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March 7, 2003

Via Hand Delivery

Dockets Management Branch
Food and Drug Administration
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02P-0505

To Whom It May Concern:

Enclosed, please find one original and one copy of *Comments of the Peanut Institute in Support of Petition for a Health Claim for Nuts and Coronary Heart Disease,* which we are filing on behalf of The Peanut Institute.

The comments are submitted in response to a Petition submitted by the International Tree Nut Council Nutrition Research and Education Foundation (ITNC) on August 27, 2002, and filed by FDA on December 5, 2002. As discussed more fully in the enclosed, The Peanut Institute submits these comments 1) in support of the Petition submitted by the International Tree Nut Council Nutrition Research and Education Foundation (ITNC) to obtain authorization by the Food and Drug Administration (FDA) of a health claim, pursuant to 21 C.F.R. § 101.14, for nuts and reduction of risk of coronary heart disease (CHD); and 2) 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.

Thank you for your consideration of these comments.

Very truly yours,

John S. Eldred

John S. Eldred

02P-0505

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Before the United States
Food and Drug Administration

Docket No. 02P-0505

Comments of The Peanut Institute In Support of Petition for a Health Claim for Nuts and Coronary Heart Disease

The Peanut Institute submits these comments 1) in support of the Petition submitted by the International Tree Nut Council Nutrition Research and Education Foundation (ITNC) to obtain authorization by the Food and Drug Administration (FDA) of a health claim, pursuant to 21 C.F.R. § 101.14, for nuts and reduction of risk of coronary heart disease (CHD); and 2) 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.

I. Introduction and Background

ITNC, by Petition submitted August 27, 2002, and filed by the FDA on December 5, 2002, seeks authorization of a health claim for nuts for the claim "Diets containing one ounce of nuts per day can reduce your risk of heart disease." The Petition comprises a lucid and thorough analysis of the data in support of the claim. 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).

The Petition cites and discusses evidence of several types in support of the claim. First, seven "observational" or epidemiology studies are reviewed that clearly show a strong correlation between nut consumption and a decrease in CHD morbidity and mortality. In addition, 19 controlled dietary intervention studies of consumption of various nuts show significant reductions in total cholesterol and LDL-cholesterol in the nut-consuming groups in both normal and moderately hypercholesterolemic subjects. By way of corroboration, six additional intervention studies demonstrated favorable serum lipid effects in subjects who consumed nuts as part of dietary intervention trials with other foods. Moreover, six major review articles of the data obtained from the above-described studies conclude that there is a reduced risk of CHD associated with regular consumption of nuts as part of a balanced diet. Finally, the Petition points out recent authoritative statements of the American Heart Association, the United States Department of Agriculture, the Federation of American Societies for Experimental Biology Life Sciences Research Office, and the National Cholesterol Education Program of the National Institutes of Health, all of which encourage regular nut consumption as a useful tool in decreasing CHD risk.

The Peanut Institute is a non-profit organization dedicated to expanding knowledge regarding peanuts and peanut products. A special emphasis is placed on establishing sound science as the basis for food, nutrition, and health discussions about peanuts. The Institute pursues its mission through research programs, educational initiatives, and the promotion of healthful lifestyles to consumers of all ages. As an independent forum, The Peanut Institute is uniquely positioned to work with all segments of the food industry, the research community, academia, consumer organizations, and government. The Peanut Institute supports scientific research designed to improve knowledge of the nutritional composition of peanuts, and the effects of eating peanuts on health and disease. The Institute engages highly respected scientists and researchers in the United States and around the world to advise on and conduct these research projects.

Relying on FDA precedent in this area, ITNC's Petition seeks authorization for the claim for any food containing at least 7.1 g of nuts per reference amount customarily consumed (RACC). ITNC also requests, with convincing argument, an exemption for foods containing higher than the disqualifying levels for total fat as set forth in 21 C.F.R. § 101.14(a)(4), as well as that for saturated fat for Brazil nuts, cashew nuts, and macadamia nuts. Pursuant to Section 101.14(a)(4), FDA's disqualifying level rule applies when the saturated fat content exceeds 4 g per RACC or, for foods whose RACC is equal to or less than 30 g or 2 Tbsp., per 50 g of food. ITNC's Petition states that for formulated foods, i.e., foods which contain more than an insignificant amount of other foods, the disqualifying level rules would apply. Such a result would, perhaps inadvertently, exclude most peanut butter products, because the saturated fat levels of most peanut butters is marginally above the disqualifying level, as explained below. Although peanut butter must contain a minimum of 90% peanuts, it may contain up to 10% of other ingredients.

FDA's disqualifying level for saturated fat (SF) is 4 g per RACC. 21 C.F.R. § 101.14(a)(4). According to the USDA food composition tables, peanut butter contains 3 g of

SF per RACC (and 5 g per 50 g.)[1] The RACC for peanut butter is, according to FDA regulations, 2 Tbsp., or approximately 32 g. 21 C.F.R. § 101.12 (Table 2). Pursuant to FDA regulations, when foods have a RACC of 2 Tbsp. or less, the disqualifying level applies per 50 g of food. 21 C.F.R. § 101.14(a)(4). As a result, if the RACC for peanut butter were only slightly greater than it is, *e.g.,* 33 g or greater than 2 Tbsp., peanut butter would be entitled to bear the health claim under the Petition since it would not contain a disqualifying level of saturated fat per RACC. But because the RACC is at the cutoff limit of 2 Tbsp., the "per 50 g" standard applies unless FDA grants an exemption, which The Peanut Institute accordingly seeks.

Peanuts, including peanut butter, account for more than two-thirds of the total annual tree nut and peanut consumption in the United States. (*See* Figure 1; *see also*, USDA Center for Nutrition Policy and Promotion, Nutrition Insights No. 23, December 2000, which shows that, in 1997, peanuts accounted for 68% of total nut consumption (in a statistic that presumably included coconuts as a tree nut). This document is attached as Exhibit A.)

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1 USDA National Nutrient Database for Standard Reference, Release 15 (August 2002). [http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl] As cited in the table. Five grams is the mean level of the "crunchy" and "creamy" varieties.

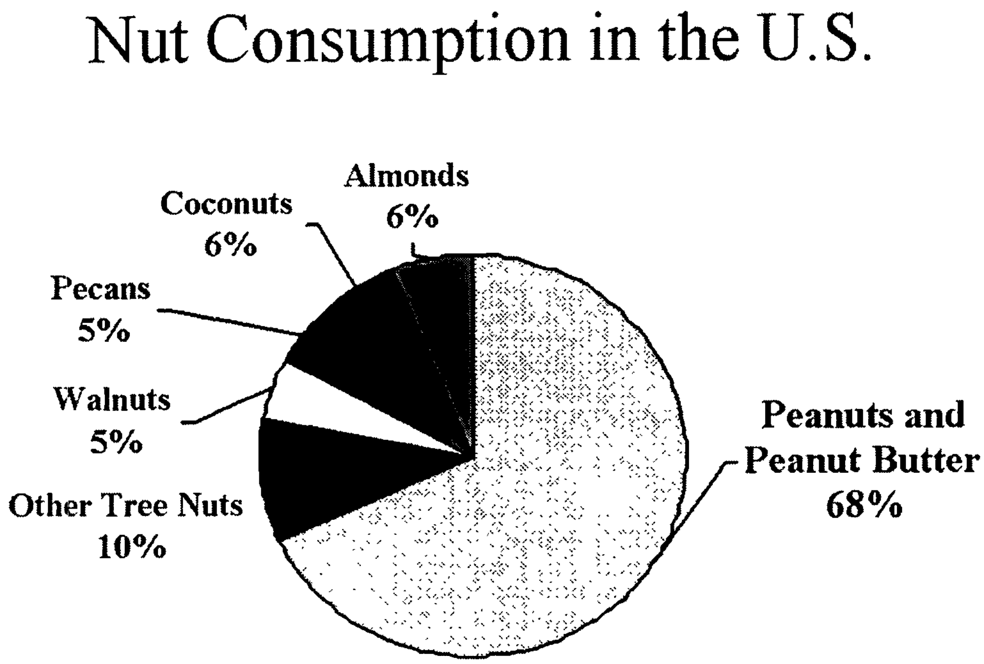

Figure 1

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. (*See* Figure 2, USDA National Agricultural Statistics Service data attached as Exhibit B, Table 9.) 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.

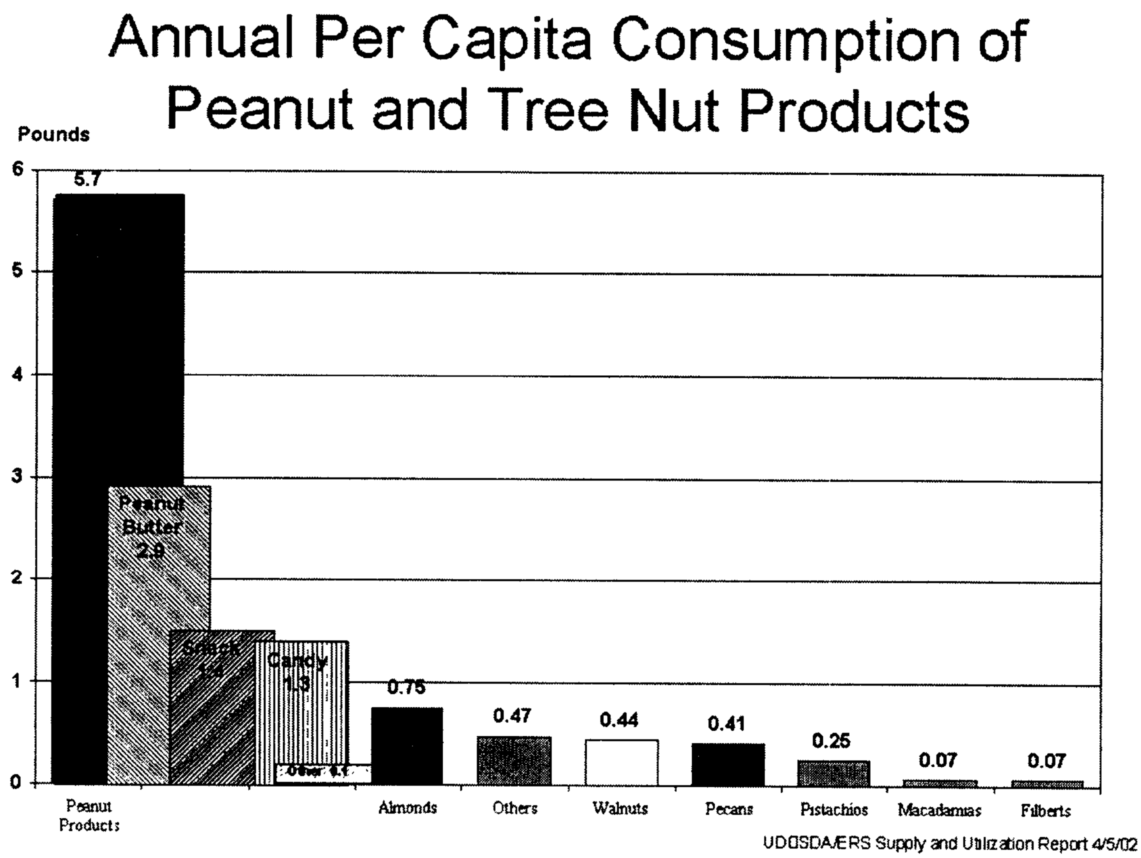

Figure 2

The Peanut Institute believes that the totality of the scientific data, as elaborated upon in the ITNC Petition, and as supplemented below, demonstrates that there is significant scientific agreement within the meaning of 21 C.F.R. § 101.14(c) in support of the proposed claim for peanuts as well as peanut butter. Accordingly, The Peanut Institute urges FDA to promptly and favorably act upon the ITNC Petition, with one exception: FDA should grant an exemption from the "per 50 g" requirement for the disqualifying level of saturated fat for peanut butter, without waiving the requirement per RACC.

