



OCT 16 2012

Rose Marie Robertson, MD, FAHA, FACC
Chief Science Officer
The American Heart Association
7272 Greenville Avenue
Dallas, Texas 75231

RE: Petition to Amend Health Claim – Dietary Saturated Fat and Cholesterol and
Risk of Coronary Heart Disease (21 C.F.R. §101.75)

Dear Dr. Robertson:

This letter acknowledges receipt on October 1, 2012 by the Food and Drug Administration (FDA) of the petition that you submitted, on behalf of the American Heart Association, pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)). The petition requests that the agency amend 21 C.F.R. §101.75 to permit raw fruits and vegetables, as well as single-ingredient or mixtures of frozen or canned fruits and vegetables that contain no added fat or sugars (except 100% fruit juice as a packing medium), which fail to comply with the “low fat” definition and/or the ten percent of the RDI or DRV minimum nutrient content requirement, to be eligible to bear the claim.

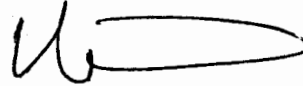
The petition is undergoing initial FDA review. In accordance with §101.70, within 100 days of receipt of your petition, you will be notified of FDA’s decision to either file the petition for comprehensive review or to deny the petition. A denial may either be by FDA action within the initial 100-day period, which ends on January 9, 2013, 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.

We note that in the final sentence of your petition, on page 84, you have referred to the proposed amendment of the health claim as a “proposed qualified health claim.” Because your petition clearly lays out a request for amending the applicable regulations of an authorized health claim (§101.75), we believe that the description as a “proposed qualified health claim” was a misstatement and will not be considering it as such.

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Please feel free to contact me at 240-402-1774 if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'V. de Jesus', with a long horizontal stroke extending to the right.

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