

April 17, 2006



The SCHWAN FOOD COMPANY™

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

**[Docket No. 2006D-0066] Dietary Guidance for Industry and FDA Staff:  
Whole Grain Label Statements; Availability**

Dear Sir or Madam:

The Schwan Food Company (hereinafter "Schwan") welcomes the opportunity to comment on the proposed whole grain dietary guidance document as outlined in the *Federal Register* notice dated February 17, 2006.

By way of introduction, Schwan is one of the largest branded frozen food companies in the world. The company employs approximately 22,000 people in the processing, manufacturing, transportation, distribution and sales of frozen foods nationally and internationally.

Schwan commends FDA's characterization of whole grains and issues related to current standards of identity. FDA's whole grain definition is consistent with the definition issued by American Association of Cereal Chemists (AACC) and currently used by many companies in the food industry.

Through the years, the health and nutritional benefits of whole grains have been reported by leading researchers and the federal government. The *2005 Dietary Guidelines for Americans*, developed jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA), recommends that Americans "consume 3 or more ounce-equivalents of whole grain products per day." Additionally, the document indicates, "in general, at least half of the grains [eaten each day] should come from whole grains." Heightened media and health communications regarding the whole grain recommendation have triggered a wave of consumer interest and demand. The food industry has responded positively by introducing a variety of whole grain products.

To help consumers identify products made with whole grains, it is essential that manufacturers be allowed to communicate these benefits beyond quantitative statements. Schwan concurs that label statements about whole grains should be truthful and not misleading in accordance with section 403(a) of the Federal Food, Drug, and Cosmetic Act

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(FDCA). However, mere quantitative statements regarding whole grain content do not adequately assist consumers attempting to follow the *Dietary Guidelines*.

Schwan disagrees with the agency's conclusion that label statements characterizing the amount of whole grains present in food are inappropriate. Schwan believes label statements that "imply a particular level of the ingredient, i.e. 'high' or 'excellent'" should be defined and encouraged in food labeling. Such statements will better assist consumers in identifying, purchasing, and ultimately consuming more whole grains, which will contribute to FDA's and industry's shared goal of encouraging Americans to increase their whole grain consumption. Such claims are not inherently improper as proven by myriad other similar, authorized claims, and should be evaluated in the context of other information. Context includes conveying the recommended consumption of at least 3-ounce equivalents of whole grains per day (which equates to 48 grams of whole grains daily) or providing a direct reference or link to *MyPyramid* in factual terms. Schwan believes that the three one-ounce equivalents or 48 grams of whole grains per day is adequate to serve as the basis for establishing criteria for whole grain content claims.

Using the 48 grams of whole grain a day reference, Schwan recommends the agency define "made with whole grain" at  $\geq 5$  g (or  $\geq 4.8$  g) whole grains, a "good source" at  $\geq 8$  g whole grains, and an "excellent source" at  $\geq 16$  g whole grain per Reference Amount Customarily Consumed (RACC). This approach to consumer-friendly terms accommodates a "made with" option at 10% of a 48 g daily amount of whole grains and equates a one-ounce equivalent of whole grain to an "excellent source" and half of a one-ounce equivalent to a "good source."

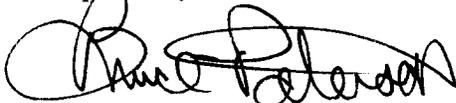
Food manufacturers have responded to the message that Americans need to increase their consumption of whole grains by adding whole grains to a broad array of products. While manufacturers can make some products with 100% whole grains, it is not feasible, nor essential, to make all whole grain products with 100% whole grain flour. Requiring pizza crust to be made with 100% whole grain flour in order to define a whole grain pizza will likely delay, if not block, pizza manufacturers' incorporation of significant amounts of whole grain into products. High percentages of whole grain flour require significant investment in production equipment to accommodate the altered functionality of the dough and maintain throughput volumes. The rheology of the dough requires slower speed production, both for dough production and proofing. Furthermore, additional equipment is needed to handle alternate ingredients that are often required to achieve proper dough conditioning and acceptable finished product characteristics (i.e. taste, texture, etc.). There currently are no pizza crusts in the marketplace made with 100% whole grains. A significant capital investment would be necessary in order to accomplish it. This, coupled with consumer response to 100% whole grain products, does not justify the required investment to achieve a 100% whole grain pizza crust.

Substantial whole grain flour can feasibly be added to dough formulas, resulting in the delivery of 1/2 to 1 ounce equivalent serving of whole grains per slice. Because of the wide consumption of pizza among children, teens and young adults, the addition of whole grains to pizza crust has the potential of positively influencing the consumption of whole grains in these populations. Requiring 100% whole grain flour for pizza crust will impede this avenue of whole grain options.

Schwan is committed to truthful and non-misleading food labeling that assists consumers to implement national food and dietary recommendations from the *2005 Dietary Guidelines for Americans* and *MyPyramid* food guidance system. The company believes these Guidelines establish the nutritive value of whole grains as an ingredient and substance in food products, and provide an authoritative statement for the development of whole grain content claims. Schwan also believes that FDA has adequate policy and scientific framework to establish content claims for whole grains through its own initiative.

The Schwan Food Company encourages FDA to consider comments presented and to promulgate a final guidance document on this matter. Thank you for the opportunity to comment on this important issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce Paterson". The signature is fluid and cursive, with a large initial "B" and "P".

Bruce Paterson, Ph.D.  
Vice President  
Research & Development