Thus, the claim sought by The Peanut Institute would read "diets containing one ounce of nuts or 2 tablespoons peanut butter per day can reduce your risk of heart disease," and foods containing 8 or more grams peanut butter per RACC would be allowed to bear the claim provided the food meets the remaining requirements of 21 C.F.R. § 101.14.[2] The proposed health claim regulation submitted by ITNC, modified in accordance with these comments to permit the claim for peanut butter, is attached as Exhibit C.

II. The Data Support the Use of the Claim for Peanut Butter

A. Peanut Consumption Reduces CHD Risk

Data in the ITNC Petition plus other new data support the view that regular consumption of peanuts reduces the risk of CHD. Epidemiological studies have consistently demonstrated beneficial effects of nut consumption on CHD morbidity and mortality in population groups that reflect the general population of the United States. Clinical intervention studies in which peanuts, peanut butter, and tree nuts were incorporated into the diet have consistently reported favorable effects on plasma lipid profiles *e.g.*, reduced values of total cholesterol, LDL cholesterol, and triglycerides while having a minor impact, if any, on HDL cholesterol. The effect of peanuts and peanut butter on plasma lipids are exactly the effects sought by the National Cholesterol Education Program.[3] Thus, both epidemiological and clinical intervention studies support the view that the favorable fatty acid profile of peanuts and peanut butter contributes to a plasma lipid profile that reduces the risk of CHD. Other components of peanuts and peanut

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2 Two tablespoons is the appropriate statement for peanut butter as it is the RACC, as defined by FDA. 21 C.F.R. § 101.12 (Table 2). As it happens, 2 tablespoons of peanut butter weighs 32 grams, and thus 2 tablespoons of peanut butter containing the minimum 90% level of peanuts would provide more than one ounce of peanuts (32 g less 10% equals 28.8 g). For the sake of consistency with the ITNC Petition, the claim for peanut butter-containing foods would apply if the food contained at least 8 grams peanut butter, which would supply a minimum of 7.2 g peanuts.

3 ATP III (2001): *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel III). National Cholesterol Education Program, National Institutes of Health.

butter, such as sterols and antioxidant vitamins may confer additional cardioprotective effects.[4] One peanut butter RACC contains about 50 mg phytosterols, more than 80% of which is beta-sitosterol.[5] In addition, consumption of diets including peanuts and peanut butter have been shown to reduce the risk of diabetes and facilitate satiety and weight loss, two independent risk factors for CHD identified in the ATP III report.

1. Epidemiological Studies Consistently Show Reduced Risk of CHD

Several observational epidemiological studies have suggested that diets that include regular nut consumption significantly reduce the risk of CHD. Most of these studies did not generally differentiate between types of nuts eaten. Because two-thirds of all nuts that are consumed in the U.S. are peanuts, or peanut butter, the conclusions derived from epidemiological evaluations of diets high in nuts would refer primarily to the impact of peanuts and peanut butter. Over the past two decades several studies have shown that a person that consumes peanuts regularly has a reduced relative risk of CHD morbidity and mortality ranging from 50% to 60% of the risk experienced by persons not consuming nuts.[6]

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4 *See* comparative nutrient content tables (Exhibit D).

5 Awad, A.B., et al., *Peanuts as a Source of B-sitosterol, A Steroid with Anti-Cancer Properties,* NUTR. CANCER 36(2), pp. 238-41 (2000).

6 *See, e.g.,* Albert, C.M., et al., *Nut Consumption and Decreased Risk of Sudden Cardiac Death in the Physician's Health Study,* ARCH. INTER. MED., Vol. 162, pp. 1382-87 (2002); Ellsworth, J.L., et al., NUTR. METAB. CARDIO. DIS., Vol. 11(6), pp. 362-71 (2001); Hu, F.B., et al., *Frequent Nut Consumption and Risk of Coronary Heart Disease in Women: Prospective Cohort Study,* BRIT. MED. J., Vol. 317, pp. 1341-45 (1998).

Six of seven epidemiological studies evaluated the impact of "nuts" in the diet of specific populations (nurses, doctors, etc.).[7] The applicability of the conclusions of these studies are by inference derived primarily from peanuts and peanut butter because of their relative predominance in the diet compared with other nuts, as set forth in evidence (cited above) that peanuts comprise two thirds of the nuts consumed and that approximately one-half of total dietary peanuts are consumed as peanut butter.

2. Intervention Studies Employing Peanuts and/or Peanut Butter

Several studies (19 to date) have demonstrated that plasma lipid profiles are improved after the inclusion of a variety of nuts in the diet. Two of the studies cited in the ITNC Petition specifically included peanuts, peanut butter, or peanut oil in experimental diets. Neither study reported quantities of peanut food in the diet, but rather were designed to assure moderate amounts of monounsaturated fats (MUFA) relative to dietary saturated fat (SF). For example, in the Kris-Etherton, et al. (1999) study,[8] MUFA comprised 17% or 18% of total energy and SF comprised 7% or 8% of total energy in the diet. In the O'Byrne, et al. (1997) study,[9] MUFA comprised 14% and SF comprised 5% of the peanut containing diet. Thus, each of these intervention studies incorporated a ratio of MUFA/SF of at least 2.5, whereas the average

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7 The Lavedrine study did not evaluate the general dietary consumption of "nuts." *See* Lavedrine, F., et. al., *Blood Cholesterol and Walnut Consumption: A Cross-Sectional Survey in France,* PREVENT. MED., Vol. 28(4), pp. 333-39 (1999).

8 Kris-Etherton, P.M., et al., High-Monounsaturated Fatty Acid Diets Lower Both Plasma Cholesterol and Triacylglycerol Concentrations, AM. J. CLIN. NUTR., Vol. 70, pp. 1009-15 (1999).

9 O'Byrne, D.J., et al., *Low Fat-Monounsaturated Rich Diets Containing High-Oleic Peanuts Improve Serum Lipoprotein Profiles,* LIPIDS, Vol. 32, pp. 68795 (1997).

American diet defined in the Kris-Etherton, et al., paper indicated that most Americans consume a diet with a MUFA/SF ratio of less than one.

Low-fat, high carbohydrate diets, such as the American Heart Association (AHA) Step-I and Step-II cholesterol lowering diets, increase plasma triacylglycerol (triglyceride) levels and decrease HDL-cholesterol levels. Recently, the third report of the Adult Treatment Panel (ATP III) of the National Cholesterol Education Program (NCEP) indicated that an elevated plasma triglyceride level has been determined to be an independent risk factor for CHD. Thus, the effect of the AHA low-fat diets on triglycerides and HDL-C work in opposition to the goals of ATP III's Therapeutic Lifestyle Change diet. Consequently, efforts have been made to search for diets that reduce saturated fat intakes while maintaining lower carbohydrate intakes. Recent approaches to therapeutic diets have focused on increased levels of MUFA and adequate amounts of PUFA. Peanuts and peanut butter are natural sources of MUFA and PUFA that result in lower plasma triglyceride concentrations in addition to lower total cholesterol and LDL-cholesterol levels.

a. Kris-Etherton, P.M., et al. (1999). Am. J. Clin. Nutr., Vol. 70, pages 1009-1015. High-Monounsaturated Fatty Acid Diets Lower Both Plasma Cholesterol and Triacylglycerol Concentrations.

In this study several plasma lipid and lipoprotein measures were assessed for persons consuming one of 5 diets:

Diet	Total Fat (TF)	Saturated Fat (SF)	Monounsaturated Fat (MUFA)
Average American (AAD)	34%	16%	11%
AHA Step II	25%	7%	12%
Olive Oil Diet	34%	7%	21%
Peanut Oil Diet	34%	7%	17%
Peanuts-Peanut Butter Diet	36%	8%	18%

The study employed a well-controlled design that incorporated randomization of 22 subjects and double-blinding with a 5-period crossover wherein all subjects consumed each of the five diets for 24 days. All subjects were healthy adults with normal plasma lipid profiles. Each subject consumed all five diets. Plasma lipid and lipoprotein measures were total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, apolipoprotein A, apolipoprotein B, lipoprotein(a).

The high MUFA diets, including the peanut/peanut butter diet, lowered total cholesterol by 10% and LDL cholesterol by 14% relative to the average American diet. The peanut-peanut butter diet used equal amounts of both peanuts and peanut butter and resulted in an 11% lower total cholesterol, 14% lower LDL cholesterol, a 13% lower triglyceride level, and an unchanged HDL cholesterol level, relative to the average American diet. A similar response was obtained with the AHA Step II diet, except that triglyceride concentrations were 11% higher and the HDL cholesterol was 4% lower , relative to the average American diet. None of the modified diets lowered HDL cholesterol significantly relative to the average American diet. The results of this study compare well with the results of the meta-analysis provided in the ITNC Petition (at pp. 90-95). The meta-analysis showed an average decrease of total cholesterol of 3.2% and of LDL cholesterol of 5.5%. Kris-Etherton, et al., found a decrease of total cholesterol of 11% and of LDL cholesterol of 14% for the diet in which peanuts and peanut butter were the sources of MUFA, suggesting an important role for both peanuts and peanut butter in a heart-healthy diet.

