



April 30, 2004

Jillonne Kevala, Ph.D.  
Food and Drug Administration  
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Re: Health Claim Petition – To amend 21 CFR §101.80 to authorize a noncariogenicity dental healthy claim for sucralose

Dear Dr. Kevala:

Thank you for your April 14, 2004, letter concerning the McNeil Nutritionals health claim petition referenced above. I am writing to inform you that we are in the process of compiling the information requested, as required by 21 CFR §101.70 (c) and (d), with respect to the non-clinical and clinical trials cited in the petition.

We apologize for the oversight and will submit this information in the very near future.

Sincerely,

A handwritten signature in black ink that reads "Richard R. Reo".

Richard R. Reo  
Director, Regulatory Affairs  
Phone: 732-524-6774  
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email: rreo@mspus.jnj.com

2004P.0294

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