

# United States Senate

WASHINGTON, DC 20510

July 7, 2003

Mark B. McClellan, M.D., Ph.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. McClellan:

We write to urge the Food and Drug Administration's favorable and expedient consideration of comments submitted by The Peanut Institute regarding the inclusion of peanut butter in the Agency's consideration of a health claim for nuts and reduced risk of coronary heart disease (CHD).

On March 7, 2003, The Peanut Institute submitted comments in support of a previous Petition submitted by the International Tree Nut Council Nutrition Research and Education Foundation (ITNC) to obtain authorization from FDA to make a health claim, pursuant to 21 C.F.R. § 101.14, for nuts and reduction of risk of CHD.<sup>1</sup> The second objective of The Peanut Institute in filing comments was to request that the conditions under which the health claim will be permitted be modified in a minor way so as to permit the claim to be made for peanut butter. As fully explained in The Peanut Institute's comments, peanuts, including peanut butter, account for more than two-thirds of the total annual tree nut and peanut consumption in the United States. Moreover, peanut butter, by law, consists of a minimum 90% shelled and roasted peanuts (FDA Standard of Identity, 21 C.F.R. § 164.150). More than one-half of all peanuts consumed in the United States are consumed as peanut butter. Thus, of total nut consumption in the United States, approximately one-third are consumed as peanuts, one-third as peanut butter, and one-third the combined total of all tree nuts. Scientific evidence has demonstrated that the same cholesterol and CHD-lowering health benefits offered by peanuts are also offered by peanut butter.

We would encourage the Agency to consider The Peanut Institute comments in conjunction with the ITNC Petition and the walnut Petition and issue one health claim proposal addressing nuts and peanut butter. First, this is the most efficient means of considering all relevant data regarding the nut and CHD health claim. Further, we believe that a single Agency action addressing all nuts and peanut butter is needed in order to prevent confusion among consumers who might construe multiple Agency actions to mean that certain nuts are more healthful than peanut butter or other nuts.

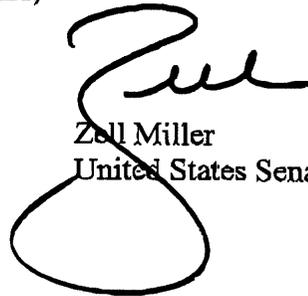
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<sup>1</sup> The ITNC's Petition, submitted August 27, 2002, and filed by the FDA on December 5, 2002, followed an earlier petition by another organization seeking authorization of a claim for walnuts, and seeks authorization for the claim "Diets containing one ounce of nuts per day can reduce your risk of heart disease." Nuts that would be allowed to bear the claim include legume peanuts and nine tree nuts (almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, and walnuts). [Docket No. 02P-0505]

In light of the cardioprotective benefits offered by peanut butter, as set forth in The Peanut Institute's comments, and the usefulness of this information to consumers seeking to make informed and healthy food choices, we respectfully urge your timely and favorable action regarding the comments, as well as the requests made therein. Thank you for your consideration of this request.

Very truly yours,

  
Saxby Chambliss  
United States Senate

  
Zell Miller  
United States Senate