

March 14, 2003
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Teriaka

Kathleen Ellwood, Ph.D. 5 5 4 '03 APR -2 P2:14
Assistant Director for Nutrition Science
Division of Standards and Labeling Regulation (HFS-830)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, Room 4A026
College Park, MD 20740 USA

Re: Request for Enforcement Discretion: Health Claim (21 101.83) and
Phytosterols

Teriaka Ltd
Leikosaarentie 32
POB 15
FIN-00981 Helsinki
Finland
Telephone +358 9 31981
Telefax +358 9 3218 290
Trade Reg. No 763.705

Dear Dr. Ellwood:

In a letter dated February 14, 2003, the FDA advised Cargill Health & Technologies that it would use enforcement discretion in applying 21 CFR 101.83 – Interim Health Claim – to Cargill's phytosterol-containing products with the limitations as set forth in that letter. We read in a trade sheet that this enforcement discretion was applied specifically to Cargill. Based on a recent discussion between a member of your Office and our US consultant, we were advised to submit a letter officially requesting that the agency use the same enforcement discretion in applying 21 CFR 101.83 to our phytosterol-containing products. This letter represents our official request.

Teriaka submitted a GRAS Notice (GRN 000112) on August 15, 2002 for its phytosterol ingredients intended for use in a variety of food products, including margarine and vegetable-based spreads; yogurt and yogurt-like products; milk-based juice beverages; ice cream and non-standardized ice cream products; cream cheese and cream cheese-like products; snack bars (health bars); salad dressing, mayonnaise, French dressing, and dressings for salads; and white bread, white rolls and buns, and comparable non-standardized white bread products. The agency responded with a 'no-object' letter February 4, 2002. Subsequently,

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Teriaka has self-determined its phytosterol ingredients to be safe in dietary supplements and therefore these products are included in this request.

We look forward to a positive response to this request. If you have any question, please contact me at 011- 358 9-3198502 or via email at leena.morander@paulig.fi. Also you may contact our US consultant, C. K. Gund, Ph.D., Phoenix Regulatory Associates, Ltd. at 703-406-0906 or phoenix@phoenixrising.com.

Thank you in advance.

Sincerely,

A handwritten signature in black ink, appearing to read "Leena Morander". The signature is fluid and cursive, written in a professional style.

Leena Morander, M.Sc.

Product Development Manager

RE: Facsimile and Federal Express