⁴³ After CSPI threatened to sue General Mills for this deceptive practice, the company advised CSPI that it planned to stop using the "Whole Grain Guaranteed" slogan, and instead state simply "With Whole Grain," listing the actual number of grams of whole grain per serving of that cereal.⁴⁴

A recent study illustrates how slogans like "Whole Grain Guaranteed" ("whole grain" and "fiber" were among the claims tested) create a "halo" effect that misleads consumers into thinking a product is of higher nutritional value than it actually is.⁴⁵ The study assessed parents' interpretations of nutrient-related claims for children's cereals. The authors found that "The majority of parents misinterpreted the meaning of claims commonly used on children's cereals. They inferred that cereals with claims were more nutritious overall and might provide specific health-related benefits for their chil-

⁴³ For example, General Mills' Basic 4 cereal contains substantial amounts of refined corn meal in addition to whole grain wheat. However, a consumer cannot determine whether the "corn meal" in the product is whole or refined by reading the label. CSPI had to contact Customer Relations at General Mills to learn that the corn meal is refined. Telephone conversation between Customer Relations, General Mills, and Erika Knudsen, CSPI (Feb. 01, 2011).

⁴⁴ As of this date, many products with the old labels are still in stores. However, recently Mills has introduced products that are labeled "Whole Grain First Ingredient." This is not what Mills promised CSPI and does not effectively cure the deception, because (1) it is unlikely the average consumer will understand the qualifier and (2) the words "Whole Grain" are far larger and more noticeable than the supposed qualifier "First Ingredient" and many cereals labeled as such still have refined flour.

⁴⁵ See Rudd Center Report, *supra* note 26.

dren.”⁴⁶ In particular, “half of the respondents believed that General Mills’ ‘Whole Grain Guaranteed’ claim meant that the cereal contains more whole grains than other brands of children’s cereals.”⁴⁷

Conclusion and Recommendations

For the reasons discussed above, CSPI urges FDA to take several actions:

1. FDA should require all manufacturers of products with whole grain claims to include a prominent disclosure as to (1) the amount (number of grams) and percentage of the grain that is whole and (2) whether specific grains listed in the ingredient statement are whole.⁴⁸ For example, “40% whole wheat (8 grams).”

2. FDA should make the 2006 Draft Guidance final, and make it clear that use of the terms “wheat,” “whole grain,” “made with whole grain,” “multigrain,” and “stone-ground” on products with grain ingredients that are not 100% whole grain is misleading unless one of the following disclosures appears prominently on product labels:

- “This product does not contain any whole grain.”
- “This product contains X% whole grain and X% refined grain.”
- “One serving contains X grams of whole grains and X grams of refined grains.”⁴⁹

3. FDA should require that all grains (other than white flour, enriched white flour, and whole wheat flour) listed in the ingredient statement be followed by the terms “whole grain” or “refined” in parentheses.

4. FDA should issue warning letters (along the lines of those referenced in Dr. Kessler’s 1993 letter to CSPI) to companies that mislead consumers by using artificially coloring to create the dark color that consumers associate with whole grain products.⁵⁰

⁴⁶ *Id.*, at 1.

⁴⁷ *Id.*, at 3.

⁴⁸ The suggestion that ingredients be preceded by the words “whole grain” if they are indeed whole grains is supported by several commenters on the 2006 Draft Guidance. See, for example, AACC International’s comment on the 2006 Draft Guidance at 6.

⁴⁹ Several commenters on the 2006 Draft Guidance called for no definition of “made with,” thus leaving it up to the FDA or the consumer to determine whether a product is misbranded and how much whole grain it actually contains. See, for example, Campbell Soup Company’s comment on 2006 Draft Guidance at 3; Bimbo Bakeries USA, Inc.’s comment on 2006 Draft Guidance. CSPI recommends that FDA reject these positions and clearly prohibit misleading “made with” claims.

⁵⁰ For information on the dangers of caramel coloring, see CSPI’s regulatory petition to bar the use of carcinogenic caramel colorings filed on February 16, 2011.

Petition to Bar the Use of Caramel Colorings Produced With Ammonia and Containing the Carcinogens 2-Methylimidazole and 4-Methylimidazole, FDA-2011-P-0407, available

5. FDA should inform the Whole Grains Council that the basic Whole Grain Stamp is misleading. The Agency should urge the Council to revise the Whole Grain Stamp to include either the percent of grains that are whole or to include the grams of refined grains the product contains in addition to the grams of whole grains the product provides.

In an ideal world, FDA would initiate rulemaking to address these problems. However, given FDA's resource constraints, issuing a final version of the 2006 Draft Guidance — accompanied by related warning letters targeted at violations with the greatest impact on public health and the consumer's pocketbook — would appear to be the next-best path to take.

We hope that under your leadership FDA will be able to fulfill the commitments Dr. Kessler made in 1993.

Sincerely,

Michael Jacobson, Ph.D.
Executive Director

Stephen Gardner
Litigation Director

Ainat Margalit
Litigation Staff Attorney

Erika Knudsen
Litigation Paralegal

By:



Stephen Gardner

cc:

Michael Taylor
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William Correll
Jennifer Thomas
Barbara Schneeman
Steven Musser
Susan Berndt

Philip Spiller
Mary Poos
Paula Trumbo
Jillonne Kevala
Felicia Billingslea
Lynn Szybist
Michael Roosevelt

at <http://www.regulations.gov/#/documentDetail;D=FDA-2011-P-0407-0001> (last visited Dec. 18, 2011).

Attachment 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 1, 1993

CJL:am

SAC
TAKOGEN

Dr. Michael F. Jacobson
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W. Suite 300
Washington, D.C. 20009-5728

Dear Dr. Jacobson:

I am writing in response to your recent letter about use of the term "whole wheat" in the common or usual name of various products. CSPI has filed a petition with the Food and Drug Administration objecting to the lack of enforcement action on specific products and requesting new regulations on the use of the term "whole wheat" on product labeling. Your letter asked for my personal attention to this matter. Please accept my apologies for the delay in responding. However, because this issue involves ongoing enforcement matters, FDA had an obligation to devote some time to the careful consideration of the releasability of this information.

The CSPI petition will be reviewed under the applicable agency procedure as resources and priorities permit. In the meantime, this letter is intended as an interim response. While the agency reviews this matter, I want to inform you of the actions that the agency has taken on the use of the term "whole wheat."

