



LAW DEPARTMENT

VIA DHL

April 28, 2006

Tomoko Shimakawa, Sc.D.  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Room 4A036  
5100 Paint Branch Parkway, HFS-830  
College Park, MD 20740-3835

Dear Dr. Shimakawa:

Thank you for your email dated April 27, 2006 in which FDA requested an extension of time to take action on the above petition until September 30, 2006. We are sorry to hear that the agency will not be able to meet the statutory deadline date of May 16, 2006 to make a determination on our petition. The Quaker Oats Company is willing to agree to the extension you have requested.

Due to the fact that, as we discussed in our original conversations, this petition does not pose particularly novel or complex issues for the agency, we would hope that:

- (1) FDA will be willing to issue an interim final rule when it ultimately publishes its disposition of the petition; and
- (2) The extension until September, 2007 will be the only one.

The hot cereal season commences upon the beginning of the school year around Labor Day. We had hoped that a timely ruling in May, combined with the grant of an interim final rule, would allow Quaker to make packaging changes and build inventory through the summer in time for the start of this year's hot cereal season. In the event that an interim final rule issues in September instead, we may still be able to reflect the ruling on packaging available for the second half of the hot cereal season (January through March, 2007). However, any delay beyond September, 2006 will surely mean that the value of

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communicating the heart health claim on our reduced sugar product will be lost for an entire hot cereal season, with the attendant loss of consumer and public health benefits. Please don't hesitate to contact us if you have any questions or comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark L. McGowan', with a long horizontal flourish extending to the right.

Mark L. McGowan  
Vice President, Legal  
Foods Division & PepsiCo Nutrition

cc: Mark Andon  
Michael O'Flaherty