High MUFA, cholesterol-lowering diets provided an overall better plasma lipid-lipoprotein profile than low-fat high-carbohydrate diets previously recommended for lowering the risk of CHD. Both peanut-peanut butter and peanut oil-supplemented diets provided better plasma lipid profiles than the AHA Step II diet. Therefore, the data show that a diet that includes peanuts and peanut butter, even though relatively high in total fat, was superior to the low fat AHA Step II diet.

Although the paper as published does not quantify the amount of peanut butter and peanuts consumed by the study subjects, we have been advised via personal communication with the study author that the amounts were 42 grams and 39 grams for peanuts and peanut butter respectively. However, the meta-analysis performed by Dr. Victor Fulgoni and included in the ITNC Petition suggests that significant benefits will also be achieved with a daily consumption of 1 oz./2 Tbsp. Moreover, as discussed below, scientifically-established predictive calculations demonstrate that total cholesterol will be significantly lower for diets containing 1 oz. peanuts, 2 Tbsp. peanut butter, or 1 oz. mixed nuts, when they are substituted for small servings of ground beef or cheddar cheese in a 2,000 calorie diet.

b. O'Byrne, D.J., et al. (1997). Lipids, Vol. 32, pages 687-695. Low-Fat Monounsaturated Rich Diets Containing High-Oleic Peanuts Improve Serum Lipoprotein Profiles.

As noted above, diets high in MUFA and PUFA and low in saturated fat have resulted in reductions in serum cholesterol and LDL cholesterol concentrations without adversely affecting HDL cholesterol, apoprotein A1, or triglycerides. Peanuts, peanut butter and tree nuts are natural sources of MUFA and PUFA that could result in lower plasma triglyceride concentrations while contributing to lower total cholesterol and LDL cholesterol levels. In addition, other constituents in peanut butter, peanuts and tree nuts may be at work such as vitamin E, magnesium, fiber, and others. (See comparative nutrient data in Exhibit D.) A high-oleic acid peanut cultivar developed at the University of Florida in which 76-80% of the lipid content of the peanut is MUFA was used in this study. [10]

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[10] Peanuts generally contain approximately 50% of total fat as MUFA.

The objective of the O'Byrne study was to determine if a low fat diet rich in MUFA from peanuts would result in an improved serum lipid and lipoprotein profile in "free-living" postmenopausal hypercholesterolemic women. The study design incorporated a six-month diet intervention using free-living hypercholesterolemic postmenopausal women who were consuming a typical American diet containing 34% total total fat and 11% saturated fat, who were provided in the experiment with a low-fat monounsaturated rich (LFMR) diet (26%TF, 14% MUFA, 5% SF). The plasma lipid profiles of the subjects consuming the LFMR diet were compared to a cohort of hypercholesterolemic postmenopausal women already consuming a low-fat (LF) diet (20-30% TF; 7% MUFA, <10% saturated fat, <300 mg cholesterol). After six months 12 of 20 women who started the LFMR diet and 13 of 16 women consuming the LF diet had completed the experimental dietary regimens. Plasma lipid and lipoprotein measures were total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, apolipoprotein A, apolipoprotein B, lipoprotein(a).

Total cholesterol decreased 10% (264 to 238 mg/dL) and LDL cholesterol decreased 12% (182 to 161 mg/dL) in the LFMR group compared to the LF group. Serum triglycerides and apoprotein A1 did not change in the LFMR group. A moderate decrease in HDL cholesterol, HDL3 cholesterol, and apolipoprotein B occurred in both groups, but only the LFMR group showed a trend toward beneficial changes in the LDL cholesterol/HDL cholesterol ratio and apoprotein (A1/B) ratio.

The high-MUFA peanut-containing diet provided an overall better plasma lipid-lipoprotein profile than low-fat high-carbohydrate diets previously recommended for lowering the risk of CHD.

3. Peanuts and Peanut Butter Reduce the Risk of Diabetes and Facilitate Weight Loss and Weight Maintenance

Below, we discuss studies relevant to two additional risk factors for CHD identified in ATP III: type 2 (or late onset) diabetes and obesity. The data suggest that these two risk factors for CHD may be controlled by the inclusion of peanuts and peanut butter in the diet.

Evaluation of the diets of greater than 80,000 women participating in the Nurses Health Study indicated that persons frequently consuming peanuts and peanut butter had a lower relative risk of type 2 diabetes. For example, the study found that consuming a half serving (one tablespoon) of peanut butter or a full serving of peanuts or other nuts (an ounce), five or more times a week is associated with a 21%-27% reduced risk of developing type 2 diabetes, respectively. The authors of the study recommended replacing refined grain products and processed meats with nuts and peanut butter.[11]

Several studies have demonstrated that the frequent consumption of nuts facilitates satiety and weight loss and maintenance. Kirkmeyer and Mattes (2000) found that following consumption of peanuts and peanut butter, hunger ratings were significantly lower than after the consumption of low-energy foods.[12] Alper and Mattes (2002) found similar effects of peanuts when peanuts replaced an equal amount of other fats in the diet of healthy adult subjects. The authors concluded that despite being energy dense, peanuts have a high satiety value and

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11 Jiang, R., Manson, J.E., Stampfer, M.J., Liu, S., Willett, W.C., Hu, F.B., *Nut and Peanut Butter Consumption and Risk of Type 2 Diabetes in Women*, J. AM. MED. ASSOC., Vol. 288, pp. 2554-60 (2002).

12 Kirkmeyer, S.V. and Mattes, R.D., *Effects of Food Attributes on Hunger and Food Intake,* INT. J. OBESITY, Vol. 24, pp. 1167-75 (2000).

frequent ingestion evokes strong dietary compensation and little change in energy balance. [13] Other studies have supported these observations. [14]

In a free-living study of 101 overweight men and women conducted by the Harvard School of Public Health, half followed a low fat diet (20% calories from fat) and half followed a moderate fat diet (35% calories from fat, mostly monounsaturated). Analysis from food intake records showed the recommended foods subjects chose to include in their daily diets most frequently were peanut butter (0.7 servings), peanuts (0.5 servings), tree nuts (0.4 servings) and vegetable oils.[15] All participants were given guidelines to eat a diet of approximately 1,200-1,500 calories that was low in saturated fat and cholesterol.

Only one in five study participants were able to remain on the low fat diet while more than half adhered to the moderate fat diet. Both groups lost an average of 11 pounds in the first year. However the moderate fat group kept a significant amount of weight off for 18 months (-4.1 kg), whereas the low fat group did not (- 2.9 kg). The moderate fat group was followed for an additional year (2 1/2 years total) and still kept a significant amount of weight off (- 3.5 kg).

By helping to control these important risk factors for CHD, it appears that peanuts and peanut butter may have not only the direct effect on blood lipids that provide therapeutic protection against CHD, but also may help reduce risk by helping to control indirectly the risk of

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13 Alper, C.M. and Mattes, R.D., *Effects of Chronic Peanut Consumption on Energy Balance and Hedonics*, INT. J. OBESITY, Vol. 26, pp. 1129-37 (2002).

14 *See* Fraser, G.E., et al., *Effect on Body Weight of a Free 76 Kilojoule (320 Calorie) Daily Supplement of Almonds for Six Months,* J. AM. COLL. NUTR., Vol. 21(3), pp. 275-83 (2002).

15 McManus, K., et al, *A Randomized Controlled Trial of a Moderate-Fat, Low-Energy Diet Compared with a Low-Fat, Low-Energy Diet for Weight Loss in Overweight Adults*, INT. J. OBESITY, Vol. 25, p. 1503 (2001).

type 2 diabetes and weight gain. These data clearly corroborate a claim for consumption of peanuts and peanut butter and the reduction of CHD risk.

B. Data Demonstrating Cardioprotective Effect of Peanuts are Equally Applicable to Peanut Butter

Peanut butter is compositionally equivalent to peanuts and compares very favorably in many respects to the tree nuts.[16] As a legume, peanuts are higher in protein than any of the tree nuts.

Peanut butter must contain a minimum of 90% peanuts. The RACC of peanut butter (2 Tbsp.) will therefore supply at least one ounce of peanuts, along with the cardioprotective effects identified above and in the ITNC Petition. In addition, the Kris-Etherton study cited above, as well as the studies focusing on type 2 diabetes and satiety, specifically included peanut butter, with beneficial results, providing direct evidence of peanut butter's ability to reduce CHD risk.

Moreover, the beneficial serum lipid effects of peanut butter are virtually identical to those found empirically for peanuts and tree nuts based on well-recognized predictive equations. The predictive equation of Hegsted, et. al. (1993)[17] was used to estimate the expected change in total cholesterol when a serving of peanuts (1 oz.) or peanut butter (2 tbsp.) or mixed nuts (1 oz.) was substituted for a serving of ground beef (3 oz.), or cheese (1.5 oz.). Table 1 presents the calorie, fatty acid, and cholesterol profile of the foods used in the blood cholesterol predictive equation.

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16 *See* data chart in Appendix D.

17 Hegsted DM, et al. *Dietary Fat and Serum Lipids: An Evaluation of the Experimental Data,* AM. J. CLIN. NUTR., Vol. 57, pp. 875-83 (1993).

Table 1

Nutrients in Foods Used to Predict Total Cholesterol

Food	Amount	Energy Kcal	Saturated Fat, g	Monounsat. Fat, g	Polyunsat. Fat, g	Cholesterol mg
Ground Beef	3 oz.	197	4.7	5.2	0.3	73
Cheddar Cheese	1.5 oz.	171	9.0	4.1	0.45	45
Peanuts	1 oz.	164	1.8	7.2	4.2	0
Peanut Butter	2 Tbsp.	190	3.3	7.8	4.4	0
Mixed Nuts	1 oz.	174	2.6	9.4	3.2	0

The predicted change in blood total cholesterol shown below was calculated on the basis of a 2,000 calorie diet that has 11.3% of calories from saturated fat and 6.4% of calories from polyunsaturated fat; the average intake of saturated fat and polyunsaturated fat consumed by respondents of the CSFII (1994-1996) survey. [18]

Table 2 shows the change in total cholesterol after substituting one serving of peanuts, peanut butter or mixed nuts for one serving of ground beef or cheddar cheese. One serving of peanuts or peanut butter results in a significant blood cholesterol lowering effect. Peanuts elicit the greatest cholesterol lowering effect because of their fatty acid profile (i.e., lowest in saturated fat, and higher in polyunsaturated fat than mixed nuts, and slightly higher than peanut butter). Although peanut butter is higher in saturated fat compared with mixed nuts, it also is higher in polyunsaturated fat which accounts for the same blood cholesterol response as does mixed nuts.