As you know, in the 1950s and 1960s FDA established standards of identity for wheat flour, whole wheat flour, and many products made with wheat flours. Some of these standards, such as the standard for whole wheat bread, rolls, and buns, require the use of 100% whole wheat or bromated whole wheat flour. In addition, over the years, FDA has consistently advised manufacturers that a product that uses "whole wheat" as part of its common or usual name must be made from enough whole wheat to characterize the food. In addition, FDA addressed whether identity statements can be considered implied health claims (e.g., "whole wheat bagels" as an implied fiber claim) in the preamble to the final rule on nutrient content claims (21 CFR §101.65; 58 FR 2302, 2423, January 6, 1993).

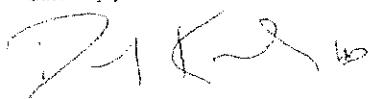
When appropriate, FDA has taken action against specific products. Among the more recent actions were those against two products that were mentioned in your petition. FDA issued a warning letter on April 1, 1992 (copy enclosed) on Sunshine's "HiHo Deluxe Whole Wheat Crackers" and "Krispy Whole Wheat Saltine Crackers" because whole wheat flour was not the predominant flour ingredient in the products. The labels now read "HiHo Deluxe Crackers Made With Enriched Flour And Whole Wheat Flour" and "Krispy Saltine Crackers Made with Enriched Flour and Whole Wheat Flour."

Dr. Jacobson - Page 2

More recently, FDA issued a warning letter on April 26, 1993 (copy enclosed) on Keebler's "Wheatables White Cheddar Whole Wheat Snacks" because, among other things, whole wheat flour was not the predominant flour ingredient.

I assure you that FDA will continue to take actions like the ones described above when necessary, and we will be making a complete assessment regarding the merits of the CSPI petition. Thank you for writing.

Sincerely yours,



David A. Kessler, M.D.
Commissioner of Food and Drugs

Enclosures

Attachment 2

Question E1 -- All or nearly all is whole grain Summary

Which statement BEST describes each of the following products?

										Race							
										Region			Hispanic				
										North	Midwest	South	West	(L)	(M)	(N)	
	Sex															(O)	
	Female	Male	18-24	25-34	35-44	45-54	55-64	65+	East	North	Midwest	South	West	(I)	(J)	(K)	(P)
Total (A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(N)	(Non-Hispanic)	
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251	320	263	826	51	72	
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	368	227	678	109*	137*	
Cheerios	318	154	164	38	74	53	54	46	57	85	105	71	218	27	54		
	32%	32%	32%	30%	41%FG	29%	27%	35%	27%	31%	39%L	28%	31%	32%	25%	40%	
Total Cinnamon Crunch	297	137	160	35	52	69	61	36	44	69	75	85	67	202	39	35	
	30%	28%	31%	28%	29%	38%HI	31%	24%	26%	37%L	34%L	23%	30%	30%	36%	25%	
Lance Crackers	218	119	99	31	42	46	34	26	39	48	48	77	45	127	30	44	
	22%	25%	19%	25%	23%	25%	17%	17%	23%	26%	22%	21%	20%	19%	28%	32%N	
Home Pride Wheat Bread	209	102	106	36	46	34	25	28	39	48	43	79	39	116	37	41	
	21%	21%	21%	29%G	26%G	19%	13%	19%	23%G	26%G	19%	22%	17%	17%	34%N	30%N	
Wheatsworth	196	102	94	30	40	42	35	19	31	43	40	72	41	110	22	42	
	20%	21%	18%	23%H	22%H	23%H	18%	13%	19%	23%	18%	20%	18%	16%	21%	31%N	
Eggo	181	94	88	19	39	36	31	18	38	42	45	56	37	107	23	43	
	18%	19%	17%	15%	22%H	20%	16%	12%	23%H	23%L	21%	15%	16%	16%	21%	31%	
Melba Snacks	170	74	96	22	36	33	23	27	29	23	46	62	39	108	17	31	
	17%	15%	19%	17%	20%G	18%	12%	18%	17%	12%	21%J	17%	17%	16%	15%	23%	
Thomas' English Muffin	165	83	82	22	31	31	29	26	25	35	45	52	33	107	17	32	
	17%	17%	16%	18%	17%	17%	15%	17%	15%	19%	21%	14%	15%	16%	16%	23%	
Premium Saltine Crackers	80	44	36	10	27	18	9	8	8	17	13	29	21	38	7	24	
	8%	9%	7%	8%	15%GH	10%G	5%	5%	9%	6%	8%	9%	6%	6%	6%	17%N	

Proportions/Means: Columns Tested (5% risk level) = B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap formulae used. * small base

Question E1 -- All or nearly all is whole grain Summary

Which statement BEST describes each of the following products?

	Household Income										H.H. Size										Children In H.H.										Education									
	\$25K- LT			\$40K- LT			\$50K- LT Or \$75K More			1 (G)			2 (H)			3 Or More (I)			None Total (J)			Under 13- (L)			Incomplete (M)			HS (N)			Incom- plete (O)			HS (P)			Incom- plete (Q)			
	Total (A)	LT (B)	\$25K (C)	LT (D)	\$40K (E)	\$50K (F)	LT (G)	\$75K (H)	More (I)	1 (G)	2 (H)	3 Or More (I)	None Total (J)	Under 13- (L)	13- (M)	17 (L)	17 (M)	Under (N)	13 (M)	17 (L)	17 (M)	HS (N)	Grad (O)	Plete (P)	Grad (Q)	HS (N)	Grad (O)	Plete (P)	Grad (Q)	HS (N)	Grad (O)	Plete (P)	Grad (Q)							
Unweighted Total	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	438																							
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12*	201	387	400																							
Cheerios	318	45	52	34	78	109	33	137	148	214	104	82	49	8	77	113	119																							
Total Cinnamon Crunch	297	36	42	39	74	106	29	120	147	197	100	74	55	3	72	113	109																							
Lance Crackers	218	31	39	24	54	71	26	82	111	133	85	68	43	3	58	84	73																							
Home Pride Wheat Bread	209	38	42	23	49	56	25	88	96	137	72	55	37	2	53	77	77																							
Wheatsworth	196	31	36	20	57	53	19	81	95	125	71	53	35	1	56	67	71																							
Eggo	181	30	32	14	49	56	13	80	88	115	66	52	32	3	53	67	58																							
Melba Snacks	170	26	18	50	20	73	77	110	60	43	30	12	30	1	38	63	67																							
Thomas' English Muffin	165	24	35	16	41	50	15	66	84	100	65	51	34	6	33	65	61																							
Premium Saltine Crackers	80	19	16	5	18	22	3	33	44	48	32	24	14	2	26	26	27																							
	8%	15%DF	11%	5%	8%	6%	2%	8%G	10%G	7%	10%	10%	10%	15%	13%PQ	7%	7%																							

Proportions/Means: Columns Tested (5% risk level) = $B/C - D/E/F - G/H/I - J/K - N/O/P/Q$
 Overlap formulae used. * small base; ** very small base (under 30) ineligible for sig testing

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Question E1 -- All/nearly all/at least half of the grain is whole grain Summary
 Which statement BEST describes each of the following products?

			Race											
			Sex			Age			Region			Hispanic		
			Female	18-24	25-34	35-44	45-54	55+	North	Mid-west	South	West	(M)	(N)
Total	(A)	Male	24	34	44	54	64	65+ (I)	(K)	(J)	(L)	(M)	(O)	(P)
		(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251	320	263	826
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	368	227	678
Total Cinnamon Crunch	727	334	393	96	132	138	148	101	112	142	166	258	160	490
Cheerios	724	343	381	89	140	127	146	109	112	137	164	259	163	494
Wheatsworth	634	303	332	83	115	119	123	88	106	124	143	239	128	420
Home Pride Wheat Bread	611	308	303	90	108	113	114	83	104	126	126	231	129	391
Eggo	594	279	315	73	118	116	117	75	94	118	143	203	129	396
Lance Crackers	573	281	292	82	102	109	106	75	98	104	131	212	125	381
Thomas' English Muffin	566	268	298	68	107	100	107	89	95	116	118	216	116	375
Melba Snacks	547	256	291	69	103	104	105	81	85	91	132	215	110	373
Premium Saltine Crackers	425	211	213	57	87	86	76	58	60	85	97	158	84	267
	42%	44%	41%	45%	49%	47%	39%	36%	46%	44%	43%	37%	39%	44%

Proportions/Mean: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap formulae used. * small base

Question E1 -- All/nearly all/at least half of the grain is whole grain Summary

Which statement BEST describes each of the following products?

		Household Income						H.H. Size						Children In H.H.						Education					
		\$25K-	\$40K-	\$50K-	\$75K	LT Or	LT More	1	2	3 Or More	None	Total (J)	Under 13 (L)	13-17 (M)	18+ (N)	HS Incomplete (O)	HS Complete (P)	HS Grad (Q)	Coll (R)	Coll (S)	Incom-plete (T)	Grad (U)	Plete (V)	Grad (W)	Coll (X)
Total	\$25K-\$40K	LT (B)	LT (C)	\$50K (D)	\$75K (E)	LT (F)	More (G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)								
Total (A)	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	438								
Unweighted Total																									
Weighted Total																									
Total Cinnamon Crunch	727	86	104	78	171	288	89	301	337	492	235	176	116	10	158	276	283								
Cheerios	724	84	108	72	173	286	93	284	347	482	242	189	110	11	160	274	278								
Wheatsworth	634	85	88	67	161	233	79	261	295	431	203	152	101	9	145	248	233								
Home Pride Wheat Bread	611	77	82	69	145	238	68	259	284	414	197	151	95	9	144	232	226								
Eggo	594	79	93	69	134	219	82	234	277	394	199	155	91	9	134	210	241								
Lance Crackers	573	76	93	60	128	215	75	236	263	388	186	143	93	9	136	211	217								
Thomas' English Muffin	566	69	87	60	135	215	77	239	249	391	175	133	81	8	129	209	220								
Melba Snacks	547	76	86	56	130	198	69	218	261	362	185	137	92	7	127	205	207								
Premium Saltine Crackers	425	55	69	46	105	149	51	170	203	281	144	107	71	7	107	159	151								
	42%	44%	46%	46%	46%	38%	36%	41%	46%	41%	45%	48%	63%	7	53%	41%	38%								

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Overlap formulae used. * small base; ** very small base (under 30) ineligible for sig testing

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Question E1A

Which statement BEST describes each of the following products?

A. Eggs

	Sex	Age	Region						Race		
			North		Mid-west		South		White	Black	Hispanic
			(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Any Race)
Total	Female	18-24	25-34	45-54	65+ (H)	65+ (I)	65+ (J)	65+ (K)	65+ (L)	65+ (M)	65+ (N)
(A)	Male	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(N)
Unweighted Total	506	543	137	189	228	191	131	173	215	251	320
Weighted Total	1000	485	515	126	178	182	196	151	166	220	368
At least half or more is whole grain (Net)	594	279	315	73	118	116	117	75	94	143	203
All or nearly all the grain is whole grain	181	94	88	19	39	36	31	18	38	42	45
At least half the grain is whole grain	412	185	228	54	80	86	57	55	76	98	147
Less than half is whole grain (Net)	406	206	200	53	60	66	78	76	73	76	165
Less than half the grain is whole grain	311	150	160	43	38	52	60	58	60	60	128
These is little or no whole grain	96	56	40	11	22	15	18	13	10	16	36
	10%	12%	8%	8%	12%	8%	9%	12%	8%	7%	10%

Proportions/Means: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P

Overlap formulae used. * small base

Question E1A

Which statement BEST describes each of the following products?

A. Eggos

	Household Income										H.H. Size										Children In H.H.										Education														
	\$25K- LT			\$40K- LT			\$50K- LT			\$75K- Or More			1 More (E)			2 More (F)			3 Or More (G)			None (H)			Total (J)			Under 13- (L)			13- 17 (M)			HS Incom- plete (N)			HS Grad (O)			Incom- plete (P)			Coll Grad (Q)		
	Total	\$25K (A) (B)	\$40K (C)	\$50K (D)	\$75K (E)	Or More (F)	1 More (G)	2 More (H)	3 Or More (I)	None (J)	Total (K)	Under 13- (L)	13- 17 (M)	HS Incom- plete (N)	HS Grad (O)	Incom- plete (P)	Coll Grad (Q)																												
Unweighted Total	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	438																												
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387	400																												
At least half or more is whole grain (Net)	594	79	93	69	134	219	82	234	277	394	199	155	91	9	134	210	241																												
All or nearly all the grain is whole grain	181	30	32	14	49	56	13	80	88	115	66	52	32	3	53	67	58																												
At least half the grain is whole grain	412	49	61	54	85	163	70	154	189	279	133	102	59	6	81	142	183																												
Less than half is whole grain (Net)	406	45	57	32	94	178	59	179	168	296	110	81	58	2	67	178	160																												
Less than half the grain is whole grain	311	34	37	25	70	144	45	137	128	229	82	59	44	2	51	137	120																												
These is little or no whole grain	96	11	20	6	24	34	14	43	39	68	28	22	14	0	16	40	40																												

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Overlap formulae used. * small base; ** very small base (under 30) ineligible for sig testing

Question E1B

Which statement **BEST** describes each of the following products?

B. Thomas' English Muffin

	Sex	Age	Region						Race		
			North		Mid-west		South		West	White	Black
			(K)	(J)	(L)	(M)	(N)	(O)	(P)	Only	Hispanic
Total	Male	18-24	25-34	35-44	45-54	55-64	65+ (I)	(J)	(K)	Only	Only (Any Race)
(A)	Male	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(Non-Hispanic (Any Race))	(Non-Hispanic (Any Race))
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220
At least half or more is whole grain (Net)	566	268	298	68	107	100	107	89	95	116	118
All or nearly all the grain is whole grain	165	83	82	22	31	31	29	26	25	35	45
At least half the grain is whole grain	401	185	215	46	76	69	78	62	70	81	73
Less than half is whole grain (Net)	434	216	218	58	72	82	88	63	72	70	101
Less than half the grain is whole grain	319	159	159	45	48	63	68	48	48	57	46%
These is little or no whole grain	115	57	58	14	24	18	21	15	24	13	29

Proportions/Mean: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Proportions/Mean: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap formulae used. * small base

Question E1B

Which statement BEST describes each of the following products?

Thomas' English Muffin

Household Income		H.H. Size			Children In H.H.			HS			Coll		
		\$25K-	\$40K-	\$75K+	1	2	3 Or More	Under 13	13-17	Incom-plete	H.S. Grad	Plete	Grad (Q)
LT	LT	LT	LT	Or More	(E)	(F)	(G)	(K)	(L)	(M)	(N)	(O)	(P)
Total	\$25K (A)	\$40K (B)	\$50K (C)	\$75K (D)	\$100K (E)	\$125K (F)	\$150K (G)	\$175K (H)	\$200K (I)	\$225K (J)	\$250K (K)	\$275K (L)	\$300K (M)
Unweighted Total	1049	125	151	97	247	429	154	421	474	713	336	256	150
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149
At least half or more is whole grain (Net)	566	69	87	60	135	215	77	239	249	391	175	133	81
All or nearly all the grain is whole grain	165	24	35	16	41	50	15	66	84	100	65	51	34
At least half the grain is whole grain	401	46	52	45	93	165	62	173	165	291	110	83	47
Less than half is whole grain (Net)	434	55	64	40	94	182	64	175	195	299	135	103	68
Less than half the grain is whole grain	319	41	38	32	71	137	49	125	145	214	105	79	52

Proportions/Means: Columns Tested (5% risk level) = $B/CDE^{1-\alpha}$ - $\frac{C}{E}$ - 30, ineligible for sig testing

Question E1C

Which statement BEST describes each of the following products?

C. Lance Crackers

	Sex	Age	Race						
			North		Mid-west		South		
			(I)	(J)	(K)	(L)	(M)	(N)	
Total	Male	18- 24 (B)	25- 34 (C)	35- (E)	45- (G)	55- (H)	65+ (I)	75+ (J)	White Black Hispanic (Any Race)
	Female	25- 34 (D)	34- (E)	44- (F)	54- (G)	64- (H)	65+ (I)	75+ (J)	Only Only (Non-Hispanic Race)
Unweighted Total	1049	506	543	137	189	228	191	131	173
Weighted Total	1000	485	515	126	178	182	196	151	166
At least half or more is whole grain (Net)	573	281	292	82	102	109	106	75	98
All or nearly all the grain is whole grain	218	119	99	31	42	46	34	26	39
At least half the grain is whole grain	355	162	193	51	60	63	72	50	59
Less than half is whole grain (Net)	427	204	223	44	77	73	89	76	68
Less than half the grain is whole grain	285	139	146	30	50	44	65	51	45
These is little or no whole grain	142	65	77	14	27	29	24	25	23

Proportions/Means: Columns Tested (5% risk level) - B/C - D/E/F/G/R/I - J/K/L/M - N/O/P

Overlap formulae used. * small base

Question E1C

Which statement BEST describes each of the following products?

C. Lance Crackers

	Household Income				H.H. Size				Children In H.H.				Education			
	\$25K-	\$40K-	\$50K-	\$75K+			3 Or		Under	13-	HS	Incom-	Coll			
	LT	LT	LT	Or	(E)	(F)	More	(G)	1	2	More	None	Total	17	HS	Coll
Total (A)	\$25K (\$B)	\$40K (\$C)	\$50K (\$D)	\$75K+ (\$E)					(H)	(I)	(J)	(K)	(L)	(M)	(N)	Grad
Unweighted Total	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387
At least half or more is whole grain (Net)	573 57%	76 61%	93 62%	60 56%	128 54%	215 53%	75 57%	236 59%	263 56%	388 60%	186 61%	143 61%	93 62%	9 76%	136 68% ^{PQ}	211 54%
All or nearly all the grain is whole grain	218 22%	31 25%	39 26%	24 24%	54 18%	71 18%	26 20%	82 25%	111 19%	133 27%	85 29%	J 29%	58 29%	3 29%	58 29% ^Q	84 22%
At least half the grain is whole grain	355 36%	45 36%	54 37%	37 33%	144 36%	144 35%	49 37%	154 34%	151 37%	254 33%	101 33%	101 33%	76 33%	50 33%	78 47%	127 39%
Less than half is whole grain (Net)	427 43%	48 39%	58 38%	40 40%	181 44%	181 46%	67 47%	178 43%	182 41%	303 44%	124 40%	93 39%	56 38%	3 24%	65 32%	176 46% ^O
Less than half the grain is whole grain	285 29%	34 27%	30 22%	30 30%	69 30%	119 30%	41 29%	116 28%	128 29%	206 30%	79 26%	62 26%	31 21%	3 24%	45 23%	115 30%
These is little or no whole grain	142 14%	14 12%	25 12%	9 17%	31 9%	31 9%	3 14%	62 16%	25 18%	54 15%	97 12%	44 14%	31 13%	25 17%	0 0	19 10%

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Overlap formulae used. * small base; ** very small base (under 30) ineligible for sig testing

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Question E1D

Which statement BEST describes each of the following products?

