



May 19, 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:

As a follow-up to my April 30, 2004, letter, I am writing to provide the information required by 21 CFR §101.70 (c) and (d) with respect to the non-clinical and clinical trials cited in the above-referenced health claim petition.

Nonclinical laboratory studies:

The petition cited four nonclinical laboratory studies involving the use of sucralose, as follows:

1. Young, DA, Bowen, WH: The Influence of Sucralose on Bacterial Metabolism. *J. Dent. Res.* 69: 1480-1484, 1990.
2. Bowen, WH, Young, DA, Pearson, SK: The Effects of Sucralose on Coronal and Root-surface Caries. *J. Dent. Res.* 69: 1485-1487, 1990.
3. Drucker, DB, Verran, J: Comparative Effects of the Substance-Sweeteners Glucose, Sorbitol, Sucrose, Xylitol and Trichlorosucrose on Lowering of pH by Two Oral *Streptococcus Mutans* Strains *In Vitro*. *Arch. Oral Biol.* 24: 965-970, 1980.
4. Bowen, WH, Pearson, SK, Falany, JL: Influence of Sweetening Agents in Solution on Dental Caries in Desalivated Rats. *Archs. Oral Biol.* 35: 839-844, 1990.

These studies were not conducted in accordance with good laboratory practices. The studies were conducted by independent investigators with sucralose supplied by McNeil. The results of these studies were subjected to peer review prior to their journal publication.

Clinical trials:

The petition cited two clinical trials involving the use of sucralose, as follows:

1. Steinberg, LM, Odusola, F, Yip, J, Mandel, ID: Effect of Aqueous Solutions of Sucralose on Plaque pH. *Am. J. of Dent.* 8: 209-211, 1995.

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2. Meyerowitz, C, Syrrakou, EP, Raubertas, RF: Effect of Sucralose – Alone or Bulked with Maltodextrin and/or Dextrose – on Plaque pH in Humans. *Caries Res.* 30: 439-444, 1996.

These clinical trials were carried out in accordance with the requirements for institutional review, as set forth in 21 CFR §56, and in accordance with the requirements for informed consent, as set forth in 21 CFR §50.

Sincerely,



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