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

Brent A. Baglien  
Vice President  
Government Affairs

RE: [Docket No. 2006D-0066] Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements; Availability  
71 *Federal Register* 8597, February 17, 2006.

Dear Sir or Madam:

ConAgra Foods, Inc ("ConAgra") appreciates the opportunity to submit comments to the docket referenced above in connection with the Food and Drug Administration's ("FDA") Draft Guidance for Whole Grain Label Statements ("Draft Guidance").

ConAgra is a diversified food company with sales across a wide variety of product categories, including frozen meals, soups, pizzas and popcorn. ConAgra products that comprise our 50 major brands include Healthy Choice, Chef Boyardee, Marie Callender, Banquet, Act II and Orville Redenbacher's.

ConAgra generally concurs with the comments separately submitted to FDA on this issue from the Grocery Manufacturers of America (GMA) and the Food Processors Association (FPA). However, there are a few proposed guidance points on which we wish to offer additional comment.

### Overview

ConAgra appreciates FDA's attention to this issue and fully supports the agency's goal to promote whole grain consumption, the dietary deficiency for which is well chronicled, by issuing guidance on whole grain claims. In this regard, ConAgra concurs that FDA has accurately characterized US dietary guidance and the authoritative statement regarding recommended daily dietary intake of whole grains from the 2005 Dietary Guidelines for Americans—

*Consume 3 or more ounce-equivalents of whole-grain products per day,  
with the rest of the recommended grains coming from enriched or whole-*

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*grain products. In general, at least half the grains should come from whole grains.<sup>1</sup>*

We further concur that label statements about whole grains are permissible in accordance with section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

However, ConAgra respectfully disagrees with FDA's initial conclusion that label statements characterizing the level of whole grain in food (e.g., "excellent source of whole grain") are impermissible under the FFDCA. Specifically, ConAgra believes that "good source" and "excellent source" label statements regarding the presence of whole grains in foods are both permissible and beneficial for consumers. In that regard, we contend that the criteria should be established as a minimum of 5g of whole grain per serving for "good source" claims and 10g per serving for "excellent source" claims.

### **I. Recommendations To Expand Options Available To Manufacturers For Whole Grain Label Statements**

#### **A. Quantitative Labeling - "Good Source" and "Excellent Source"**

ConAgra believes that quantitative labeling statements that characterize the level of whole grain in food products are permissible under sections 403(a) and 201(n) of the FFDCA given that whole grain is an ingredient of food, not a nutrient.<sup>2</sup> Such statements will assist the public in making informed food choices and otherwise provide the food industry with additional labeling tools to inform consumers about whole grains in a manner consistent with dietary and food guidance.

ConAgra believes that descriptive claims such as "good source" and "excellent source" can be used effectively with products containing whole grains. These are straight forward terms with which consumers are familiar, and are proven communication tools. To provide the necessary context for such claims, we recommend FDA use the MyPyramid "3 one ounce-equivalents" recommendation for whole grains as the functional equivalent of the Dietary Reference Intake (DRI) for nutrients. This provides

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<sup>1</sup> Dietary Guidelines for Americans 2005. US Department of Health and Human Services and US Department of Agriculture. See <http://www.healthierus.gov/dietaryguidelines/>. Executive Summary, page viii, and Chapter 5, Key Recommendations, page 24.

<sup>2</sup> ConAgra has long supported accurate, substantiated claims in accordance with sections 403(a) and 201(n) of the FFDCA. FDA currently allows, and has articulated in guidance, accurate, substantiated label statements and claims that characterize food and food components in a manner intended to assist consumers in making personal food choices in accordance with their individual needs and values. FDA policy distinguishes such claims from "nutrient content claims," which are subject to FDA regulations established in support of national public health objectives concerning diet and health matters. Whole grain label statements and characterizing claims would not be bound by these FDA regulations. FDA's previous actions are clear that there is a basis to provide additional label statements about whole grains that characterize the level in foods or describe them in dietary context. Statements can be made that meet the 403(a) and 201(n) standards, and substantiation would be assessed by companies based on the competent and reliable evidence standard. These standards are well established and require claims to be supported by the kind of evidence that experts in the field would regard as an appropriate scientific basis for such claims.

the necessary predicate for deciding how much of added whole grains is a meaningful amount. The *Dietary Guidelines* recommend the consumption of at least 3 one ounce-equivalents of whole grains per day. USDA has determined that a one ounce-equivalent of whole grains contains at least 16 grams of grain. Accordingly, 3 one-ounce equivalents of whole grains would provide a minimum of 48 grams of grain.

Having established 48 grams as the minimum recommended daily consumption of whole grain, ConAgra contends that FDA should establish quantitative requirements for "good source" claims as 5 grams of whole grains present in food per Reference Amount Customarily Consumed (RACC) and per labeled serving, and "excellent source" claims as 10 grams of whole grains present per RACC and per serving. These are the amounts that equate to 10% and 20% of the 48 grams minimum requirement per day for whole grain -- that is, 10% of the minimum daily recommended amount of 48 grams is approximately 5 grams, and 20% of the minimum daily recommended amount of whole grains is approximately 10 grams. ConAgra further contends that 10% and 20% of the recommended minimum 48 grams are meaningful amounts that will further incent manufacturers to add whole grains to more food products.

Specifically, at the 5 and 10 gram levels, food manufacturers can more readily add whole grains to a wide variety of foods with a lower likelihood of adversely affecting their taste. Additionally, manufacturers would be able to add a meaningful amount of whole grains to foods with smaller RACCs. The consequence is that consumers would have many more choices of food products that contain whole grains because food manufacturers will be encouraged to add whole grains to their products at these amounts. Thus, implementation of "good" and "excellent source" claims for foods containing 5 grams and 10 grams of whole grains per RACC and per labeled serving, respectively, would provide consumers with even more whole grain containing products in order to more easily meet the minimum daily recommended amount of whole grain consumption.

ConAgra understands that the agency has received alternate suggestions that would require a higher inclusion level to make good/excellent source claims. ConAgra believes a higher threshold level would create a disincentive for manufacturers to incorporate whole grains in their products, thereby limiting the number of products that consumers could source to incorporate whole grain in their diet. In this regard, we believe the key for consumers to be able to meet dietary recommendations for whole grain consumption is to be able to include whole grain throughout their daily menu.<sup>3</sup> We note that the sample menus provided for seven days (one week) in the MyPyramid materials provide a range

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<sup>3</sup> A recent national consumer survey commissioned by ConAgra supports the view that consumers are looking to incorporate whole grains in their diets from a variety of foods. Specifically, in the "What's In Store" Survey conducted for ConAgra between April 25-27, 2006 among a nationally representative sample of 1,023 adult consumers, 54% responded that they are looking to add whole grains into their diet, 48% indicated they are adding more whole grains foods to their menus, 26% indicated they are replacing foods that aren't whole grain with ones that contain 100% whole grain, and 23% indicated they are replacing foods that aren't whole grain with ones that contain a portion or blend of whole grains. The last response in particular reinforces that consumers are seeking whole grains from a variety of foods, not just foods that are solely or predominating whole grains.

of whole grain intake per day from two to four, one-ounce equivalents of whole grains per day, with an average of 3.4 one-ounce equivalents per day.<sup>4</sup> In addition to those menus, we have prepared daily sample menus provided in an attachment to these comments. Note that under our sample menus with whole grain levels at 5g and 10g in a variety of foods, consumers can easily achieve 48g per day while staying within recommended caloric limits.

ConAgra wishes to draw to FDA's specific attention that the Agency came to the same general conclusion that 10% and 20% are meaningful levels during its consideration of regulations implementing the Nutrition Labeling and Education Act (NLEA). Although the context pertained specifically to nutrients, the situation otherwise is analogous and instructive with respect to similar claims for whole grain. In the NLEA regulatory process, FDA determined that 20 percent of the RDI for a nutrient was appropriate for a "high" or "excellent" claim and 10 percent appropriate for a "good source". In responding to critics that suggested the 20 percent level was too low and a new higher claim should be allowed, FDA stated "allowing such a term ("very high") could discourage consumption of a wide variety of foods in favor of fewer highly fortified foods and supplements." See *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food* (58 Federal Register page 2302, January 6, 1993) page 2344. The agency went on to reiterate one of its general principles and stated that "defining a term such as "very high" could discourage adherence to current dietary guidelines such as those stated in "Nutrition and Your Health: Dietary Guidelines for Americans", which emphasize the need to select a diet from a wide variety of foods and to obtain specific nutrients from a variety of foods rather than from a few highly fortified foods or supplements" (Id at 2345). FDA also spent considerable time expressing its desire to encourage product innovation, not stifle it. In the current whole grain labeling debate, that philosophy should also be maintained.

#### B. Context Labeling – "Good Source" and "Excellent Source"

As an alternative to the quantitative labeling option of "good source" and "excellent source", manufacturers could place such content claims in context of the daily diet and/or expressly link them into the Dietary Guidelines and My Pyramid. By providing the additional contextual information, use of the "good" and "excellent" source terms clearly would not be false or misleading given the transparency of the claim, i.e., consumers would clearly understand the basis for the claim. Below are examples of context labeling "good source"/"excellent source" claims as well as truthful and non-misleading whole grain label statements characterized in the context of the daily diet and/or expressly linked to the Dietary Guidelines and My Pyramid.

##### **Cheese pizza (5g whole grain)**

*Good source of whole grain. Provides 10% of your whole grains per day. My Pyramid recommends at least 3 servings (3, 1 ounce equivalents) of whole grains per day.*

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<sup>4</sup> [http://www.mypyramid.gov/downloads/sample\\_menu.pdf](http://www.mypyramid.gov/downloads/sample_menu.pdf)

or

*Good source of whole grain. Provides 5g whole grain per serving, 48 g are recommended daily*

**Pasta, vegetable frozen dinner** (1/2 c pasta per MyPyramid)

*Excellent source of whole grain. Provides 11 g whole grain per serving, 48 g are recommended daily*

or

*Provides 2/3 of a serving of whole grain, My Pyramid recommends 3 servings per day*

## **II. Use of "Whole Grain" as Characterizing Term in Product Name**

In the Draft Guidance, FDA states that "we recommend that pizza that is labeled 'whole grain' or 'whole wheat' only be labeled as such when the flour ingredient in the crust is made entirely from whole grain flours, or whole wheat flours, respectively." We believe that FDA's guidance for pizza dough is too narrow. Product performance issues generally prohibit a 100% whole grain (or whole wheat) pizza crust. Today, substantial amounts of whole grain flour can be added to pizza dough formulas, resulting in the delivery of 1/3, 1/2 or even up to 1 ounce equivalent of whole grain per slice. Because of the wide use and acceptance of pizza among children, teens, and young adults, the addition of any whole grains to pizza crust can positively effect the consumption of whole grains in their diets. Imposing a 100% whole grain flour requirement for pizza crust will impede an important avenue to increase American's consumption of whole grains.

Further, from a labeling standpoint, ConAgra does not believe that "whole grain" has the same meaning as "100 percent whole grain." When the product contains >50% whole grain in the grain component, we believe the labeling could state "whole grain." If the product contains ≤50% whole grain, labeling disclosing the percentage of whole grain should be expressed (i.e., "[X]% whole grain [name of product]") or other meaningful characterizing descriptions in labeling. The same would apply for pizza dough or other non-standardized products with whole grain and grain mixtures.

## **III. Definition**

In labeling whole grain products, we support products labeled as whole grain when the final grain product is in natural proportions and derived from a single identifiable source - such as hard red winter wheat.

Conversely, for accurate and truthful labeling, when a grain product is assembled from multiple sources, it should be labeled "whole grain (from components)".

For example a whole grain product comprised of the germ of hard red spring wheat, the bran of soft white wheat and the endosperm from durum wheat should accurately convey that it was manufactured from components.

This labeling distinction is similar to that made between 100% orange juice and orange juice made from concentrate. According to 21 CFR 102.33(g), any single juice or blend of juices which come from concentrate must bear a statement indicating this. The most common way in which that is expressed is either "from concentrate" or "reconstituted".

#### IV. Summary

With regard to food and public health, ConAgra subscribes to three principles 1) truthful and non-misleading label statements, 2) clearly communicated information to empower the consumer to make healthful choices, and 3) policy frameworks which promote public health by encouraging manufacturers to produce a wide variety of healthful products.

ConAgra believes that the 2005 Dietary Guidelines establishes the dietary importance of whole grains as a food and as an ingredient in food products, and provide an authoritative basis for industry to develop and use whole grain characterizing label statements.

Thank you for the opportunity to comment on this important issue.

Sincerely,



Brent Baglien

VP Government Affairs

## SAMPLE MENUS

Meal	Product	Number of servings	Per serving	Whole Grains (grams)/serving	Total WG	Calories/serving	Total Calories
<b>DAY 1</b>							
Breakfast	Bread	2	1 slice	5	10	60	120
Lunch	Chx noodle soup	1	245g	5	5	110	110
Snack	Popcorn	1		21	21	110	110
Dinner	Frz dinner pasta*	1	227g	11.5	11.5	240	110
<b>Total</b>					<b>47.5</b>		<b>450</b>

<b>DAY 2</b>							
Breakfast	Oat flakes cereal	1		11	11	110	110
Lunch	Bread	1	1 slice	13.9	13.9	70	70
Dinner	Tortilla	1		10	10	150	150
Snack	Granola bar	1	2 bars	16	16	180	180
<b>Total</b>					<b>50.9</b>		<b>510</b>

\* Calorie level for pasta only