D. Cheerios

		Sex		Age		Region		Race				
		Male	Female	18- (B)	25- (C)	35- (D)	45- (E)	North (I)	Mid- west (J)	White Only (N)	Black Only (O)	His- panic (Any Race) (P)
Total	Male	24 (A)	24 (B)	25- (D)	34 (C)	44 (E)	54 (F)	64 (G)	65+ (H)	65+ (I)	65+ (J)	Hispanic (Any Race) (P)
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251	72
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	72
At least half or more is whole grain (Net)	724 72%	343 71%	381 74%	89 70%	140 79%	127 70%	146 75%	109 72%	112 67%	137 74%	164 75%	259 75%
All or nearly all the grain is whole grain	318 32%	154 32%	164 32%	38 30%	74 41%FG	53 29%	54 27%	46 35%	57 31%	85 31%	105 39%	163 28%
At least half the grain is whole grain	406 41%	189 39%	217 42%	51 40%	67 37%	74 41%	93 47%	55 40%	66 43%	80 36%	79 36%	155 42%
Less than half is whole grain (Net)	276 29%	142 29%	134 26%	38 30%	38 21%	55 30%	49 25%	42 35%	54 33%	48 26%	55 25%	109 30%
Less than half the grain is whole grain	216 22%	109 22%	107 21%	35 27%	28 16%	45 25%	35 18%	33 22%	40 24%	37 20%	40 18%	91 21%
These is little or no whole grain	60 6%	33 7%	27 5%	3 2%	10 5%	15 8%	9 6%	14 8%	12 9%	15 7%	16 5%	37 5%

Proportions/Mean: Columns Tested (5% risk level) - B/C = D/E/G/H/I = J/K/L/M = N/O/P
 Overlap formulae used. * small base

Question E1D

Which statement BEST describes each of the following products?

D. Cheerios

	Household Income						H.H. Size						Children In H.H.						Education					
	\$25K- LT (B)	\$40K- LT (C)	\$50K- LT (D)	\$75K Or (E)	More (F)		1	2	3 Or (H)	More (I)	None (J)	Total (K)	Under 13- (L)	13- 17 (M)	17- (N)	HS Incom- plete (O)	HS Grad (P)	HS Incom- plete (Q)	Coll. Grad (R)					
	Total (A)	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	438						
Unweighted Total	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	438							
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387	400							
At least half or more is whole grain (Net)	724	84	108	72	173	286	93	284	347	482	242	189	110	11	160	274	278							
All or nearly all the grain is whole grain	318	45	52	34	78	109	33	137	148	214	104	82	49	8	77	113	119							
At least half the grain is whole grain	406	39	57	37	96	177	59	147	200	268	138	107	61	3	83	161	159							
Less than half is whole grain (Net)	276	40	42	29	55	110	49	130	97	209	68	47	39	1	40	113	122							
Less than half the grain is whole grain	216	32	30	22	45	87	39	97	80	164	52	37	31	1	28	85	102							
These is little or no whole grain	60	8	12	6	10	24	10	33	17	44	16	10	8	0	12	29	20							

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Overlap Formulae used. * small base; ** very small base (under 30) ineligible for sig testing

JANUARY 06-07, 2011

Question E1E

Which statement BEST describes each of the following products?

E. Melba Snacks

	E. Melba Snacks	Sex	Age				Region				Race							
			18-		25-		35-		55+		North		Mid-					
			Male	Female	Male	Female	Male	Female	Male	Female	West	South	West	Only				
Total (A)	1049	Male (B)	543	506	137	189	228	191	131	173	215	251	320	263	826	51	72	
Unweighted Total		Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	368	227	678	109*	137*
At least half or more is whole grain (Net)	547	55%	256	291	69	103	104	105	81	85	91	132	215	110	373	64	72	
All or nearly all the grain is whole grain	170	15%	74	96	22	36	33	23	27	29	23	46	62	39	108	17	31	
At least half the grain is whole grain	377	38%	182	195	47	67	71	82	54	56	68	86	153	70	265	47	41	
Less than half is whole grain (Net)	453	45%	229	224	57	75	78	91	70	81	95	88	153	117	305	45	65	
Less than half the grain is whole grain	326	33%	162	165	46	60	56	60	45	61	68	67	115	76	216	38	46	
These is little or no whole grain	126	13%	67	60	11	16	23	31	25	20	26	21	38	41	89	7	19	

Proportions/Mean: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P

Overlap Formulae used. * small base

Question E1E

Which statement BEST describes each of the following products?

E. Melba Snacks

		Household Income				H.H. Size				Children In H.H.				Education				
		\$25K- LT (A)	\$40K- LT (B)	\$50K- LT (C)	\$75K- Or (D)	1 More (E)	2 More (F)	3 Or (G)	None (H)	Total (J)	13- Under (K)	17 (L)	HS Incom- plete (M)	HS Grad (N)	Coll Incom- plete (O)	Coll Grad (P)	Coll Grad (Q)	
Total		25K \$25K (A)	40K \$40K (B)	50K \$50K (C)	75K Or (D)	1 More (E)	2 More (F)	3 Or (G)	None (H)	Total (J)	13- Under (K)	17 (L)	HS Incom- plete (M)	HS Grad (N)	Coll Incom- plete (O)	Coll Grad (P)	Coll Grad (Q)	
Unweighted Total		1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	
Weighted Total		1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387	
At least half or more is whole grain (Net)		547 55%	76 61% F	86 57%	130 56%	198 57%	69 50%	218 48%	261 53%	362 53%	185 58%	137 60% J	92 58%	7 63%	127 64% PQ	205 53%	207 52%	
All or nearly all the grain is whole grain		170 17%	26 21% F	18 17%	22% F	13% 14%	14% 18%	73 17%	77 17%	110 16%	60 19%	43 18%	30 20%	1	38 12%	63 19%	16% 17%	
At least half the grain is whole grain		377 38%	50 40%	60 39%	39 35%	81 37%	148 34%	49 35%	145 41%	184 36%	252 41%	125 40%	94 40%	6 42%	90 51%	142 45% Q	140 37%	
Less than half is whole grain (Net)		453 45%	48 39%	65 43%	44% 43%	98 50% B	198 52% I	73 47%	196 41%	183 48% K	329 40%	124 40%	100 42%	57 38%	4 37%	73 36%	182 47% O	193 48% P
Less than half the grain is whole grain		326 33%	35 28%	39 26%	32% 32%	75 37% C	145 35%	50 33%	135 32%	142 33%	229 31%	97 31%	82 35%	4 37%	56 28%	28% 34%	34% 34%	
These is little or no whole grain		126 13%	13 11%	25 17%	12% 10%	23 13%	53 17% I	24 15% I	61 9%	42 14% K	100 9%	27 8%	18 10%	0 0	17 9%	51 0	58 13% 15%	

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
Overlap Formulae used. * very small base; ** small base (under 30) ineligible for sig testing

JANUARY 06-07, 2011

Question E1F

Which statement BEST describes each of the following products?

F. Premium Saltine Crackers

		Sex		Age		Region		Race								
		Female	Male	18-24	25-34	35-44	45-54	55-64	North	Mid-west	South	West	Hispanic	White Black	Hispanic	
		(D)	(C)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	
Total	Male	24	34	44	54	64	64	65+	-east					Only	Only	
(A)	(B)	(D)	(C)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251	320	263	826	51	72
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	368	227	678	109*	137*
At least half or more is whole grain (Net)	425	211	213	57	87	86	76	58	60	85	97	158	84	267	48	70
All or nearly all the grain is whole grain	80	44	36	10	27	18	9	8	8	17	13	29	21	38	7	24
At least half the grain is whole grain	345	167	177	47	60	67	67	51	52	69	84	129	63	229	41	46
Less than half is whole grain (Net)	575	274	302	69	91	97	119	93	106	100	123	210	142	411	61	68
Less than half the grain is whole grain	398	191	207	52	65	66	78	63	74	66	90	149	94	279	40	52
These is little or no whole grain	177	83	95	18	26	31	41	30	32	34	33	61	49	132	21	16
	18%	17%	18%	14%	14%	17%	21%	20%	19%	18%	15%	17%	21%	19%	19%	12%

Proportions/Mean: Columns Tested (5% risk level) - B/C = D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap Formulae used. * small base

JANUARY 06-07, 2011

Question Elf

Which statement BEST describes each of the following products?

F. Premium Saltine Crackers

		Household Income										Education										
		\$25K- LT			\$40K- LT			\$50K- \$75K (D)			H.H. Size	Children In H.H.			HS			Coll.				
		\$25K (A)	\$40K (B)	\$50K (C)	\$75K (E)	More (F)	Or (G)	1 (H)	2 (I)	3 Or More (J)	None (K)	Total (L)	Under 13 (M)	13- 17 (N)	18+ (O)	Incom- plete (P)	HS Grad (Q)	Coll. Grad (R)	Coll. Grad (S)	Incom- plete (T)	HS Grad (U)	Coll. Grad (V)
Unweighted Total	1049	125	151	97	247	429	154	421	474	713	336	256	150	12	193	406	438					
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387	400					
At least half or more is whole grain (Net)	425	55	69	46	105	149	51	170	203	281	144	107	71	7	107	159	151					
All or nearly all the grain is whole grain	80	19	16	5	18	22	3	33	44	48	32	24	14	2	26	26	27					
At least half the grain is whole grain	345	36	53	41	87	127	48	138	159	233	112	82	56	6	81	133	125					
Less than half is whole grain (Net)	575	69	82	54	123	247	91	244	241	410	165	129	78	4	94	228	249					
Less than half the grain is whole grain	398	54	52	35	85	172	61	158	179	276	121	98	51	4	72	153	168					
These is little or no whole grain	177	16	30	19	38	75	30	86	62	134	44	32	27	0	21	75	81					

Proportions/Mean: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Proportions/Mean: * small base; ** very small base; *** ineligible for sig testing
 Overlap formulae used.

Question E1G

Which statement BEST describes each of the following products?

G. Wheatsworth

	Sex	Age	Region						Race		
			North		Mid-west		South		White	Black	Hispanic
			(I)	(J)	(K)	(L)	(M)	(N)	Only (Non-Hispanic)	Only (Non-Hispanic)	(Any Race)
Total	Male	25-	55-	55+	North	Mid-west	South	West	White	Black	Hispanic
(A)	Female	24	34	54	(I)	(K)	(L)	(M)	Only (Non-Hispanic)	Only (Non-Hispanic)	(Any Race)
	(B)	(D)	(E)	(G)							
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220
At least half or more is whole grain (Net)	634	303	332	83	115	119	123	88	106	124	143
All or nearly all the grain is whole grain	196	102	94	30	40	42	35	19	31	43	40
At least half the grain is whole grain	438	201	238	53	75	78	89	69	75	81	103
Less than half the grain is whole grain (Net)	366	182	184	43	63	63	72	63	61	62	76
Less than half the grain is whole grain	270	131	139	32	47	49	57	41	46	47	47%
These is little or no whole grain	95	51	44	12	17	14	15	22	15	15	22
	10%	10%	9%	9%	9%	9%	8%	15%	9%	8%	10%

Proportions/Mean: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap Formulae used. * small base

Question E1G

Which statement BEST describes each of the following products?

G. Wheatsworth

	Household Income						H.H. Size			Children In H.H.					
	\$25K- LT	\$40K- LT	\$50K- LT	\$75K- Or (E)	1 (G)	3 Or More (H)	None (I)	Total (J)	Under 13 (L)	13- 17 (M)	HS Incom- (N)	HS Grad (O)	Coll Incom- (P)	Coll Grad (Q)	
	Total (A)	\$25K (B)	\$40K (C)	\$50K (D)	\$75K (F)	More (G)	None (I)	Total (J)	Under 13 (L)	13- 17 (M)	HS Incom- (N)	HS Grad (O)	Coll Incom- (P)	Coll Grad (Q)	
Unweighted Total	1049	125	151	97	247	154	421	474	713	336	255	150	12	193	406
Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201
At least half or more is whole grain (Net)	634	85	88	67	161	233	79	261	295	431	203	152	101	9	145
All or nearly all the grain is whole grain	196	31	36	20	57	53	19	81	95	125	71	53	35	1	56
At least half the grain is whole grain	438	54	53	48	104	180	60	179	200	306	132	98	67	8	89
Less than half is whole grain (Net)	366	39	63	33	67	164	63	153	149	260	106	85	48	2	56
Less than half the grain is whole grain	270	24	43	26	49	128	44	109	118	190	80	68	33	2	41
These is little or no whole grain	95	15	20	7	18	36	20	44	32	69	26	17	15	1	15

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Overlap Formulae used. * small base; ** very small base (under 30) ineligible for sig testing

Question E1H

Which statement BEST describes each of the following products?

H. Home Pride Wheat Bread

	Age										Region						Race									
	Sex		Female		25-		35-		45-		55+		North		Mid-west		South		West		White		Black		Hispanic	
	Total	Male	Male	Female	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)	(R)	(S)	(T)	(U)	(V)	(W)	(X)	
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)	(R)	(S)	(T)	(U)	(V)	(W)	(X)	(Y)		
Unweighted Total	1049	506	543	137	189	228	191	131	173	215	251	320	263	826	51	72										
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	368	227	678	109*	137*										
At least half or more is whole grain (Nat)	611	308	303	90	108	113	114	83	104	126	126	231	129	391	79	97										
All or nearly all the grain is whole grain	209	102	106	36	46	34	25	28	39	48	43	79	39	116	37	41										
At least half the grain is whole grain	403	206	196	53	62	79	89	55	65	77	83	152	90	275	42	57										
Less than half is whole grain (Net)	389	176	212	37	70	70	81	68	63	60	94	137	98	288	30	40										
Less than half the grain is whole grain	267	123	144	31	46	47	55	43	46	42	61	102	63	191	21	31										
These is little or no whole grain	121	53	69	6	24	22	26	25	17	18	33	35	36	96	8	9										
	12%	11%	13%	5%	14%D	12%D	14%D	17%D	10%	15%	9%	16%L	14%	8%	7%											

Proportions/Means: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap Formulae used. * small base

Question E1H

Which statement BEST describes each of the following products?