[18] Hegsted equation: ΔTC in mg/dL = $2.10\Delta S - 1.16\Delta P + 0.067\Delta C$, where ΔS is the difference in saturated fat, ΔP is the difference in polyunsaturated fat, and ΔC is the difference in energy between the two food items.

Table 2

Predicted Total Cholesterol Changes From Food Substitutions (mg/dL)

Food	Amount	Peanuts 1 oz.	Peanut Butter 2 Tbsp.	Mixed Nuts 1 oz.
Ground Beef	3 oz.	-7.21	-5.87	-5.94
Cheddar Cheese	1.5 oz.	-10.28	-8.96	-9.01

As discussed below, at page 22, the higher saturated fat levels for peanut butter as compared with peanuts (Table 1) are due to the fact that peanut butter producers typically add 1-2% hydrogenated vegetable oil to stabilize the product and prevent separation of oil and solids. Yet 55-65% of this "added" saturated fat is stearic acid, which has been shown to be cholesterol neutral in contrast to the other saturated fats.[19] The Table 2 calculations assume, however, that all of the saturated fat will have an adverse impact on serum cholesterol. If one were to reduce the increase in saturated fat levels in peanut butter as contrasted with peanuts by one-half in order to reflect the stearic acid component, the blood cholesterol lowering response is even greater than as shown in Table 2 and is greater than that achieved by mixed nuts.

Peanut butter contains beneficial nutrients beyond mono and polyunsaturated fat. A phytosterol, beta-sitosterol (β-SIT), previously been shown to inhibit cancer growth, has been identified in peanuts and peanut products.[20] β-SIT may offer protection from colon, prostate and breast cancer, all of which tend to occur at higher rates in Americans than in other populations. Researchers at the State University of New York at Buffalo examined the total phytosterol (PS)

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19 The Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences, concluded in a report last year that "[i]n general, stearic acid has been shown to have a neutral effect on total and LDL cholesterol [blood] concentrations." Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, and Amino Acids 2002, p. 383.

20 *See* Awad, *supra* note 5.

content (β-SIT, campesterol and stigmasterol) of peanuts, peanut butter, peanut flour and peanut oil. They found snack peanuts contain 65 mg β-SIT /100 gm and commercial, creamy peanut butter contains 135 mg β-SIT /100 gm. [21]

Peanut butter and peanut also contain resveratrol, the phytochemical found in red wine and grape skins that has been associated with a reduced risk of cardiovascular disease and some cancers. Research at USDA's Agricultural Research Service identified resveratrol in samples of peanuts. According to this analysis, peanuts contain 0.02 – 1.79 ug resveratrol/gram, compared to 0.6 – 8.0 ug/ml in red wine. [22]

Resveratrol works as an antioxidant to counteract the effects of oxidative stress by suppressing harmful free radicals and thereby protecting cell membranes. Research also shows that resveratrol has other positive effects (aside from its antioxidant characteristics) on cell adhesion, or sticking to artery walls. Resveratrol was shown to have a positive effect on cell adhesion molecules, thereby decreasing the risk of clogged arteries. [23]

Proanthocyanidins, a class of polyphenolic compounds, are found in peanuts and in several other plant species. This class of compounds is gaining attention due to the rapidly growing body if evidence that suggests that they offer a wide range of health benefits. For example, polyphenols in grapes and red wine have been associated with potential cardiovascular benefits and tea catechins have been associated with potent antioxidant activity. [24]

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[21] *Id.*

[22] Sanders, T.H., et al., *Occurrence of Resveratrol in Edible Peanuts,* J. AG. FOOD CHEM., Vol. 48(4), pp. 1243-46 (2000).

[23] Ferrero, M.E., et al., *Activity In Vitro of Resveratrol on Granulocyte and Monocyte Adhesion to Endothelium,* AM. J. CLIN. NUTR., Vol. 68(6), pp. 1208-15 (1998).

[24] Schmitz, H., et al., *High-Performance Liquid Chromatography/mass Spectrometry Analysis of Proanthocyanidins in Foods and Beverages*, J. AG. FOOD CHEM., Vol. 47(9), pp. 3693-3701 (1999).

Peanuts and peanut butter contain the most plant protein of any other "nut" and have the highest arginine content. Arginine is a precursor to nitric oxide, an endothelium derived relaxing factor. Nitric oxide (NO) is a potent vasodilator and can inhibit platlet adhesion and aggregation. It has been proposed that the anti-atherogenic effect of nuts might be partly related to the arginine-NO pathway. [25]

Peanuts are a good source of folic acid and other B vitamins. Peanuts and peanut butter are particularly high in niacin. Adequate consumption of folic acid is important for preventing elevated homocysteine concentrations, which have been shown to correlate with severe carotid-artery stenosis. Data from the Nurses Health Study on over 80,000 women shows that higher intakes of folate were associated with a lower risk of heart disease. [26]

Fiber can also play an important role in a heart-health diet. Peanuts and peanut butter both supply about 2 grams of fiber per serving. One study suggests that a 10g/day increase in total fiber intake was associated with a 19% decrease in CHD risk. [27]

Peanut butter is a good source of magnesium, which is important in maintaining the proper balance of calcium to potassium. In addition, low magnesium can contribute to dysrhythmias, myocardial infarction, and possibly hypertension.[28]

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[25] Cooke, J.P., et al., *Anti-Atherogenic Effect of Nuts: Is the Answer NO?*, ARCH. INT. MED., Vol. 153, pp. 898-99 (1993).

[26] Kris-Etherton, P.M., et al., *Nuts and Their Bioactive Constituents: Effects on Serum Lipids and Other Factors that Affect Disease Risk,* AM. J. CLIN. NUTR., Vol. 70(suppl), pp. 504S-511S (1999); Rimm, E., et al., *Folate and Vitamin B6 from Diet and Supplements in Relation to Risk of Coronary Heart Disease Among Women*, J. AM. MED. ASSOC., Vol. 279, pp. 359-64 (1998).

[27] Wolk, A., et al., *Long-Term Intake of Dietary Fiber and Decreased Risk of Coronary Heart Disease Among Women*, J. AM. MED. ASSOC., Vol. 281(21). pp. 1997-2004 (1999).

[28] *See* Kris-Etherton, et al., *supra* note 26.

Peanut butter and peanuts also contain copper, a nutrient not commonly found in food, that plays a key role in heart health. Diets low in copper have been associated with adverse changes in lipids, glucose tolerance, blood pressure and electrocardiograms.[29]

Peanut butter is a good source of vitamin E. According to the National Institutes of Health, vitamin E may help delay or prevent coronary heart disease by limiting the oxidation of low-density lipoprotein (LDL), or bad, cholesterol. [30]

Observational studies, such as the US Health Professionals' Follow-up Study, have found an association between higher intakes of vitamin E and lower risks of heart disease. The Iowa Women's Health Study also suggested a protective effect of vitamin E on death from stroke. In this study, the beneficial effects were seen for vitamin E-rich foods, but not for supplemental vitamin E or other antioxidant vitamins. [31]

C. The Rationale for the 50 g Disqualifier Should Not Apply to Peanut Butter

The ITNC Petition convincingly argues for a waiver of FDA's total fat disqualifying level, which is equally applicable to peanut butter. The Peanut Institute believes FDA should also waive the saturated fat disqualifying level per 50 g of peanut butter. FDA is justified in exempting peanut butter from the disqualifying level of saturated fat because the original intention of setting the disqualifying level per 50 g of food in foods with low RACCs was to prevent the claim that an undesirable nutrient such as saturated fat is not present in normally

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29 *Id.*

30 NIH Clinical Center: Facts About Dietary Supplements. May 2002. [http://ww.cc.nih.gov/ccc/supplements/vite.html#rda]

31 Kushi, L.H., et al., *Intake of Antioxidant Vitamins and Risk of Death from Stroke in Postmenopausal Women*, AM. J. CLIN. NUTR., Vol. 72, pp. 476-83 (2000); Emmert, D.H. and Kirchner, J.T., *The Role of Vitamin E in the Prevention of Heart Disease,* ARCH. FAM. MED., Vol. 8(6), pp. 537-42 (1999).

consumed servings. Peanut butter must contain a minimum of 90% peanuts according to FDA's Standard of Identity, which allows for the addition of up to 10% total seasoning and stabilizing ingredients. These ingredients include salt, sugar, and, if oil products are used as stabilizing ingredients, they must be hydrogenated or partially hydrogenated vegetable oils. 21 C.F.R. § 164.150(c). The use of hydrogenated vegetable oils (typically used at 1-2%) may account for the fact that peanut butter, on a per 50 g basis, contains slightly more than the disqualifying level of saturated fat (5 g v. 4 g).[32] However, 55 – 65% of the added saturated fat is stearic acid, a fat that has been demonstrated to have no effect on blood cholesterol levels.[33]

A large part of the Agency's argument for establishing the 50 g weight-based criteria, at least in the context of "low" nutrient content claims, and inferentially for disqualifying levels for health claims, stemmed from the Agency's concern that people might consume more than one serving per day of foods with small RACCs, and thus would actually intake a significant amount of the disqualifying nutrient contained in each product. Specifically, the Agency argued that the weight-based criteria was needed because some foods are consumed in small amounts and have small serving sizes. The Agency was concerned that such a food could be dense in a nutrient,

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[32] The hydrogenated vegetable oil added to peanut butter is generally completely hydrogenated. Analysis of peanut butter for trans fats found none at or above the limit of detection. *See*, Sanders, T., *Non-detectable Levels of trans-Fatty Acids in Peanut Butter,* J. AGRIC. FOOD CHEM., Vol. 49, pp. 2349-51 (2001).

[33] Grundy, S.M., Ch.75, Nutrition and Diet in the Management of Hyperlipidemia and Atherosclerosis in Modern Nutrition in Health and Disease, 9 Ed. Shils ME, Olson JA, Shike M, Ross AC Editors Lippincott, Williams & Wilkins pp. 1199-1216 (1999); Yu, S., Derr, J., Etherton, T.D., and Kris-Etherton, P.M, *Plasma Cholesterol-Predictive Equations Demonstrate That Stearic Acid Is Neutral and Monounsaturated Fatty Acids Are Hypocholesterolemic,* AM. J. CLIN. NUTR., 61, 1129-39 (1995). *See also* Food and Nutrition Board, *supra* note 19.

e.g., fat, but still qualify for a health claim because the serving size of the food was so small that there was not a sufficient amount of the nutrient present to disqualify the food. *See* 58 Fed. Reg. 2478, 2496 (Jan. 6, 1993). To prevent these foods from bearing health claims, FDA developed the weight-based criteria to address foods with small serving sizes that might be consumed more than once per day. *Id.* FDA believed that foods with RACCs higher than 30 g or 2 tablespoons were of a size sufficient to prevent nutrient-dense foods from bearing health claims.

