DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-38

FEB 10 2004

3/11/04 jb

James H. Skiles, Esq.
Vice President and General Counsel
Grocery Manufacturers of America
Second Floor
2401 Pennsylvania Avenue N.W.
Washington, DC 20037

Re: Petition to Establish Nutrient Content Claims for Carbohydrates

Dear Mr. Skiles:

This letter acknowledges receipt on February 3, 2004, by the Food and Drug Administration (FDA) of your petition to establish nutrient content claims for carbohydrates. This petition was submitted pursuant to Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)).

Your petition is currently undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.69(m), within 100 days of receipt of a petition, the petition will either be filed for comprehensive review or denied. A denial may be either by FDA action within the 100-day period, which ends on May 12, 2004 or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

If you have any questions please feel free to contact Ritu Nalubola at (301) 436-2371.

Sincerely yours,

Shellee Anderson

Shellee Anderson
Team Leader
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2004P-0110

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