Home Pride Wheat Bread

Propositions/Meanings: Columns Tested (5% risk level) = $B/C/D/E/F$ $S_{1,2,3,4,5}$
 Overlap formulae used. * small base; ** very small base (under 30) ineligible for sig testing

Question ELI

Which statement BEST describes each of the following products?

I. Total Cinnamon Crunch

	Sex	Age	Region						Race							
			North		Mid-west		South		West		White		Black		Hispanic (Any Race)	
			Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	(N)	(P)
Total (A)	Male (B)	18-24 (D)	25-34 (E)	35-44 (F)	45-54 (G)	55+ (H)	64 (I)	65+ (J)	67+ (K)	77+ (L)	251	320	263	826	51	72
Unweighted Total	1049	506	543	137	189	228	191	131	173	215						
Weighted Total	1000	485	515	126	178	182	196	151	166	185	220	368	227	678	109*	1377*
At least half or more is whole grain (Net)	727	334	393	96	132	138	148	101	112	142	166	258	160	490	85	96
All or nearly all the grain is whole grain	297	137	160	35	52	69	61	36	44	69	75	85	67	70%	72%	78%
At least half the grain is whole grain	430	197	233	61	80	69	87	65	68	73	91	172	93	202	39	35
Less than half is whole grain (Net)	273	150	123	30	47	45	47	50	54	43	53	110	66	188	24	41
Less than half the grain is whole grain	214	112	102	27	36	37	38	34	42	33	41	92	48	147	21	29
These is little or no whole grain	59	38	21	3	11	7	9	16	12	10	12	19	19	42	4	12

Proportions/Means: Columns Tested (5% risk level) = B/C - D/E/F/G/H/I - J/K/L/M - N/O/P
 Overlap formulae used. * small base

Question E11

Which statement BEST describes each of the following products?

I. Total Cinnabon Crunch

	Household Income						H.H. Size						Children In H.H.						Education															
	\$25K- (B)	\$40K- (C)	\$50K- (D)	\$75K- (E)	\$50K- Or (F)	\$75K- More (G)	1 (H)	2 (I)	3 Or More (J)	None (K)	Total (L)	Under 13- (M)	13- 17 (N)	17- 21 (O)	Incom- plete (P)	HS Grad (Q)	HS Incom- plete (R)	HS Grad (S)	HS Incom- plete (T)	HS Grad (U)	HS Incom- plete (V)	HS Grad (W)	Coll (X)											
	Total (A)	1049	125	97	247	429	154	421	474	713	336	256	150	12	193	406	438	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387	400
Unweighted Total	1049	125	97	247	429	154	421	474	713	336	256	150	12	193	406	438	Weighted Total	1000	124	151	100*	228	396	142	414	444	691	309	236	149	12**	201	387	400
At least half or more is whole grain (Net)	727	86	104	78	171	288	89	301	337	492	235	176	116	10	158	276	283	73%	69%	69%	78%	73%	63%	63%	73%	76%	71%	71%	71%	71%	71%	71%		
All or nearly all the grain is whole grain	297	36	42	39	74	106	29	120	147	197	100	74	55	3	72	113	109	30%	29%	28%	32%	27%	33%	29%	32%	32%	31%	37%	37%	37%	36%	29%	27%	
At least half the grain is whole grain	430	50	62	39	97	182	60	180	190	294	136	102	62	7	86	162	175	43%	40%	41%	46%	42%	43%	43%	43%	43%	43%	43%	43%	43%	43%	43%	42%	44%
Less than half is whole grain (Net)	273	38	47	22	57	109	53	113	107	199	74	60	33	2	43	112	117	27%	31%	22%	27%	37%	37%	31%	24%	24%	24%	24%	24%	24%	24%	21%	29%	29%
Less than half the grain is whole grain	214	29	32	21	44	87	40	82	92	152	62	50	29	1	33	93	88	21%	24%	21%	28%	20%	21%	19%	20%	21%	19%	19%	19%	19%	16%	24%	22%	
These is little or no whole grain	59	9	15	1	13	21	13	31	15	47	12	10	4	1	10	19	29	6%	7%	5%	5%	5%	9%	7%	4%	4%	4%	3%	3%	5%	5%	5%	7%	

Proportions/Mean: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q
 Overlap formulae used. * small base; ** very small base (under 30) ineligible for sig testing

Attachment 3



Center for
Science in the
Public
Interest

Publisher of

Nutrition Action Healthletter

102.0 101.13(i)(3)

May 9, 2006

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

Re: FDA's Guidance on Whole Grain Label Statements [Docket No. 2006D-0066]

I. Introduction

The Dietary Guidelines for Americans and USDA's new food pyramid encourage the public to "make half your grains whole." This recommendation is appropriate given the growing body of evidence that people who eat more whole grains have a lower risk of heart disease, diabetes, and obesity. However, many whole grain claims are misleading because they appear on foods that are not whole grain, and some are largely refined grain (see Attachment, pages 1-7).

In its February 2006 guidance on Whole Grain Label Statements, FDA said that "manufacturers can make factual statements about whole grains on the label of their products such as "100% whole grain" (as percentage labeling under 21 CFR 102.5(b)) or "10 grams of whole grains" (21 CFR 101.13(i)(3)) provided that the statements are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and do not imply a particular level of the ingredient, i.e., "high" or "excellent" source.

2006D-0066

C 23

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HF-D-6

FDA's voluntary guidance will discourage companies from making some misleading claims, such as "good source of whole grain" or "excellent source of whole grain." However, the guidance does not go far enough to ensure that consumers are not misled because the policy is voluntary and because it does not address other commonly made whole grain claims, such as "made with whole grain." Furthermore, FDA's guidance does not require labels to disclose whole grain content using clear, informative units such as percentages.

To encourage the consumption of whole grains and prevent deceptive label claims, CSPI urges the FDA to:

- Require all foods that make whole grain (or similar) claims to disclose on the principal display panel the percentage of grain that is whole grain.
- If FDA does not require a percentage whole grain disclosure, it should prohibit the use of claims such as "made with whole grain" or "a good source of whole grain" to avoid misleading people who are trying to consume more whole grains.

