



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

8798 6 MAR 24 12:02

MAR 2 2006

Guy H. Johnson, Ph.D.
Johnson Nutrition Solutions LLC
8711 Swan Street
Kalamazoo, MI 49009

RE: Qualified Health Claim Petition – Unsaturated Fatty Acids from Canola Oil and
Reduced Risk of Coronary Heart Disease

Dear Dr. Johnson:

On January 9, 2005, the Food and Drug Administration (FDA) acknowledged receipt of the petition you submitted, on behalf of the U.S. Canola Association, pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requests a qualified health claim for the relationship between the consumption of unsaturated fatty acids from canola oil and a reduction in risk of coronary heart disease.

In accordance with the FDA's guidance, "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (<http://www.cfsan.fda.gov/~dms/nuttf-e.html>), FDA is to determine, within 45 days of receipt of a qualified health claim petition, whether the petition is complete and can be filed for further review. Consequently, today we are filing the qualified health claim for unsaturated fatty acids from canola oil and its relationship to coronary heart disease. The petition is posted at this web address: (<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA>) and we are requesting comment on it for 60 days. Interested persons may submit comments until May 1, 2006. Within 270 days of the receipt of the petition, we will notify you of our final decision regarding the requested qualified health claim. We have calculated this date to be October 6, 2006.

2006 Q-0091

LET 1

Page 2 - Guy H. Johnson, Ph.D.

Please feel free to contact Vincent de Jesus at 301-436-1450, if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in cursive script that reads "Barbara Schneeman".

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety and Applied
Nutrition