



APR 14 2004

Food and Drug Administration  
College Park, MD 20740

7969 04 L-7 2210

Richard R. Reo  
Director, Regulatory Affairs  
McNeil Nutritionals  
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 Mr. Reo:

This letter acknowledges receipt on April 2, 2004 by the Food and Drug Administration (FDA) of the petition you submitted on behalf of McNeil Nutritionals. The petition requested that the FDA amend the regulation authorizing a health claim on sugar alcohols and dental caries (21 CFR 101.80) to include sucralose as a substance eligible for the claim.

The petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2), within 100 days of receipt of a petition, it will be either filed for comprehensive review or denied. A denial may be by FDA action within the 100-day period, which ends on July 11, 2004, or by lack of FDA action within the 100-day period in which case the petition will be deemed to be denied unless an extension is mutually agreed upon by the FDA and the petitioner. The FDA will notify you by letter on or before July 11, 2004 of the disposition of the petition.

In addition, we would like to inform you that the petition does not contain information required in 21 CFR 101.70(c) with respect to non-clinical trials or 21 CFR 101.70(d) with respect to clinical or other human investigations. This minor problem can be remedied by submitting to FDA an addendum containing the requested information (21 CFR 101.70(c) and (d)).

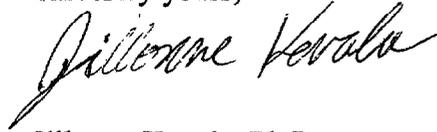
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ACK1

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Please feel free to contact me at 301-436-1848, if you have any questions concerning the status of the petition.

Sincerely yours,

A handwritten signature in cursive script that reads "Jillette Kevala". The signature is written in black ink and is positioned directly below the typed name "Jillette Kevala".

Jillette Kevala, Ph.D.  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition