



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

9 0 8 2 '00 MAY 30 P1:45

Dr. Gilbert A. Leveille
McNeil Consumer Healthcare
7050 Camp Hill Road
Fort Washington, PA 19034

MAY 25 2000

RE: "Petition for Health Claim: Plant stanol esters and heart disease"

Dear Dr. Leveille:

This is in reference to the health claim petition that you submitted on February 15, 2000 to the Food and Drug Administration. In accordance with section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(r)(4)) and 21 C.F.R. § 101.70(j)(2), we will be filing this petition. At the time of filing, health claim petitions are placed in a public docket and become available for public review.

The filing of a health claim petition does not indicate that the agency has completed its review nor determined whether all preliminary requirements for the petition have been satisfied. FDA is required to make a decision about whether to issue a proposed regulation within 90 days of the filing date and, therefore, will be conducting further review of the information in your petition.

Please contact me at the above address or call me at 202-205-5372 if you have any questions.

Sincerely,

Lynn A. Larsen, Ph.D.
Director, Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling and Dietary
Supplements
Center for Food Safety and Applied Nutrition

00P-1276

LET2

cc:

GCF-1 (Nickerson)

HFA-224

HFA-305 (Dockets Management Branch; Docket Number 00P-1276)

HFS-800 (Lewis)

HFS-830 (Larsen)

HFS-832 (Ross, yellow copy)