



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JAN 23 2006

0411 6 MAR -2 P2:17

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

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

Dear Dr. Johnson:

This letter acknowledges receipt on January 9, 2006 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of the U.S. Canola Association, 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. Your petition did not state under which section of the Federal Food, Drug, and Cosmetic Act (the Act) the petition was being submitted but in our telephone call on January 23, 2006, you confirmed that the petition was being submitted pursuant to Section 403(r)(4) of the Act (21 U.S.C. § 343(r)(4)).

The petition is undergoing initial FDA review. In accordance with interim procedures set forth in the aforementioned Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttftoc.html>), within 45 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 45-day period, which ends on February 23, 2006, or by a lack of action by FDA within the initial 45-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.

2006Q-0091

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Please feel free to contact me at 301-436-1450 if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Vincent de Jesus', written in a cursive style.

Vincent de Jesus, M.S., R.D.  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition