

M U C H S H E L I S T

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VIA FEDERAL EXPRESS

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

Re: Docket No. 2006D-0066

Ladies and Gentlemen:

We represent Barilla America, Inc. ("Barilla"), a manufacturer and distributor of pasta and pasta sauce products. On behalf of Barilla, we respectfully submit the following comments regarding the Food and Drug Administration's ("FDA") February 17, 2006 Draft Guidance for Industry and FDA Staff, Whole Grain Label Statements (the "Draft Guidance").

Barilla is very much in favor of the FDA's attempt to clarify its position on the appropriate uses of "whole grain" labeling statements and claims. Barilla has found throughout the pasta industry that, in the absence of specific regulations on the topic, "whole grain" claims are being used in many different ways to mean different things, often aggressively in a manner that is deceptive or misleading to consumers. Barilla hopes that the Draft Guidance, when finalized, will help to bring uniformity in the use of "whole grain" in the pasta industry, resulting in more certainty for consumers.

To be a more complete and effective step toward uniformity and consumer certainty, however, Barilla believes that the Draft Guidance should be clarified to prohibit the practice of labeling products not made entirely from whole grain flours as "whole grain blend", "whole wheat blend" or something similar. This labeling practice is misleading to consumers and is occurring with increasing frequency in the pasta industry.

Although the Draft Guidance provides significant guidance as to the use of "whole grain", it does not address "whole grain blend" labeling. The Draft Guidance suggests in Question 7 that a "whole grain" statement appearing on a label could be construed as meaning the product is 100% whole grain. In Questions 7 and 8, the Draft Guidance suggests that pizza, bagels and pastas should only be labeled "whole grain" if they are made entirely from whole grain flours. These statements together indicate that unqualified "whole grain" labeling should not appear on products not made entirely from whole grain flours. However, they do not specifically foreclose

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the use of "whole grain blend" labeling for such a product, which is made partially, but not entirely, of whole grain flour.

Barilla is concerned that the misleading practice of labeling products that are not made entirely, or even principally, from whole grain flours as "whole grain blend" will continue if it is not specifically prohibited under the Draft Guidance. Under the Draft Guidance such labeling remains in a perceived "gray area" between the unqualified "whole grain" labeling allowed for entirely whole grain products and the quantitative whole grain labeling (i.e. "10 grams whole grain") that the FDA encourages for non 100% whole grain products. Those looking to aggressively label their non-whole grain products "whole grain blend" may justify this labeling under the Draft Guidance on the basis that the "blend" qualification prevents the labeling from being construed as meaning 100% whole grain and/or the presence of some whole grain in the product makes the "whole grain blend" labeling "factual".

The practice of labeling non-whole grain products as "whole grain blend" is misleading because consumers are likely to mistake "whole grain blend" statements as meaning a product is 100% whole grain. Barilla has commissioned consumer research on label statements including "whole grain blend", and this research has confirmed that consumers most often do not distinguish between product packages bearing "whole grain blend" statements and those bearing unqualified "whole grain" statements, and take both to indicate identical nutritional benefits.

The harm to consumers, of course, is that non 100% whole grain products do not have the same nutritional benefits as 100% whole grain products. As the Department of Health and Human Services recently recognized in its *Dietary Guidelines for Americans 2005*, valuable vitamins, minerals, lignans, phytoestrogens, phenolic compounds, and phytic acid are lost when grain is refined. *Dietary Guidelines*, p. 25. Some manufacturers are using a fiber additive to increase the dietary fiber content of their "whole grain blend" products to the level that would be associated with a 100% whole grain product, but this does not restore the other nutrients lost from "whole grain blend" products and only serves to further mislead consumers trying to distinguish between products based on their labels.

Barilla requests that the FDA take this opportunity to further help consumers in making their nutritional decisions by eliminate any doubt and clearly foreclosing misleading "whole grain blend" labeling of non 100% whole grain products by stating in its final guidance that "whole grain blend" and similar labeling statements should not be used in products that are not made entirely of whole grain.

Barilla further encourages the FDA to take the next step and memorialize its non-binding guidance in formal regulations. Whole grain labeling has taken a new prominence as manufacturers try to capitalize on the recommendations in the *Dietary Guidelines*. Making the FDA's guidance binding on manufacturers would provide consumers further help in the increasingly difficult task of distinguishing between products and choosing more nutritious foods for their families.

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Thank you for your time and consideration.

Respectfully,

A handwritten signature in cursive script that reads "David A. Alman". The signature is fluid and extends to the right.

David A. Alman