



JUL 7 2004

Mr. Richard R. Reo
Director, Regulatory Affairs
McNeil Nutritional
317 George Street
P.O. Box 2400
New Brunswick, NJ 08903-2400

RE: Health Claim Petition - To amend 21 CFR 101.80 to authorize a noncariogenicity dental health claim for sucralose

Dear Reo:

This letter is in reference to the subject health claim petition, dated March 31, 2004, and received in the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration on April 2, 2004. We informed you on April 14, 2004, that the date by which FDA would either file or deny your petition is July 11, 2004. We have completed our initial review of this petition and are filing it as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act). The filing date will be July 9, 2004, the last business day preceding July 11. We will inform you of the Docket number for your petition when it has been assigned. We will either publish a proposal in response to the petition or deny the petition within 90 days of the filing date, i.e., not later than October 7, 2004.

Sincerely yours,

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

2004P-0294

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