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October 7, 2004

Kathleen Ellwood, 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: Docket 2004P-0294 -- Health Claim Petition to amend 21 CFR §101.80
to authorize a noncariogenicity dental health claim for sucralose

Dear Dr. Ellwood:

In response to FDA's request and in accordance with the provisions of 21 CFR 101.70 (j)(3)(iii), McNeil Nutritionals agrees to a six-month extension (until April 2005) of the review process for the above-referenced health claim petition.

Sincerely,

A handwritten signature in black ink that reads "Richard R. Reo" with a long horizontal line extending to the right.

Richard R. Reo
Director, Regulatory Affairs
Phone: 732-524-6774
Fax: 732-524-2189
email: rreo@mopus.jnj.com

2004P-0294

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