



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

**JAN 10 2013**

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RE: Petition to Amend Health Claim – Dietary Saturated Fat and Cholesterol and Risk of  
Coronary Heart Disease (Docket No. FDA-2013-P-0047)

Dear Dr. Robertson:

This letter is in reference to the health claim petition received by the Food and Drug Administration (FDA or the agency) on October 1, 2012, that you submitted, on behalf of the American Heart Association. The petition requested that the agency amend Title 21 of the Code of Federal Regulations §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, which fail to comply with the “low fat” definition and/or the minimum nutrient content requirement, to be eligible to bear the claim. The petition was submitted pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)).

We have completed our initial review of the petition and are filing it for further action in accordance with section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). The filing date is January 9, 2013. FDA will either publish a proposal to amend § 101.75 in response to your petition, or deny the petition, within 90 days of the filing date, i.e., not later than April 9, 2013. Denial may be made by FDA action or by lack of FDA action, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

Please feel free to contact Vincent de Jesus at 240-402-1774 if you have questions concerning this petition.

Sincerely yours,

Philip Spiller  
(Acting) Director  
Office of Nutrition, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition