



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 9 2007

Rocco Papalia
Senior Vice President
Research and Development
Frito-Lay, Inc.
7701 Legacy Drive
Plano, Texas 75024-4099

RE: Notification for a health claim based on an authoritative statement

Dear Mr. Papalia:

This letter acknowledges receipt on January 24, 2007 by the Food and Drug Administration (FDA) of the health claim notification you submitted pursuant to Section 403(r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(r)(3)(C)). The notification is informing FDA of a health claim characterizing the relationship between the consumption of unsaturated fatty acids from vegetable oils and a reduced risk of heart disease. The health claim is based on authoritative statements from 1) a National Academy of Sciences (1989) report entitled "Diet and Health: Implications for Reducing Chronic Disease Risk," 2) an Institute of Medicine (2002) report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)," 3) a U.S. Department of Health and Human Services (2000) report entitled "Healthy People 2010," 4) a National Heart, Lung, and Blood Institute (2002) report entitled "Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report," and 5) a U.S. Department of Health and Human Services and U.S. Department of Agriculture (2005) report entitled "Dietary Guidelines for Americans 2005."

The notification is undergoing FDA review. In accordance with Section 403(r)(3)(C) of the Act, within 120 days (ending on May 24, 2007) of receipt of your health claim notification, you will be informed by FDA if the notification does not comply with Section 403(r)(3) of the Act. A lack of action by FDA within the 120-day period will deem the proposed health claim approved and will allow a food with a label containing the claim to be introduced into interstate commerce.

2007Q-0192

ACK 1

Page 2 - Rocco Papalia

Please feel free to contact me at 301-436-1774 or at vincent.dejesus@fda.hhs.gov, if you have any questions concerning this petition.

Sincerely,

A handwritten signature in black ink, appearing to read 'Vincent de Jesus', written over a horizontal line.

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

cc: Kari Hecker Ryan, PhD, RD, Manager, Nutrition & Food Safety