However, USDA's Continuing Survey of Food Intakes by Individuals (CSFII) data indicates that the one day average intake of peanut butter is 27 g per day, while the two day average is 13 g per day. The long-term average intake of peanut butter can be estimated using the National Health and Nutrition Examination Survey (NHANES) which shows that the average consumer of peanuts, peanut butter, or other nuts consumes such products an average of 8 times per month.[34] If the serving size per eating occasion is taken as the amount of peanut butter consumed on one day, 27 g, then the average intake over 30 days is 7 g per day. Thus, the long-term average intake of peanut butter is substantially below the RACC of 2 Tbsp. or 32 g per day.

As a result, it is highly likely that even increased consumption of peanut butter will not result in average consumption rates at or above the RACC, much less the disqualifying level of 50 g per day. Because the long-term average daily consumption of peanut butter is so far below the RACC, and is estimated to be approximately one-seventh of the 50 g limiting intake, we believe FDA should exempt peanut butter from the disqualifying nutrient levels for saturated fat on a per 50 g basis.

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[34] National Health and Nutrition Examination Survey (NHANES) III, 1988-94. National Center for Health Statistics, Center for Disease Control and Prevention. CD-ROM Series 11, No. 1, Revised October 1997; Sets Version 1.22a. *See also* Food and Nutrition Board, *supra* note 19.

The saturated fat waiver is also justified for several other reasons. First, the data indicates there is no detectable trans fat in peanut butter.[35] Also, the amount of dietary saturated fat consumed from peanut butter is insignificant and would remain insignificant even if consumption of peanut butter were to markedly increase. Fifty grams of peanut butter contains 5 g of saturated fat, although as shown above, the average eater will only consume 7 g of peanut butter per day, which contains less than 1 g of saturated fat. Finally, it is reasonable to assume that peanut butter will replace other conventional protein foods high in saturated fat that do not offer the same cholesterol-lowering benefits. For example, peanut butter, most often consumed on a sandwich, will replace sandwiches made from meat and cheese. In fact, data on peanut butter consumption preferences indicate that in 2000, 87% of peanut butter eaters reported consuming peanut butter on a sandwich, while 44% reported consuming it on crackers, and 25% reported consuming it with fruits or vegetables. Thus consumers would benefit from the availability of information about the health benefits of peanut butter, and would likely choose to consume it in lieu of an alternative food that did not offer the same health benefits.

III. Conclusion

For the foregoing reasons, The Peanut Institute respectfully requests that FDA modify the nut and CHD health claim requested by ITNC to allow the claim to be made for peanut butter. The scientific data clearly demonstrate that peanut butter offers the same cardioprotective benefits as do peanuts and tree nuts.

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35 *See supra* note 32.

Respectfully submitted,

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March 7, 2003

A

Exhibit A

USDA Center for Nutrition Policy and Promotion
The Role of Nuts in a Healthy Diet

Nutrition Insights

The Role of Nuts in a Healthy Diet

INSIGHT 23 *A Publication of the USDA Center for Nutrition Policy and Promotion* December 2000

While not a staple in the American diet, nuts are consumed by many Americans. This *Nutrition Insight* examines the contribution nuts can make to a diet, consumption of nuts, characteristics of people who eat nuts, and the association of nut consumption with diet quality. Nuts are generally divided into two groups—tree nuts (almonds, pecans, etc.) and peanuts. Peanuts, technically a legume (a dried pea, bean, or lentil), are typically included in the nut group because they are used in a manner comparable to nuts and have a similar nutrient profile.

Contributions of Nuts to the Diet

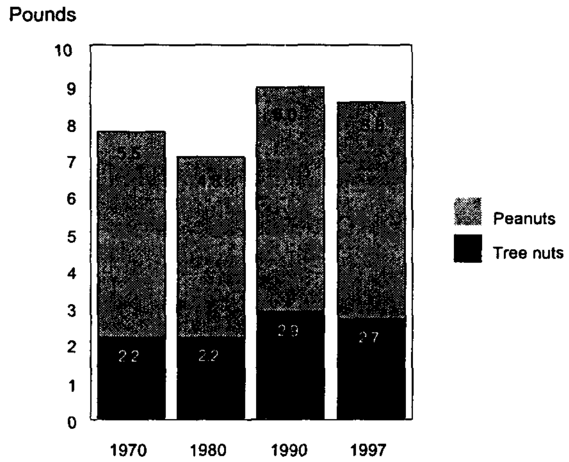
Nut consumption can make beneficial contributions to the diet but at a cost—increased calories. Recent research indicates that frequency of nut consumption may have an inverse association with the risk of heart disease for men, women, and the elderly (Sabate, 1999). Eating nuts also seems to lower serum cholesterol and favorably changes a person's lipoprotein profile (Sabate, 1993). Walnuts have specifically been studied for their effect on serum lipids and blood pressure. Results have shown that incorporating a moderate amount of walnuts into a cholesterol-lowering diet decreases serum total cholesterol levels and favorably changes the lipoprotein profile in healthy men (Sabate et al., 1993).

Growing evidence shows that nuts have bioactive constituents (like plant protein, dietary fiber, and some micronutrients) that elicit protective effects on the heart. When subjects ate test diets including nuts, the cholesterol-lowering response was greater than predicted. This suggested that constituents of nuts, other than fatty acids, have additional cholesterol-lowering effects (Kris-Etherton et al., 1999). Findings from epidemiologic studies suggest an inverse association between death from stroke and intake of the most concentrated food sources of vitamin E, such as nuts (Yochum et al., 2000). A review of the beneficial effects of vegetarian foods, including nuts, also has shown such foods lead to improved control of blood-glucose concentration, lower insulin requirements, and better weight control for diabetic patients (Segasothy et al., 1999).

Nut Consumption in the United States

Annual per capita consumption of nuts in the United States (based on food disappearance data) has ranged from 7.0 to 8.9 pounds over the 1970-97 period (see figure). Nut consumption decreased slightly between 1990 and 1997 (8.9 to 8.5 pounds). Peanuts (which include peanuts in peanut butter and candy) accounted for most of this nut consumption—68 percent of total nut consumption in 1997. Tree nuts accounted for the minority share of per capita nut consumption. In 1997, the most commonly consumed tree nuts were almonds (19 percent of per capita tree nut consumption), coconuts (18 percent), pecans (17 percent), and walnuts (17 percent). As a percentage of total annual per capita consumption of food, nuts accounted for a very small share, compared with other foods. For example, the per capita consumption of meat, poultry, and fish was 190 pounds in 1997, compared with 8.5 pounds for all nuts (Putnam et al., 1999).

Annual per capita consumption of nuts



Source: U.S. Department of Agriculture, Economic Research Service.

Nut Eaters and the Quality of Their Diet

Who in the United States eats nuts? And what is the quality of their diet? To answer these questions, we used data from the Market Research Corporation of America (MRCA) Information Services. We used information from 6,928 people for the 1992-94 period; these data were weighted to provide population estimates. MRCA collected information on people's consumption of nuts based on detailed diaries of foods eaten over a 14-day period. "Nut eaters" were defined as people who consumed any type of nut over a 14-day period, and "non-nut eaters" were defined as people who did not consume any type of nut over this same period. Forty-one percent of people were "nut eaters," and 59 percent were "non-nut eaters."

Of the five characteristics examined (gender, age, income, race, and region of residence), age and race of nut eaters and non-nut eaters were significantly different (table). Compared with non-nut eaters, a significantly higher percentage of nut eaters were younger and were White. Among nut eaters, 37 percent were under age 19, compared with 25 percent of non-nut eaters. In addition, among nut eaters, 90 percent were White, compared with 86 percent of non-nut eaters.

To answer the question of whether nut eaters have a better diet than do non-nut eaters, we used a modified version of the Healthy Eating Index (HEI). This modified version uses 9 of the original 10 HEI components. Components 1-5 measure the degree to which a person's diet conforms to serving recommendations of the Food Guide Pyramid food groups: Grains (bread, cereal, rice, and pasta), vegetables, fruits, milk (milk, yogurt, and cheese), and meat (meat, poultry, fish, dry beans, eggs, and nuts). As a percentage of total intake of food energy, component 6 measures consumption of total fat; component 7,

Characteristics of nut eaters and non-nut eaters, 1992-94

Characteristic	Nut eaters	Non-nut eaters
	Percent	
Gender		
Male	47	46
Female	53	54
Age (years)*		
< 19	37	25
19 - 51	36	51
> 51	27	24
Income		
200% of poverty or less	45	42
More than 200% of poverty	55	58
Race*		
White	90	86
Non-White	10	14
Region		
Northeast	19	20
South	25	25
Midwest	33	35
West	23	20

*Significant at .05 level, based on unweighted data.

saturated fat. Component 8 measures total cholesterol intake; component 9, sodium intake. The score for each component ranges from zero to 10, with higher component scores indicating intakes that are closer to recommendations. The MRCA data set does not provide enough information to calculate the variety of a person's diet (component 10 of the original HEI), so variety was not calculated. All total HEI scores on the modified version were adjusted to a 100-point scale. Scores greater than 80 imply a good diet; between 51 and 80, a diet that needs improvement; and less than 51, a poor diet.

For nut eaters, the mean score on the modified HEI was slightly, but significantly, higher than the score for non-nut eaters (60.8 versus 56.9). Both groups, however, had total scores that indicated their diet needed improvement. The average daily caloric intake of nut eaters also was significantly higher—about 10 percent—than that of non-nut eaters. On the individual components of the HEI, nut eaters compared with non-nut eaters had significantly higher scores for grains, fruits, milk, fat, saturated fat, and cholesterol. The higher HEI fat score—indicating nut eaters consume less fat as a percentage of total calories—may seem surprising because nuts contain fat. It appears that nut eaters consume less fat from other foods in their diet compared with non-nut eaters, or given their caloric level is higher, they consume less fat as a percentage of total energy. Non-nut eaters had significantly higher scores for vegetables and sodium than did nut eaters. The meat score for the two groups was not significantly different.

Other factors (such as age and race) may influence the modified HEI scores of nut eaters and non-nut eaters. However, even when using multivariate analytic procedures to control for all five characteristics previously examined, we found that the modified HEI score for nut eaters was significantly higher than the score for non-nut eaters.

Conclusion

Although nut consumption is low compared with other protein sources, such as meat and poultry, nuts provide many of the same nutrients to the diet and have potential health benefits. A significantly higher percentage of nut eaters than non-nut eaters were younger and were White. In addition, compared with non-nut eaters, nut eaters had a slightly better diet, albeit one that needed improvement.

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B

Exhibit B

USDA National Agricultural Statistics Services
Peanut Stocks and Processing

NASS
FACT FINDERS FOR AGRICULTURE
UNITED STATES DEPARTMENT OF AGRICULTURE
Washington, D.C.

Peanut Stocks and Processing

Released January 30, 2003, by the National Agricultural Statistics Service (NASS), Agricultural Statistics Board, U.S. Department of Agriculture. For information on "Peanut Stocks and Processing" call Mark R. Miller at (202) 720-7688, office hours 7:30 a.m. to 4:00 p.m. ET.

Peanut Stocks Down 42 Percent from Last Year

Peanut stocks in commercial storage on December 31, 2002 totaled 2.41 billion pounds of equivalent farmer stock, compared to 4.12 billion pounds last year. This total includes 1.76 billion pounds of actual farmer stock.

Shelled peanuts on hand totaled 614 million pounds of farmer stock equivalent. Roasting stock totaled 38.3 million pounds. There were no Commodity Credit Corporation uncommitted stocks on hand as of December 31, 2002.

Shelled peanut stocks totaled 462 million pounds of which 438 million pounds were edible grades and 24.0 million pounds were oil stocks. Edible grade stocks by type included 75.8 million pounds of Virginias, 338 million pounds of Runners, and 24.1 million pounds of Spanish.

December **millings** totaled 288 million pounds. Millings by type were 55.1 million pounds of Virginias, 229 million pounds of Runners, and 3.16 million pounds of Spanish.

Commercial processors utilized 110 million pounds of **shelled edible** grade peanuts during December. Utilization by type was 61.3 million pounds for all peanut butter products, 21.6 million pounds for peanut candy, and 25.9 million pounds for snack peanuts. **Crushing** for oil and cake and meal totaled 44.4 million pounds during the month.

Deliveries under the Government Domestic Feeding and Child Nutrition Programs amounted to 2.60 million pounds of peanut butter and 102,384 pounds of roasted peanuts during December.

Stocks of treated seed on hand December 31, 2002 totaled 143,000 pounds, compared with 187,000 pounds on November 30, 2002. Of the December total, 101,000 pounds were Virginias and Valencias, 29,000 pounds were Runners, and 13,000 pounds were Spanish. November stocks of treated seed included 145,000 pounds of Virginias and Valencias, 29,000 pounds of Runners, and 13,000 pounds of Spanish.

Stocks estimates refer to December 31, 2002. All other data are for the month of December.

Table 1. Stocks of Peanuts and Specified Products at Month's End, Crop of 2002-2003 [1]

Month Ending	Farmer Stock	Shelled Peanuts [2]	Roasting Stock (In Shell)	Farmer Stock Equivalent: Shelled Peanuts	Farmer Stock Equivalent: Total [3]
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	447,016	520,396	45,055	692,127	1,184,198
Sep	582,400	380,932	31,619	506,640	1,120,659
Oct	1,380,798	421,269	37,511	560,288	1,978,597
Nov	1,718,116	452,369	39,144	601,651	2,358,911
Dec	1,755,260	461,862	38,305	614,276	2,407,841
Jan 2003					
Feb					
Mar					
Apr					
May					
Jun					
Jul					
Dec 2001	3,237,636	624,973	47,310	831,214	4,116,160

[1] Excludes stocks on farms. Includes stocks owned by or held for account of peanut producers and CCC in commercial storage facilities. Farmer stock on net weight basis.
[2] Includes shelled edible grades, shelled oil stock, and shelled seed (untreated).
[3] Actual farmer stock, plus roasting stock, plus shelled peanuts X 1.33.

Table 2. Farmer Stock Peanuts, by Types, on Hand at Month's End, Crop of 2002-2003 [1]

Month Ending	Virginias	Runners	Spanish (by Areas): Virginia North Carolina	Spanish: South East	Spanish: South West	Spanish: Total	Total All Types
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	1,932	445,084	0	0	0	0	447,016
Sep	14,868	566,398	0	0	1,134	1,134	582,400
Oct	164,846	1,204,946	0	0	11,006	11,006	1,380,798
Nov	216,056	1,462,118	0	0	39,942	39,942	1,718,116
Dec	211,446	1,489,256	0	0	54,558	54,558	1,755,260
Jan 2003							
Feb							
Mar							
Apr							
May							
Jun							
Jul							
Dec 2001	433,673	2,718,487	0	0	85,476	85,476	3,237,636

[1] Excludes stocks on farms. Includes stocks owned by or held for account of peanut producers and CCC in commercial storage facilities. Farmer stock on net weight basis.

Table 3. Total Farmer Stock Peanuts on Hand at Month's End, Crop of 2002-2003 [1]

Month Ending	CCC Uncommitted Stocks	Commercial Stocks			Equivalent
		Restricted Use [2]	Other Commercial	Total	Total Farmer Stock
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	0	([3])	([3])	447,016	447,016
Sep	0	([3])	([3])	582,400	582,400
Oct	0	([3])	([3])	1,380,798	1,380,798
Nov	0	([3])	([3])	1,718,116	1,718,116
Dec	0	([3])	([3])	1,755,260	1,755,260
Jan 2003					
Feb					
Mar					
Apr					
May					
Jun					
Jul					
Dec 2001	798,174	([3])	([3])	2,439,462	3,237,636

[1] Excludes stocks on farms. Includes stocks owned by or held for account of peanut producers and CCC in commercial storage facilities. Farmer stock on net weight basis.
[2] Purchased from CCC for crushing or export.
[3] Not published to avoid disclosing individual operations.

Table 4. Shelled Peanuts and Roasting Stock (In Shell) on Hand at Month's End, Crop of 2002-2003 [1]

Month Ending	Shelled Edibles [2]				Shelled Oil Stocks [3]	Total Shelled	Roasting Stocks [4]
	Virginias	Runners	Spanish	Total			
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	110,806	357,284	37,069	505,159	15,237	520,396	45,055
Sep	78,717	262,183	23,560	364,460	16,472	380,932	31,619
Oct	75,616	289,188	32,861	397,665	23,604	421,269	37,511
Nov	77,400	318,874	34,099	430,373	21,996	452,369	39,144
Dec	75,758	337,943	24,119	437,820	24,042	461,862	38,305
Jan 2003							
Feb							
Mar							
Apr							
May							
Jun							
Jul							
Dec 2001	118,279	454,010	35,957	608,246	16,727	624,973	47,310

[1] Excludes stocks on farms. Includes stocks owned by or held for account of peanut producers and CCC in commercial storage facilities. Farmer stock on net weight basis.
[2] Shelled edible grades include blanched and shelled roasted peanuts converted to a raw basis using conversion factors of 1.08 and 1.12, respectively.
[3] Includes straight run oil stock peanuts.
[4] Cleaned and unshelled.

Table 5. Farmer Stock Peanuts Milled (Net Weight), by Months, Crop of 2002-2003 [1]

Month Ending	Virginias	Runners	Spanish (by Areas) Virginia North Carolina	South East	South West	Total	Total All Types
	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds
Aug 2002	2,604	99,108	0	0	4,188	4,188	105,900
Sep	5,002	178,948	0	0	0	0	183,950
Oct	59,810	305,396	0	0	26,294	26,294	391,500
Nov	66,770	245,744	0	0	9,416	9,416	321,930
Dec	55,120	229,358	0	0	3,164	3,164	287,642
Jan 2003							
Feb							
Mar							
Apr							
May							
Jun							
Jul							
Dec 2001	60,734	217,274	0	0	14,894	14,894	292,902
Aug 2002-Dec 2002	189,306	1,058,554	0	0	43,062	43,062	1,290,922
Aug 2001-Dec 2001	304,864	919,690	0	0	50,490	50,490	1,275,044

[1] Includes peanuts milled for seed.

Table 6. Production of Shelled and Roasting Stock (In Shell) Peanuts, by Months, Crop of 2002-2003

Month Ending	Shelled Edibles [1] Virginias	Runners	Spanish	Total	Shelled Oil Stocks [2]	Total Shelled	Roasting Stocks [3]
	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds	1,000 Pounds
Aug 2002	680	21,227	3,243	25,150	56,033	81,183	1,220
Sep	1,738	82,825	0	84,563	55,695	140,258	2,057
Oct	21,001	177,252	19,027	217,280	62,833	280,113	27,606
Nov	26,625	142,537	6,583	175,745	50,817	226,562	25,234
Dec	19,244	134,520	1,394	155,158	46,366	201,524	22,818
Jan 2003							
Feb							
Mar							
Apr							
May							
Jun							
Jul							
Dec 2001	26,743	134,789	9,103	170,635	36,859	207,494	18,184
Aug 2002-Dec 2002	69,288	558,361	30,247	657,896	271,744	929,640	78,935
Aug 2001-Dec 2001	127,048	546,441	32,742	706,231	164,074	870,305	105,127

[1] Includes peanuts milled for seed.
[2] Includes straight run oil stock peanuts.
[3] Cleaned and unshelled

Table 7. Shelled Peanuts Crushed, Production and Stocks of Peanut Oil and Cake and Meal, by Months, Crop of 2002-2003 [1]

Month Ending	Shelled Peanuts Crushed [2]	Production		Stocks (End of Period)	
		Crude Oil	Cake & Meal	Crude Oil [1]	Cake & Meal [1]
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	57,920	26,776	31,777	3,267	1,406
Sep	57,007	25,831	30,989	9,781	2,370
Oct	57,818	25,585	32,178	11,014	2,874
Nov	54,981	24,655	30,696	11,420	4,516
Dec	44,429	19,516	25,062	9,918	7,059
Jan 2003					
Feb					
Mar					
Apr					
May					
Jun					
Jul					
Dec 2001	44,209	19,180	25,801	2,208	5,696
Aug 2002-Dec 2002	272,155	122,363	150,702	–	–
Aug 2001-Dec 2001	168,849	73,900	97,069	–	–

[1] Relates to oil mills only.
[2] All crushings regardless of grade.

Table 8. Apparent Disappearance of Milled Peanut Products, by Months, Crop of 2002-2003 [1]

Month Ending	Shelled Peanuts			Roasting Stock	Crude Peanut Oil [2]	Cake & Meal [2]
	Edible Grades	Oil Stocks	Total			
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	200,841	57,444	258,285	21,314	27,381	31,663
Sep	225,262	54,460	279,722	15,493	19,317	30,025
Oct	184,075	55,701	239,776	21,714	24,352	31,674
Nov	143,037	52,425	195,462	23,601	24,249	29,054
Dec	147,711	44,320	192,031	23,657	21,018	22,519
Jan 2003						
Feb						
Mar						
Apr						
May						
Jun						
Jul						
Dec 2001	124,029	41,162	165,191	18,107	18,322	23,127
Aug 2002-Dec 2002	900,926	264,350	1,165,276	105,779	116,317	144,935
Aug 2001-Dec 2001	791,194	161,810	953,004	96,189	75,504	95,173

[1] Includes in transit, exports, and domestic use.
[2] Relates to oil mills only.

Table 9. Shelled Peanuts (Raw Basis) Used in Primary Products, and in Shell Peanuts, by Months, Crop of 2002-2003 [1]

Month Ending	Edible Grades Used In [2]					Total All Grades [6]	In Shell Peanuts [7]
	Peanut Candy [3]	Snack Peanuts [4]	Peanut Butter [5]	Other Products	Total		
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	35,039	31,998	71,668	2,546	141,251	199,171	11,226
Sep	35,229	33,385	67,889	2,986	139,489	196,496	12,114
Oct	29,194	32,384	75,734	2,525	139,837	197,655	16,375
Nov	27,677	29,505	59,689	1,554	118,425	173,406	11,590
Dec	21,625	25,904	61,338	1,285	110,152	154,581	12,637
Jan 2003							
Feb							
Mar							
Apr							
May							
Jun							
Jul							
Dec 2001	24,333	28,122	60,684	1,569	114,708	158,917	13,018
Aug 2002-Dec 2002	148,764	153,176	336,318	10,896	649,154	921,309	63,942
Aug 2001-Dec 2001	146,909	158,125	348,889	7,745	661,668	830,517	67,112

[1] Excludes peanuts milled for seed. [2] Shelled edible grades include blanched and shelled roasted peanuts converted to a raw basis using conversion factors of 1.08 and 1.12, respectively. [3] Includes peanut butter made by manufacturers for own use in candy. [4] Includes salted, unsalted, dry and honey roasted, salted and unsalted roasted. [5] Includes peanut butter made by manufacturers for own use in cookies and sandwiches, but excludes peanut butter used in candy. [6] Includes all shelled peanuts crushed regardless of grade. [7] Includes peanuts re-packaged, roasted in shell, salted in shell, and raw in shell.

Table 10. Virginias Shelled Peanuts (Raw Basis) Used in Primary Products, by Months, Crop of 2002-2003 [1]

Month Ending	Edible Grades Used In [2]				
	Peanut Candy [3]	Snack Peanuts [4]	Peanut Butter [5]	Other Products	Total
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	3,204	11,502	6,690	192	21,588
Sep	3,744	12,335	6,576	156	22,811
Oct	3,144	7,563	6,829	252	17,788
Nov	1,595	6,942	5,231	350	14,118
Dec	1,243	3,079	6,618	154	11,094
Jan 2003					
Feb					
Mar					
Apr					
May					
Jun					
Jul					
Dec 2001	1,913	7,147	8,362	235	17,657
Aug 2002-Dec 2002	12,930	41,421	31,944	1,104	87,399
Aug 2001-Dec 2001	12,101	40,286	48,255	1,425	102,067

[1] Crushings by type not available. [2] Shelled edible grades include blanched and shelled roasted peanuts converted to a raw basis using conversion factors of 1 08 and 1.12, respectively. [3] Includes peanut butter made by manufacturers for own use in candy. [4] Includes salted, unsalted, dry and honey roasted, salted and unsalted roasted [5] Includes peanut butter made by manufacturers for own use in cookies and sandwiches, but excludes peanut butter used in candy.

Table 11. Runners Shelled Peanuts (Raw Basis) Used in Primary Products, by Months, Crop of 2002-2003 [1]

Month Ending	Edible Grades Used In [2]				
	Peanut Candy [3]	Snack Peanuts [4]	Peanut Butter [5]	Other Products	Total
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	30,784	19,475	63,698	2,323	116,280
Sep	29,725	19,981	58,829	2,776	111,311
Oct	25,325	23,379	66,327	2,211	117,242
Nov	24,916	21,219	53,751	1,173	101,059
Dec	19,311	21,734	53,998	1,093	96,136
Jan 2003					
Feb					
Mar					
Apr					
May					
Jun					
Jul					
Dec 2001	21,168	19,939	51,374	1,279	93,760
Aug 2002-Dec 2002	130,061	105,788	296,603	9,576	542,028
Aug 2001-Dec 2001	126,739	110,968	296,729	6,066	540,502

[1] Crushings by type not available. [2] Shelled edible grades include blanched and shelled roasted peanuts converted to a raw basis using conversion factors of 1.08 and 1 12, respectively. [3] Includes peanut butter made by manufacturers for own use in candy. [4] Includes salted, unsalted, dry and honey roasted, salted and unsalted roasted. [5] Includes peanut butter made by manufacturers for own use in cookies and sandwiches, but excludes peanut butter used in candy.

Table 12. Spanish Shelled Peanuts (Raw Basis) Used in Primary Products, by Months, Crop of 2002-2003 [1]

Month Ending	Edible Grades Used In [2]				
	Peanut Candy [3]	Snack Peanuts [4]	Peanut Butter [5]	Other Products	Total
	1,000 Pounds	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*	*1,000 Pounds*
Aug 2002	1,051	1,021	1,280	31	3,383
Sep	1,760	1,069	2,484	54	5,367
Oct	725	1,442	2,578	62	4,807
Nov	1,166	1,344	707	31	3,248
Dec	1,071	1,091	722	38	2,922
Jan 2003					
Feb					
Mar					
Apr					
May					
Jun					
Jul					
Dec 2001	1,252	1,036	948	55	3,291
Aug 2002-Dec 2002	5,773	5,967	7,771	216	19,727
Aug 2001-Dec 2001	8,069	6,871	3,905	254	19,099

[1] Crushings by type not available. [2] Shelled edible grades include blanched and shelled roasted peanuts converted to a raw basis using conversion factors of 1.08 and 1.12, respectively. [3] Includes peanut butter made by manufacturers for own use in candy. [4] Includes salted, unsalted, dry and honey roasted, salted and unsalted roasted. [5] Includes peanut butter made by manufacturers for own use in cookies and sandwiches, but excludes peanut butter used in candy.

Table 13. Government Domestic Feeding and Child Nutrition Program, by Months, Crop of 2002-2003

Month Ending	Deliveries by Product: Peanut Butter	Roasted Peanuts	Granules	Total
	Pounds	*Pounds*	*Pounds*	*Pounds*
Aug 2002	2,513,123	69,120	0	2,582,243
Sep	3,139,682	172,800	0	3,312,482
Oct	3,861,124	33,264	0	3,894,388
Nov	4,015,203	0	0	4,015,203
Dec	2,599,843	102,384	0	2,702,227
Jan 2003				
Feb				
Mar				
Apr				
May				
Jun				
Jul				
Dec 2001	2,269,565	158,004	0	2,427,569
Aug 2002- Dec 2002	16,128,975	377,568	0	16,506,543
Aug 2001- Dec 2001	12,602,644	614,304	0	13,216,948

Source: Food and Nutrition Service.

The next "Peanut Stocks and Processing" report will be released at 3 p.m. ET on February 28, 2003.

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C

Exhibit C

Proposed Regulatory Text

PROPOSED REGULATORY TEXT

§ 101.______ Health claims: nuts and risk of coronary heart disease (CHD).

(a) *Relationship between diets that include nuts and the risk of CHD.*

(1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL) cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/1)) or above and with LDL cholesterol levels of 160 mg/dL (4.13 mmol/l) or above. Borderline high-risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/l) for total cholesterol, and from 130 to 159 mg/dL (3.36 to 4.11 mmol/l) for LDL cholesterol.

(2) Populations with moderate intakes of total fat composed predominantly of unsaturated (i.e. monounsaturated and polyunsaturated) fatty acids from nuts, certain vegetable oils, fish and other foods that include abundant amounts of fruits and vegetables tend to have a low incidence of CHD.

(3) Scientific evidence demonstrates that diets that include nuts can reduce the risk of CHD.

(b) *Significance of the relationship between diets that include nuts and the risk of CHD.*

(1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for

CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL cholesterol are major modifiable risk factors in the development of CHD.

(2) Scientific evidence establishes that including nuts in the diet helps to lower blood total and LDL cholesterol levels.

(c) *Requirements* – (1) *General.* All requirements set forth in § 101.14 shall be met, except as set forth in this paragraph.

(2) *Specific requirements* - (i) *Nature of the claim.* A health claim associating diets that include nuts with reduced risk of CHD may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that include nuts "can" or "may" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the terms "heart diseases" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "nuts" and/or one or more of the following names including common variations thereof: almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, peanuts, peanut butter, pecans, pine nuts, pistachio nuts, or walnuts;

(D) The claim does not attribute any degree of risk reduction for CHD to diets that include nuts;

(E) The claim does not imply that consumption of diets that include nuts is the only recognized means of achieving a reduced risk of CHD; and

(F) The claim specifies that the daily intake of nuts that is necessary to reduce the risk of CHD is one ounce, and the daily intake of peanut butter that is necessary to reduce the risk of CHD is two tablespoons.

(ii) *Nature of the substance - Nuts.* Tree nuts from one or more of the following species: almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, or walnuts; and peanuts.

(iii) *Nature of the food eligible to bear the claim.*

(A) The food product shall contain at least 7.1 grams of nuts or 8 grams of peanut butter as described in paragraph (c)(2)(ii) per reference amount customarily consumed (RACC), as determined by reference to § 101.12. FDA will assess whether the required amount of nuts is present for products other than those specified in paragraph (c)(2)(iii)(C) based on information identified and supplied by manufacturers, such as recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the amount of nuts in the product. Manufacturers must maintain records sufficient to substantiate the required amount of nuts for as long as the products are marketed, and must provide these records, on written request, to FDA.

(B) The food contains 20 mg or less of cholesterol per RACC and per 50 g if the RACC is 30 g or less or 2 tablespoons or less (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 10 1.9(f)(I), of all nutrients per RACC, the per 50-g criterion refers to the "as prepared" form); and

(C) The food must meet the limit for total fat in § 101.14 (a)(4), except for peanut butter and for nuts (including whole, chopped and any other physical form) that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored with a safe and suitable coating and/or flavoring that does not add a significant amount of fat (as used in this paragraph, "safe and suitable" means an ingredient that conforms to the definition in § 130.3(d), and "not... significant" means an amount of fat that may be expressed as zero in accordance with § 101.9(c)(2)) provided the label of the food bears a disclosure statement that complies with § 101.13(h); and

(D) The food must meet the limit for saturated fat in § 101.14 (a)(4), except, (1) Brazil nuts, (including whole, chopped and any other physical form) that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored with a safe and suitable coating and/or flavoring that does not add a significant amount of fat (as used in this paragraph, "safe and suitable" means an ingredient that conforms to the definition in § 130.3(d), and "not... significant" means an amount of fat that may be expressed as zero in accordance with § 101.9(c)(2)), and peanut butter, are not required to meet the limit for saturated fat provided the label of the food bears a disclosure statement that complies with § 101.13(h);and

(2) Cashew nuts and macadamia nuts (including whole, chopped and any other physical form) that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored with a safe and suitable coating and/or flavoring that does not add a significant amount of fat (as used in this paragraph, "safe and suitable" means an ingredient that conforms to the definition in § 130.3(d), and "not... significant" means an amount of fat that may be expressed as zero in accordance with § 101.9(c)(2)), and peanut butter, are not required to meet the limit for saturated per 50 g provided the label of the food bears a disclosure statement that complies with § 10 1.13(h); and

(E) The food must meet the minimum nutrient contribution requirement in § 1.14 (e)(6) except that Brazil nuts and walnuts (including whole, chopped and any other physical form) that are raw, blanched, roasted and/or, salted are not required to meet this requirement;

(F) The exemptions established by paragraphs (c)(2)(iii)(C), (D) and (E) of this section apply only to nuts and peanut butter within the scope of those paragraphs. Other foods that include nuts as an ingredient are not exempted from any provisions of§ 101.14(a)(4) and (e)(6).

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of diets that include nuts and reduced risk of heart disease includes the intermediate link of "blood cholesterol" or "blood total and LDL cholesterol."

(3) The claim may include information from paragraphs (a) and (b), which summarize the relationship between diets that include nuts and the risk of CHD and the significance of the relationship.

(4) The claim may include information from the following paragraph on the relationship between nuts and the risk of CHD: The scientific evidence establishes that diets moderate in fat, containing predominantly monounsaturated and polyunsaturated fatty acids, and low in saturated fat, are associated with reduced risk of CHD. Public health authorities have concluded that such diets are equally effective in reducing the risk of CHD as low-fat, high-carbohydrate diets that are also low in saturated fat. Recommended cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets that contain one ounce of nuts or two tablespoons peanut butter per day are associated with lower blood total and LDL cholesterol levels.

(5) The claim may state that diets that include nuts are consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated total and LDL cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total and/or LDL cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information about the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans,"

U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between diets that include nuts and reduced risk of heart disease:

(1) Diets containing one ounce of nuts <u>or two tablespoons peanut butter</u> per day can reduce your risk of heart disease.

(2) Eating a diet that includes one ounce of nuts <u>or two tablespoons peanut butter</u> daily may reduce your risk of heart disease.

D

Exhibit D

Nutrients in 100g of Peanuts, Peanut Butter, and Tree Nuts

Nutrients in 100g of Peanuts, Peanut Butter and Tree Nuts

NUTRIENT	UNITS	OIL-ROASTED PEANUTS	CREAMY PEANUT BUTTER	PEANUT BUTTER CRUNCH	ALMONDS	CASHEWS	HAZEL NUTS	MACA-DAMIAS	PECANS	PINE NUTS	BAZIL NUTS	PISTA-CHIOS	WALNUTS
CALORIES	kcal	581	593	589	578	581	646	716	715	566	656	568	654
PROTEIN [1]	g	26	25	24	21	16.8	15	8	9.2	24	14	21.3	15.2
TOTAL FAT	g	49	51	50	51	48	62.4	76	75	51	66	46	65.2
CARBOHYDRATE	g	19	19	22	20	30	17.6	13	13	14	12.8	27	14
FIBER	g	9.2	6	6.6	11.8	3.3	9.4	8	9.5	4.5	5.4	10.3	6.7
SUGARS	g	NA	NA	NA	5	5	4.9	4	4	NA	NA	7.8	2.6
CALCIUM [2]	mg	88	38	41	248	43	123	70	67	26	176	110	98
IRON	mg	1.8	1.8	1.9	4.3	6	4.38	2.65	2.47	9.2	3.4	4.2	2.9
MAGNESIUM	mg	185	159	159	275	273	173	118	121	233	225	120	158
PHOSPHORUS	mg	517	369	317	474	531	310	198	263	508	600	485	346
POTASSIUM	mg	682	669	747	728	632	755	363	392	599	600	1042	441
SODIUM	mg	433	467	486	1	308	0	265	393	4	2	405	2
ZINC	mg	6.6	2.92	2.78	3.4	5.35	2.5	1.3	4.5	4	4.59	2.3	3
COPPER	mg	1.3	0.14	0.52	1.1	2	1.75	0.57	1.2	1	1.8	1.3	1.6
MANGANESE	mg	2	0.45	1.87	2.5	1.7	5.55	3.04	3.7	4	0.8	1.3	3.4
SELENIUM [3]	µg	7.5	7.5	7.5	4.4	20	4.1	3.6	6.0	17	2960	8.0	4.6
VITAMIN C	mg	0	0	0	0	0.3	3.8	0.7	0.7	1.9	0.7	2.3	1.3
THIAMIN	mg	.23	0.8	0.13	0.24	0.36	0.34	0.7	0.47	0.8	1	0.84	0.34
RIBOFLAVIN	mg	.1	0.11	0.11	0.81	0.2	0.12	0.1	0.11	0.2	0.12	0.16	0.15
NIACIN	mg	14	13.4	13.7	3.9	1.7	2.05	2.3	1.2	3.6	1.6	1.4	1.99
PANTHOTHENIC ACID	mg	1.4	0.81	0.96	0.35	0.88	0.92	0.6	0.74	0.2	0.24	0.5	0.57
VITAMIN B6	mg	.25	0.45	0.5	0.13	0.32	0.62	0.4	0.2	0.1	0.25	1.7	0.54
FOLATE	mg	125.7	74	92	29	25	88	10	15	57	4	50	98
VITAMIN B12	mg	0	0	0	0	0	0	0	0	0	0	0	0
VITAMIN A [4]	IU	0	0	0	10	0	61	0	104	29	0	533	41
VITAMIN A [5]	µg RE	0	0	0	1	0	3	0	5	1	0	27	2
VITAMIN E	mg αT	7.4	10	9.6	26	1.5	15.4	0.57	5.2	3.5	7.6	4.3	2.9
CHOLESTEROL	mg	0	0	0	0	0	0	0	0	0	0	0	0
SATURATED FAT	g	6.8	10.3	9.6	3.8	8.5	4.5	12	7.2	7.8	16.1	5.5	6.1
MONOUNSATU-RATED FAT	g	24.4	24.3	23.6	32	25.9	46.6	59.3	41	19.1	23	24.2	8.9
POLYUNSATU-RATED FAT	g	15.6	13.8	14.2	12.2	8.5	8.5	1.5	23.6	21.3	24	13.9	47.2
LINOLEIC ACID (18:2)	g	15.6	13.7	14	12.2	8.5	8.4	1.3	22.5	20.7	23.8	13.6	38.1
LINOLENIC ACID (18:3)	g	0	0.1	0.1	0	0	0	0.2	1.03	0.6	0.06	0.3	9.1

Nutrients in 100g of Peanuts, Peanut Butter and Tree Nuts

NUTRIENT	UNITS	OIL-ROASTED PEANUTS	CREAMY PEANUT BUTTER	PEANUT BUTTER CRUNCHY	ALMONDS	CASHEWS	HAZEL NUTS	MACA-DAMIAS	PECANS	PINE NUTS	BAZIL NUTS	PISTA-CHIOS	WALNUTS
AMINO ACIDS													
TRYPTOPHAN	g	.25	0.25	.23	0.19	0.27	0.19	0.07	0.09	0.3	0.26	0.29	0.17
THREONINE	g	.90	0.86	.82	0.68	0.64	0.50	0.36	0.31	0.76	0.46	0.70	0.60
ISOLEUCINE	g	.93	0.89	.85	0.69	0.73	0.55	0.31	0.34	0.93	0.6	0.94	0.63
LEUCINE	g	1.71	1.64	1.6	1.47	1.36	1.06	0.59	0.60	1.73	1.19	1.62	1.17
LYSINE	g	.95	0.91	0.86	0.60	0.86	0.42	0.02	0.29	0.9	0.54	1.20	0.42
METHIONINE	g	.32	0.31	0.3	0.19	0.33	0.22	0.02	0.18	0.43	1.0	0.35	0.24
CYSTINE	g	.34	0.32	0.31	0.28	0.36	0.28	0	0.15	0.43	0.35	0.37	0.21
PHENYL-ALANINE	g	1.37	1.31	1.25	1.15	0.88	0.66	0.65	0.43	0.92	0.75	1.10	0.71
TYROSINE	g	1.07	1.03	0.98	0.53	0.47	0.36	0.50	0.22	0.88	0.46	0.43	0.41
VALINE	g	1.11	1.06	1.01	0.80	1.01	0.70	0.36	0.41	1.2	0.91	1.29	0.75
ARGININE	g	3.15	3.02	2.9	2.47	1.96	2.22	1.38	1.18	4.7	2.39	2.11	2.28
HISTIDINE	g	.67	0.64	0.61	0.59	0.42	0.43	0.19	0.26	0.58	0.40	0.53	0.39
ALANINE	g	1.05	1.00	0.96	1.00	0.77	0.73	0.38	0.40	1.2	0.57	0.96	0.70
ASPARTIC ACID	g	3.21	3.08	2.9	2.73	1.66	1.68	1.08	0.93	2.2	1.36	1.89	1.83
GLUTAMIC ACID	g	5.51	5.27	5.02	5.17	4.17	3.73	2.23	1.83	4.1	3.15	3.97	2.82
GLYCINE	g	1.63	1.52	1.45	1.47	0.87	0.73	0.45	0.45	1.2	0.66	0.99	0.82
PROLINE	g	1.16	1.11	1.06	0.97	0.75	0.56	0.46	0.36	1.3	0.76	0.84	0.71
SERINE	g	1.30	1.24	1.18	1.00	1.0	0.74	0.41	0.47	1.0	0.75	1.28	0.93

Notes: 1. g=gram 2. mg=milligram 3. mcg=microgram 4. IU=International Units 5. RE=Retinol Equivalents

All nuts are salted. Data from the USDA National Nutrient Database for Standard Reference, Release 15 (August 2002).
[http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl]