

**BEFORE THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**In the Matter of  
Draft Guidance for Industry and FDA Staff:  
Whole Grains Label Statements**

**Docket No. 2006-0066**

**Comments of the Staff of  
the Bureau of Consumer Protection,  
the Bureau of Economics,  
and the Office of Policy Planning  
of the Federal Trade Commission**

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## I. INTRODUCTION

Adequate consumption of whole grains is an important part of a healthy diet. The 2005 Dietary Guidelines for Americans identify whole grains as a significant source of fiber and other nutrients and encourage increased consumption as a way to reduce the risk of several chronic diseases and to help with weight maintenance.<sup>1</sup> Specifically, the Guidelines recommend that people “consume 3 or more ounce-equivalents of whole grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products,” and that, “in general at least half the grains should come from whole grains.”<sup>2</sup> To help ensure that consumers receive consistent and reliable information about the whole grain content of food products, the Food and Drug Administration (“FDA”) has issued draft guidance for industry. The FDA guidance document clarifies what the agency considers to be “whole grain” and identifies permissible label statements that food manufacturers may use to describe the whole grain content of their products.<sup>3</sup> FDA is seeking public comment on this guidance document.

The staff of the Federal Trade Commission’s Bureau of Consumer Protection, Bureau of Economics, and Office of Policy Planning (“FTC staff”) generally supports FDA’s guidance on whole grain label statements. The FTC staff believes that the guidance will help manufacturers

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<sup>1</sup> “Dietary Guidelines for Americans, 2005,” (HHS/USDA 2005) at Chapter 5, available at <http://www.healthierus.gov/dietaryguidelines>.

<sup>2</sup> *Id.*

<sup>3</sup> “Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements,” Docket No. 2006D-0066, 71 Fed. Reg. 8597 (Feb. 17, 2006) (“Whole Grain Guidance”). The draft guidance document is available at <http://www.cfsan.fda.gov/~dms/flragui.html>. FDA has indicated that the guidance is non-binding and does not impose legally enforceable responsibilities on industry.

who make whole grain claims to use consistent terms, will help inform consumers about the importance of whole grains to diet and health, and will make it easier for consumers to choose foods rich in whole grains. The FTC staff comment provides specific suggestions concerning how FDA could expand and clarify its guidance to give consumers additional tools to make informed choices about whole grain products and to establish additional safeguards against misleading label claims.

The FTC, through enforcement of the Federal Trade Commission Act, has developed considerable expertise in food advertising and labeling issues.<sup>4</sup> The FTC staff also has experience studying the effects of regulation on market performance, including the perfor

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nutrition information that consumers receive. Labeling and advertising regulations and policies that permit manufacturers to disseminate truthful and non-misleading information about diet and health are likely to lead to better informed consumers, more competition on the health attributes of food, and formulation of healthier products.

For that reason, the FTC staff encourages FDA to consider the following three issues as it finalizes its draft guidance:

- FDA should consider expanding its guidance to allow label statements that provide greater dietary context to the factual, quantitative statements on whole grain currently permitted. Consumers need simple, easy tools to help them decide how a food fits into their diet. It is important to give consumers sufficient context for whole grain statements so that they can more easily choose foods that will help them reach the recommended consumption of 3 or more servings of whole grain daily. Because it could be an effective way to provide context, FDA should consider allowing “good source” and “excellent source” claims, such as those already in widespread use. In addition, or as an alternative, the FDA should consider providing examples of other permissible ways that food companies could provide context to their whole grain claims.
- As FDA’s draft guidance recognizes, there is potential for consumers to be misled or confused by unqualified “whole grain” claims for products that contain a mixture of whole grain and refined grain. Many consumers may interpret such unqualified claims to mean that all or nearly all of the grain in the product is whole grain. Additional guidance from FDA on the appropriate use of “100% whole grain,” “whole grain,” “made with whole grain,” and other similar terms could reduce the risk that consumers will be misled

or confused. One possible approach would be for FDA to provide guidance setting specific percentage and minimum content standards for the amount of whole grain in products bearing such unqualified claims.

- Because consumer awareness of the new dietary recommendations and whole grain label statements may be still evolving, the FTC staff also recommends that FDA solicit relevant consumer perception data and consider conducting its own copy testing to determine the most effective way to give consumers context for their whole grain food choices and to set standards for unqualified whole grain claims.

