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6952 '03 OCT 16 P1:46

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**John S. Eldred**  
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October 6, 2003

**Via Facsimile**

Dr. Kathy Ellwood  
Acting Director  
Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Re: Qualified Health Claim for Nuts and Coronary Heart Disease (Docket No. 02P-0505)**

Dear Dr. Ellwood:

Based on its July 14, 2003 letter of enforcement discretion (LED) issued to the International Tree Nut Council (ITNC) authorizing the use of a qualified health claim for nuts and nut-containing products, we are aware that the Agency is currently preparing a letter to more fully explain its decision regarding the qualified health claim. In anticipation of that explanation, we write to you on behalf of The Peanut Institute to respectfully request that FDA, in its follow-up letter, permit the amount of saturated fat contributed by the nuts in a "nut-containing product" to be excluded when determining whether such products meet the "low saturated fat" criterion established in the LED for this category. Our arguments as to why we believe the Agency should take this action are set forth below.

The LED allows a qualified health claim for certain nuts so long as the saturated fat content of the nuts does not exceed the "disqualifying level" set forth in FDA's regulations, which is 4 grams per Reference Amount Customarily Consumed (RACC) or, for products where the RACC is less than or equal to 30 grams or two tablespoons, per 50 grams of product. 21 C.F.R. § 101.14(a)(4). Thus, the claim may appear on the label of, *e.g.*, chopped or whole peanuts, almonds, or walnuts, even though the USDA-listed saturated fat value for these products are, respectively, 3.4 grams, 1.9 grams, and 3.05 grams per 50 grams (the RACC is 30 grams). See USDA National Nutrient Database for Standard Reference, Release 15 (August 2002). Yet, for nut-containing products, the LED allows the qualified health claim to appear so long as 11

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grams of qualifying nuts are present, *but only if* the nut-containing product as a whole meets the definition of a “low saturated fat” food as set forth in 21 C.F.R. § 101.62(d)(2), i.e., contains 1 gram or less saturated fat per RACC.

Thus, the LED establishes a blatant incongruity, as shown in the following example. A 30 gram serving of peanuts may bear the qualified health claim, even though it contains 2.04 grams of saturated fat according to USDA data. However, a 30 gram serving of a mixture of peanuts (20 grams) and dried fruit (10 grams) would be unable to bear the claim, even though its saturated fat content is only 1.36 grams, due solely to the saturated fat content of the peanuts. FDA has recognized that scientific evidence suggests that eating 1.5 ounces per day of most nuts may reduce the risk of heart disease. Yet if the claim can be made for a 20 gram serving of peanuts, it defies common sense to further provide that the addition of 10 grams of dried fruit to the peanuts would disqualify the nut-containing product from bearing the claim.

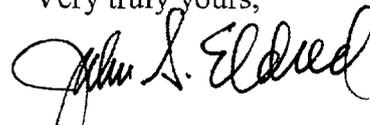
We recognize that the distinction created in the LED may have been inadvertent with regard to products such as the example cited above. FDA undoubtedly imposed the “low saturated fat” requirement on nut-containing products in furtherance of a policy decision to prevent the use of the claim on ice cream, cookies, or other products containing significant amounts of saturated fat from the non-nut ingredients present.

We submit that there is a simple way to correct the incongruity while preserving FDA’s policy aims: exclude the saturated fat content of the nuts in a nut-containing product when calculating whether the product is low in saturated fat. In the alternative, FDA could require that the non-nut portion of the finished product not provide more than 1 gram of saturated fat per RACC.

\* \* \*

We appreciate the opportunity to offer comments on this matter and thank you in advance for your consideration. Please do not hesitate to contact us if we can provide additional information or clarification on any of the issues raised in this letter.

Very truly yours,



John S. Eldred

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October 7, 2003

**Via U.S. Mail**

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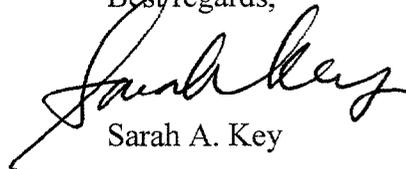
**Sarah A. Key**  
(202) 434-4236  
key@khlaw.com

**Re: Docket No. 02P-0505**

To Whom It May Concern:

Please include the enclosed letter to Dr. Kathy Ellwood in Docket No. 02P-0505. Thank you for your assistance with this matter.

Best regards,



Sarah A. Key