



LAW DEPARTMENT

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VIA UPS OVERNIGHT

September 25, 2006

Mr. Vincent DeJesus  
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

Re: Quaker Oats health claim petition to amend 21 CFR 101.81  
(Docket No. 2006P-0069)

Dear Mr. DeJesus:

Thank you for your phone message of September 18, 2006 in which FDA requested an extension of time to take action on the above petition until March 30, 2007. We are sorry to hear that the projected determination date of September 30, 2006 cannot be met. The Quaker Oats Company is willing to agree to the extension you have requested.

As we discussed in our conference call earlier today, we had hoped to have an approval by this month because the hot cereal season commences around Labor Day and continues through March. A second six month extension means that we will not have an approval in time for any portion of the 2005-2006 hot cereal season. We had hoped that a ruling this month, combined with the grant of an interim final rule, would allow Quaker to make the heart health claim on the relevant products this season. A positive determination by late March, 2007, combined with the grant of an interim final rule, will allow us to make packaging changes in time to build inventory through the summer in time for the start of the 2007-2008 hot cereal season. However, any delay beyond March, 2007 could even put at risk our ability to communicate the heart health claim on our reduced sugar products on package since such packaging must be completed in the spring, in time to be packed during July and August. We also

2006P-0069

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note that the statutory 540 day deadline expires in May, 2007 so will expect that the various internal hurdles required for approval can be accomplished before that deadline date.

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