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ROMAN MEAL COMPANY

July 26, 2005

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

Re: WHOLE GRAIN CITIZEN'S PETITION/ 2004P-0223

Dear Sir or Madam:

A letter dated June 24, 2005 from Roman Meal Company was submitted to the Division of Dockets Management. It was posted on the Dockets Managements website on July 7 as document 2005Q-0211. At the time this letter was written, the letter of comments from ConAgra Foods, to which the Roman Meal Company letter indirectly referred, was not yet published on the Dockets Management website. This document was posted July 1 as document 2004P-0223, C19. It was not possible to make direct reference to the ConAgra letter since it was not yet part of the public record.

Please allow me to clarify that the letter of comment from Roman Meal Company dated June 24 and entered as document 2005Q-0211, C1 is in reference to the ConAgra letter of comment dated June 15 and entered as document 2004P-0223, C19.

A copy of the Roman Meal Company June 24 letter of comment is included for your convenience. Roman Meal Company respectfully requests that the Food and Drug Administration consider our position in the context of the ConAgra letter of comment.

Sincerely,

Steve Buckholdt
Quality Assurance Manager

enclosure

2004P-0223

C24



Steve Buckholdt
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ROMAN MEAL COMPANY

June 24, 2005

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

Dear Sir or Madam:

On May 10, 2004, General Mills Inc. submitted a Whole Grain Descriptive Claims Citizens Petition. It is the understanding of Roman Meal Company that 120 days passed without negative comment from FDA. The descriptive claims within this petition are therefore available for use. A key feature of this petition is that it authorizes the descriptors "good source of whole grain" and "excellent source of whole grain". The qualifying levels of whole grains per serving are 8-15 grams for "good source" and 16 grams or more for "excellent source".

It has come to the attention of Roman Meal Company that another similar petition has been submitted recently. The same terms "good source of whole grain" and "excellent source of whole grain" are used, but the qualifying levels are significantly lower. The qualifying levels in this most recent petition are 5 grams per serving for "good source of whole grain" and 10 grams per serving for "excellent source of whole grain".

Roman Meal Company objects to this recent petition for the following reasons:

- 1) If the recent petition is allowed to pass the 120 day period without FDA intervention, there will exist two standards of "good source of whole grain" and "excellent source of whole grain" for bread, a very important category of food. It is possible that other foods will also be affected by the conflicting standards. This is a disservice to the consumer. It will create confusion to anyone attempting to follow dietary recommendations for consumption of whole grain foods.
- 2) On March 10, 1999, General Mills submitted a Whole Grain Foods Authoritative Statement Claim Notification. This statement describes the claim "Low fat diets rich in whole grain foods and other plant foods may reduce the risk of heart disease and certain cancers". On page 11 of this claim, it is mentioned that the level of whole grain resulting from adherence to the claim is 16 grams per serving. This level of whole grain equates to an excellent source of whole grain in

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the May 10, 2004 General Mills petition. There is value to the consumer in maintaining 16 grams of whole grain as a threshold for claims. It is a consistent standard. Roman Meal Company feels that a lower standard of 10 grams per serving is inconsistent with preceding claims and will create confusion in the mind of the consumer.

- 3) It is not clear that lower qualifying levels of whole grains are reasonable and scientifically justified. Roman Meal Company is committed to providing whole grain value to the consumer. We want foods described as "good source" and "excellent source" of whole grains to truly meet the intended meaning of these terms. We question the value to the consumer of lower qualifying levels.

Roman Meal Company greatly appreciates your time and consideration in reviewing our objections to the recent petition submitted to FDA. Our request is that you deny the recent petition asking for lower standards of 5 grams = "good source of whole grain" and 10 grams = "excellent source of whole grain".

If you require further explanation or clarification, please feel free to contact me.

Sincerely,

Steve Buckholdt
Quality Assurance Manager