## **II. BACKGROUND**

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nearly 40 percent of Americans reported not eating any whole grains in an entire day.<sup>12</sup>

The food label is an important tool to help consumers increase their whole grain consumption consistent with the new dietary recommendations. Giving consumers a simple and easy way to identify foods with substantial whole grain content can make the label a more effective tool. The factual label statements currently permitted by FDA's draft Whole Grain Guidance are useful points of reference and can help consumers compare the whole grain content of different products.<sup>13</sup> They may not, however, give consumers enough context to determine easily how much of their recommended daily amount of whole grain they are getting from a serving of a food. The FTC staff believes that many consumers may find it difficult, if not impossible, to translate a quantitative statement such as "10 grams whole grain" into meaningful information about how much of their recommended daily amount of whole grain they will receive from a serving of a food.<sup>14</sup>

It would be more helpful to allow food manufacturers to put the amount of whole grains into dietary context for consumers. Ideally, a claim would simply and clearly indicate how the

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<sup>12</sup> *Id.*

<sup>13</sup> For example, consumers would be able to compare a product labeled "10 grams whole grain" to one labeled "6 grams whole grain."

<sup>14</sup> The FTC staff has seen evidence of the difficulty consumers have with quantitative statements in other contexts. In early 1996, when the staff conducted copy tests of food advertising that presented various formats for nutrient content information, for example, it found that "most participants in the test failed to interpret such measurements correctly, whether they were expressed as absolute numbers of grams or milligrams, or as a percentage of the relevant Daily Recommended Values." The staff also found that advertising disclosures concerning high levels of risk-increasing nutrients were "most effective if framed in plain English." D. Murphy *et al.*, *A Generic Copy Test of Food Health Claims in Advertising*, Federal Trade Commission (1998) at E8-9, available at <http://www.ftc.gov/opa/1998/11/food.htm>.



amount of whole grain in a food fits with consumers' recommended dietary needs. This approach would provide enough information so that consumers would not need to look up the 2005 Dietary Guidelines for Americans or perform calculations to translate quantitative statements into number of servings.

Seals, icons, or simple claims that identify foods as either a "good source" or "excellent source" of whole grain are examples of methods for giving consumers quick and simple tools to choose among whole grain products. Prior to FDA's recent decision to deny a citizen petition requesting that the agency develop standard definitions for these terms,<sup>15</sup>

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should also establish standards describing the appropriate qualifying levels of whole grain for these claims. The FTC staff believes that allowing these claims is one way to simplify consumers' task in making whole grain food choices, and may also spur companies to reformulate or introduce new products with higher whole grain content in order to qualify for these claims.

The FTC staff recognizes that terms such as “good source” and “excellent source” have typically been defined pursuant to FDA regulations for use as nutrient content claims, for nutrients that have an established RDI or DRV (for example, “good source of fiber”) and that whole grain is not a “nutrient” and does not have a formal RDI or DRV. However, the FTC staff suggests that FDA could develop voluntary standards for the use of these terms through informal agency guidance, using the 2005 Dietary Guidelines for Americans recommendations for 3 one-ounce equivalent servings of whole grain daily as a reference amount.

In addition, or as an alternative approach, the FTC staff suggests that FDA consider expanding its draft Whole Grain Guidance to provide some specific examples of other simple ways that food companies can provide dietary context to their whole grain claims. For instance, the guidance could give examples of how a manufacturer could refer to the 2005 Dietary Guidelines in a whole grain label statement. There may be many permissible approaches, under current FDA policy and regulation, for providing dietary context to whole grain claims. The FTC staff believes it would benefit both industry and consumers if FDA were to illustrate some of these approaches in its guidance.<sup>17</sup>

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<sup>17</sup> As one possible model, USDA's Food Safety and Inspection Service (FSIS) has issued a Statement of Interim Policy Guidance for meat and poultry labeling that includes specific illustrations of how companies can give dietary context to their whole grain claims. The

Consumer awareness of dietary recommendations and whole grain label statements may be new and still evolving. The FTC staff, therefore, further recommends that, as FDA develops and refines its policy and guidance on whole grain label statements, the agency should consider relevant consumer perception data on existing whole grain claims, including “good source” and “excellent source.” FDA should also consider conducting its own copy testing to determine the most effective way to give consumers the dietary context they need to make good whole grain food choices.

#### **IV. UNQUALIFIED WHOLE GRAIN CLAIMS**

The FTC staff generally supports FDA’s guidance on unqualified whole grain statements. The draft Whole Grain Guidance indicates that products labeled as “100 percent whole grain” should not contain any grain ingredients other than whole grain. It further indicates that, “depending on the context in which a ‘whole grain’ statement appears on the label, it could be construed as meaning that the product is 100 percent whole grain.”<sup>18</sup> In an example, FDA indicates that pizza and bagels labeled as “whole grain” or “whole wheat” should only be labeled as such when the flour ingredients are made entirely from whole grain or whole wheat flours.<sup>19</sup>

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guidance covers claims made for meat and poultry food products that include a grain component,  
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FDA does not, however, provide definitive standards for either the percentage or amount of whole grain that should be in products labeled with unqualified claims. Nor does it address other common variations of these claims that are in widespread use in the marketplace, such as “made with whole grain.”

There appear to be many variations of unqualified whole grain claims currently in the marketplace. Some product labels simply claim “whole grain,” others more explicitly claim “100% whole grain,” while others use somewhat more ambiguous phrases like “made with whole grain.” It is not clear that companies are using these terms consistently or that consumers are interpreting them correctly. Depending on the context of the claim and other elements of the product label, a claim such as “made with whole grain” may convey widely discrepant messages.<sup>20</sup>

In fact, even within the government, there are discrepancies in how these terms are defined. The U.S. Department of Agriculture, for instance, in guidance to the meat and poultry industry, has indicated that it will allow whole grain claims, such as “whole wheat pasta,” and “pasta made with whole wheat,” as long as 51% of the grain components are whole grain and the product contains at least one-half ounce equivalent (8 grams) of whole grain per serving.<sup>21</sup> The USDA guidance is thus a less rigorous standard than proposed in FDA’s current draft guidance

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<sup>20</sup> On some food labels, for instance, the words “whole grain” appear in large, banner type on the front label while the words “made with,” presumably meant to qualify the “whole grain” banner, are in substantially smaller type. This may be a method that companies use to imply that their products are 100% whole grain, when they are not.

<sup>21</sup> USDA/FSIS Statement of Interim Policy Guidance: Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grain Claims. (Oct. 14, 2005), *available at* [http://www.fsis.usda.gov/OPPDE/larc/Claims/Food\\_Guide\\_MYPyramid\\_Policy.pdf](http://www.fsis.usda.gov/OPPDE/larc/Claims/Food_Guide_MYPyramid_Policy.pdf).

that products, such as bagels or pizza, labeled “whole grain” or “whole wheat” be made entirely from whole grain or whole wheat flour.

The FTC staff suggests that FDA consider establishing definitive percentage and minimum content standards for companies to use when they choose to make “100% whole grain,” “whole grain,” “made with whole grain,” and similar unqualified claims. Such specific standards would provide even greater clarity for food manufacturers and consumers and ensure the claims are being used consistently in the marketplace. The guidance should also clarify that such standards would apply to unqualified claims only, and would not restrict companies from making truthful, nonmisleading whole grain claims that are appropriately qualified to specify the amount or percentage of whole grain in the product.

#### **A. Percentage Standards for Unqualified Whole Grain Claims**

The FTC staff agrees with FDA’s draft guidance position that, in addition to the express “100% whole grain” statement, other variations of general, unqualified claims are also likely to convey that all or nearly all of the grain in the product is whole grain. Although the Commission has not done consumer research directly on this issue, studies on other types of unqualified claims, including “Made in USA” and “recycled,” suggest that many reasonable consumers interpret an unqualified claim about a product’s content to mean that it refers to the entire product. In a 1991 copy test on “Made in USA,” approximately 77% of respondents indicated that the statement meant that all or almost all of the product was made in the USA.<sup>22</sup> Similarly,

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<sup>22</sup> See FTC Enforcement Policy Statement on U.S. Origin Claims, 62 Fed. Reg. 63,757 (Dec. 2, 1997) at 63,763-34 (discussing the 1991 FTC Copy Test, Document No. B213001 of the public record, and other relevant consumer perception research). A 1995 FTC-commissioned survey of consumer attitudes provided additional confirmation, finding that the percentage of consumers agreeing with a “Made in USA” label fell dramatically as the amount of

consumer research on “recycled content” claims has shown that a majority of consumers interpret the statement as referring to all or most of the product or package.<sup>23</sup> The FTC staff believes that the consumer evidence on these unqualified claims is indicative of how consumers are likely to interpret an unqualified “whole grain” statement. Many reasonable consumers will likely understand “whole grain” to mean that all, or virtually all, of the food product is whole grain, or that all of the grain ingredients in the product are whole grains. The FTC staff suggests that setting definitive percentage standards for food companies to use when they make a hierarchy of claims, ranging from “100% whole grain” to “whole grain” to “made with whole grain,” would provide certainty in the marketplace while still allowing some leeway for claims on products that are not 100% whole grain.<sup>24</sup>

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production costs incurred abroad increased. *Id.* at 63,764 (discussing the 1995 FTC Attitude Survey, Document No. B212883 of the public record). Based in part on this and other consumer perception evidence, and on the record as a whole, the Commission’s 1997 Enforcement Policy Statement on U.S. Origin Claims provides that “unqualified U.S. origin claims should be substantiated by evidence that the product is all or virtually all made in the United States.” *Id.* at 63,767.

<sup>23</sup> See, e.g., L. Morris, M. Hastak & M. Mazis, *Consumer Comprehension of Environmental Advertising and Labeling Claims*, *The Journal of Consumer Affairs* 328, 340 (Winter 1995) (54.7% of respondents expected a “recycled” claim to mean that “all” or “most” of the materials used to make the product were recycled). Based on that research and other consumer evidence, the Commission established a standard for unqualified claims of “recycled content,” requiring that such claims only be made if the “entire product or package, excluding minor, incidental components, is made from recycled material.” FTC Guides for the Use of Environmental Marketing Claims, 16 C.F.R. § 260.7(e) (1998).

<sup>24</sup> An example of a statutory and regulatory scheme that sets similar percentage standards is the USDA’s National Organic Program. Under that Program, 1) products labeled as “100 percent Organic,” must contain 100% organically produced ingredients; 2) products labeled simply “organic” must contain at least 95% organic ingredients; and 3) multi-ingredient products labeled as “made with organic ingredients” must contain at least 70% organic ingredients and satisfy additional labeling requirements. USDA/Agricultural Marketing Services National Organic Program, 7 C.F.R. §§ 205.301(c)

## **B. Minimum Content Standards**

In addition to establishing explicit percentage standards for foods labeled as “100% whole grain,” “whole grain,” and “made with whole grain,” the FTC staff believes that FDA should also require that these foods contain a sufficient amount of whole grain, in an absolute sense, to make a meaningful contribution to the daily diet. This requirement is especially important for multiple-ingredient foods in which the grain is only one of many ingredients, for example, a product that combines pasta or rice with vegetables or meat. Without a minimum standard for the absolute amount of whole grain, a company could accurately state that its product was “100% whole grain,” even if the grain ingredients represented a small portion of the overall ingredients and the absolute amount of whole grain were insignificant.<sup>25</sup>

USDA has imposed such a standard in its Interim Policy Guidance for the meat and poultry industry. Its guidance indicates that there should be a significant amount of the whole grain component in foods making “whole grain ” or “made with whole grain” claims to ensure that statements are not misleading. USDA suggests that foods labeled with these phrases contain at least a one-half ounce equivalent of whole grain ingredients (8 grams of dry whole wheat).<sup>26</sup> This amount represents half of one of the three servings daily recommended by the 2005 Dietary

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<http://www.ams.usda.gov/nop/NOP/standards.html>. An assessment of this scheme may provide some useful guidance as to the costs and benefits of articulating definitive percentages in the context of whole grain claims.

<sup>25</sup> For example, many entree dishes contain rice or pasta combined with vegetables, dairy, or meat ingredients. Even if the pasta or rice component is 100% whole grain, the dish may provide an amount of whole grain that is insignificant in the context of an entire diet.

<sup>26</sup> The absolute standard for minimum whole grain content is in addition to USDA’s requirement that at least 51% of the grain ingredients be whole grains.

Guidelines.

The FTC staff believes that additional guidance, in the form of percentage and minimum content standards, will ensure that when consumers choose products labeled as “whole grain” or “made with whole grain,” or similar claims, they will be getting a meaningful amount of whole grain. FDA guidance standardizing these and similar terms could also provide the foundation for consumer education that ties the dietary recommendations for whole grain consumption to real world food choices at the grocery store.

As FDA considers whether to expand its guidance on unqualified whole grain claims to provide specific percentage thresholds and/or minimum content standards, the FTC staff again believes that it would be helpful for FDA to solicit relevant consumer perception data from the industry and others and, if possible, to conduct copy testing of how consumers interpret phrases such as “whole grain,” “made with whole grain,” and other similar terms. Understanding better how consumers view these claims would help inform the agency about how best to define them to minimize confusion.

## **V. CONCLUSION**

The FTC staff generally supports the FDA’s efforts to provide guidance on whole grain label statements. The draft guidance is an important step toward helping consumers evaluate whole grain food products and make better-informed choices concerning their whole grain consumption. As FDA finalizes its guidance, the FTC staff suggests that it consider giving more specific guidance on two issues. First, the staff recommends that FDA reconsider allowing the “good source” and “excellent source” claims that have already become widespread in the



marketplace, as a way to provide consumers with a simple tool for identifying foods rich in whole grains. In addition, or as an alternative approach, the staff suggests that FDA expressly identify other permissible ways that manufacturers can give dietary context to whole grain label statements. Second, the staff recommends that FDA expand on its guidance governing unqualified whole grain claims to provide specific percentage and minimum whole grain content standards for foods bearing these claims.

Adequate consumption of whole grain is important to consumer health, and many Americans are falling far short of their dietary needs. Giving consumers easy ways to choose products that provide meaningful amounts of whole grain could help them to reduce their risk of several chronic diseases as well as help them maintain a healthy weight. More specific guidance could also provide the consistency and clarity that food companies need to motivate them to introduce products with higher whole grain content.

Respectfully submitted,

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