II. FDA's recommended disclosures are misleading because they fail to disclose the refined grain content of the food.

Disclosures such as "10 grams of whole grain," "one ounce of whole grain," or "one serving of whole grain" may be misleading on non-whole grain foods because they imply that the food is all or primarily whole grain. In fact, a food that contains 10 grams of whole grain per serving might also contain 20 or 30 grams of refined grain per serving. Without a disclosure that reveals the refined grain content of the food, many

consumers would assume that food contains no refined grains. Consumers could check the ingredient list, but even that does not declare the foods' relative proportion of refined and whole grains. Without that information, consumers might unknowingly increase their intake of refined grains substantially in an effort to get more whole grains.

III. FDA's proposed disclosures do not help people follow the Dietary Guidelines' advice.

FDA's proposed disclosures, such as "10 grams of whole grain," do not help people follow the Dietary Guidelines' advice to "make half your grains whole." That advice encourages people to consume a minimum *proportion* of their grains as whole grains. Without knowing how many grams of refined grain are in a food that claims to contain X grams of whole grain, consumers cannot determine whether half their grains are whole.¹

The Dietary Guidelines also recommends that people consume at least 3 servings of whole grains a day. However, that advice was designed to give consumers a rule of thumb regarding the number of servings of whole grains they should consume. It is less applicable than the advice to "make half your grains whole," because some people consume more—and others fewer—than 6 servings of grains each day.

¹ FDA's proposed disclosures also fail to help people follow the Dietary Guidelines' advice to consume at least 3 servings of whole grains a day, because the disclosures use units like grams or ounces rather than servings. There is no easy way to convert grams or ounces into servings, because the amount of grain in a serving varies from food to food. The FDA could not solve this problem by requiring labels to disclose the number of servings of whole grains that a food provides. It would confuse many people to see that one serving of cereal, rice, bread, etc. supplied $\frac{1}{2}$ or 2 servings of whole grains.

Urging people to consume at least 3 servings of whole grains could mislead people to assume that more is always better. In fact, encouraging people to consume more calories than they should from grains, whole or refined, could promote weight gain.

IV. Disclosures such as “10 grams of whole grain” make it difficult to compare foods.

FDA’s proposed disclosures, such as “10 grams of whole grain” or “one ounce of whole grain” make it difficult to compare foods because the total grain content of foods varies so widely. For example, 10 grams of whole grain could be 60 percent of the grain in a slice of bread, but only about 33 percent of the grain in a breakfast cereal with a 30-gram serving size. Even when consumers try to compare cereals to cereals, they will have trouble sizing up a claim such as “10 grams of whole grain,” because 10 grams could comprise 33 percent of the grain in a breakfast cereal with a 30-gram serving size but just 18 percent of the grain in a breakfast cereal with a 55-gram serving size. (Both serving sizes are quite common.)

Consumers can check the label to find the weight of a serving, but for most foods, including bread, frozen pizza, and cookies, the weight of a serving is not the same as the total grain content. For foods that contain both whole and refined grains, consumers cannot figure out how the whole grain content compares to the refined grain content of the food.

As noted above, without that information, people may unknowingly consume excess refined grain in a misguided effort to consume more whole grains. FDA could

eliminate this problem by requiring labels with whole grain claims to disclose the percent of grain that is whole grain.

V. Some people may confuse grams of whole grain with grams of fiber.

Consumers may confuse grams of whole grains with grams of fiber, because they know that whole grains are usually a good source of fiber and fiber is one of the key benefits of eating whole grains. Furthermore, this confusion would lead people to overestimate the whole grain content of food. A food that contains 5 grams of fiber, for example, supplies 20 percent of the Daily Value for fiber. In contrast, a food that contains 5 grams of whole grains supplies only a small fraction of a day's worth of whole grains. A percent-whole-grain disclosure would resolve this problem.

VI. Recommendations

A. FDA should require labels with whole grain claims to disclose the percentage of grain that is whole.

FDA should require labels with whole grain claims to disclose what percent of the food's grain is whole grain.² A percent-whole-grain claim makes it clear that, unless the food is 100 percent whole grain, it also contains refined grain. People understand that a food could be, say, 50 percent whole grain and 50 percent refined grain. In fact, companies often advertise the percentage of whole grain in their products when the

² This disclosure should appear adjacent to the whole grain claim and in type that is similar in size and prominence to the whole grain claim.

foods are 100% whole grain.³ There is no reason to think that they would have trouble understanding smaller percentages.

If the food contains a whole grain component, the principal display panel (PDP) should disclose what percent of the component is whole grain. For example, a noodle soup might bear a disclosure such as “100% whole grain noodles,” a frozen entrée might declare “60% whole grain pasta,” and a pizza label might state “20% whole grain crust.”⁴

Percent-whole-grain disclosures would make it easier for consumers to see whether a food helps them follow the advice to “make half your grains whole.” Consumers could use that advice to eat an equal number of refined and 100% whole grain foods each day, or they could eat only foods that are at least 50% whole grain. We suspect that more people would use either of those rules of thumb than would tally up the number of grams, ounces, or servings of whole grains they consume each day and strive to reach some unspecified total.

Furthermore, FDA has already approved a health claim for foods that are at least 51 percent whole grain. FDA’s approval indicates that it is reasonable to use percentages to evaluate the whole grain content of foods.

B. If FDA does not require a percentage-whole-grain disclosure, it should prohibit such misleading claims as “good source of whole grain” and “made with whole grain.”

³ Canadian consumers appear to have no trouble understanding the common “60 percent whole grain” claims on breads and other foods.

⁴ To prevent companies from making claims about foods that contain very little whole grain, FDA should require a minimum level, such as 4 or 5 grams of whole grain per serving, before any claims can be made.

Foods that are labeled “made with whole grain” or “good (or excellent) source of whole grain,” but also contain refined grain, are misleading because consumers may assume that the foods are made with only whole grains. In fact, many such foods are made with more refined than whole grains (see Attachment 1, pages 6 and 7). Many people would never think to check the ingredient list to see if a food with a whole grain claim also contains refined grains. However, even consumers who check the ingredient list would be unable to determine what fraction of the grains are whole. Without that information, they would not know if the food could help them follow advice to “make half your grains whole.”

Furthermore, requiring labels with whole grain claims to disclose the grams or ounces of whole grain per serving would not eliminate the deception because consumers would not know how many grams or ounces of refined grains the food contained. In order to follow advice to “make half your grains whole,” consumers need to know what percent of the grain in a food is whole and what percent is refined.

C. FDA should require labels with whole-grain-like claims to disclose the percentage of grain that is whole.

Many people think “multigrain” or “12 grain” or “harvest grain” or “wheat bread” means whole grain. Those claims should also trigger a percentage-whole-grain disclosure. Some food manufacturers might argue that such a disclosure is unnecessary because consumers know that the food contains little or no whole grain. In that case, they should not worry that such a disclosure would make the food less appealing to customers.

Respectfully submitted,



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