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Memorandum of Meeting

Date: May 5, 2003
Place: Harvey W. Wiley Federal Building, College Park, MD
Room 4C075
Subject: Health Claim Petition- Nuts and Coronary Heart Disease
(Docket No. 02P-0505)

Participants:

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Nutritional Products, Labeling and Dietary Supplements

Christine Taylor, Ph.D., Director (HFS-800)

Joanne Lupton, Ph.D., Visiting Scientist (HFS-800)

Kathleen Ellwood, Ph.D., Director, Division of Nutrition Labeling and Programs
(HFS-830)

Nancy Crane, M.P.H, R.D., Expert Regulatory Review Scientist, Division of
Nutrition Labeling and Programs (HFS-830)

The Peanut Institute

John Powell, President, The Peanut Institute

Patricia Kearney, Nutritionist and Program Director, The Peanut Institute

John Eldred, Esq., Keller and Heckman, L.L.P.

Sarah Key, Esq., Keller and Heckman L.L.P.

Evans Plowden, Jr., Esq., Watson, Spence, Lowe and Chambless, L.L.P.

The meeting was held at the request of representatives of The Peanut Institute (PI) to discuss their submission of comments to FDA regarding a petition submitted by the International Tree Nut Council Nutrition Research and Education Foundation (INCNREF) (Docket No. 02P-0505). The INCNREF petition requested that FDA authorize a health claim about the relationship between the consumption of nuts and the reduction of risk of coronary heart disease. Among other things, the comments submitted by PI requested FDA to modify the conditions under which any health claim that FDA might approve in response to the INCNREF petition to permit the claim to be made for peanut butter. At this meeting, PI supplied and discussed additional information to support their request.

/s/

Nancy T. Crane, M.P.H., R.D.

cc: FDA meeting participants

02P-0505

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Predicted Total Blood Cholesterol Responses (mg/dL) by Substituting Peanuts, Peanut Butter, Mixed Nuts and Macadamia Nuts for Ground Beef or Cheddar Cheese in a typical American Diet

DIET:

Typical American Diet	
Energy, kcal	2009
Fat, g	75
SF, g	25.1 (11% en)
18:0, g	6.5
MUFA, g	28.6
PUFA, g	14.2 (6.4% en)
Cholesterol, mg	257

DATA SOURCE: CSFII (1994-1996)

EQUATIONS USED: Keys (1965): $\Delta TC = 1.2 (2 \Delta S' - \Delta P) + 1.5 \Delta Z$
 (where S' = saturated fatty acids other than stearic acid)

Hegsted #1: $\Delta TC = 2.10 \Delta S - 1.16 \Delta P + 0.067 \Delta C$

RESULTS: Substitute for Ground Beef, 85%lean, 15% fat, patty cooked, pan-broiled (3 oz)

Food	Keys Total-C mg/dL	Hegsted #1 Total-C mg/dL
Peanuts (1 oz)	-6.13	-7.21
Peanut Butter (2 Tbsp)	-5.77	-5.87
Mixed Nuts (1 oz)	-5.42	-5.94
Macadamia Nuts (1 oz)	-3.64	-3.71

Substitute for Cheddar Cheese (1.5 oz):

Food	Keys Total-C mg/dL	Hegsted #1 Total-C mg/dL
Peanuts (1 oz)	-8.15	-10.28
Peanut Butter (2 Tbsp)	-7.79	-8.96
Mixed Nuts (1 oz)	-7.44	-9.01
Macadamia Nuts (1 oz)	-5.93	-8.3

SUMMARY:

The Keys equation takes into account all saturated fats, but adjusts for the neutral effect stearic acid has on blood cholesterol levels. Commercial peanut butter uses approximately 1-2% stabilizer, approximately 60% of which is stearic acid. Thus, according to the more sensitive Keys analysis, peanut butter shows a slightly greater cholesterol lowering effect compared to mixed nuts.



**Observed Results in a Controlled Clinical Study vs.
Predicted Result Comparisons**

DIET:

Clinical Test Diet with Peanuts/Peanut Butter ¹	
Energy, kcal	2034
Fat, g	80.4
SF, g	15.3
18:0, g	3.3
MUFA, g	38.9
PUFA, g	20.8
Cholesterol mg	206

DATA SOURCE: ¹Kris-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)

EQUATIONS USED: Keys (1965): $\Delta TC = 1.2 (2 \Delta S' - \Delta P) + 1.5 \Delta Z$
(where S' = saturated fatty acids other than stearic acid)

Hegsted #1: $\Delta TC = 2.10 \Delta S - 1.16 \Delta P + 0.067 \Delta C$

RESULTS:

During the controlled feeding study, the effect of the peanut/peanut butter diet compared to the control average American diet was:

Total cholesterol **-23mg/dL**
LDL cholesterol **-19mg/dL**

Prediction equations comparing the expected cholesterol lowering effects of the peanut/peanut butter diet compared to the average American diet from the controlled feeding study and then looking at the expected cholesterol lowering if the peanut/peanut butter diet had only peanuts, only peanut butter or only mixed nuts:

Average American Diet vs.	Keys Total-C mg/dL	Hegsted #1 Total-C mg/dL	Hegsted #1 LDL-C mg/dL
P/PB	-24.88	-35.41	-26.24
P only	-24.61	-37.01	-27.50
PB only	-23.10	-33.62	-24.83
Mix nuts only	-22.29	-33.66	-25.05

SUMMARY: The predicted cholesterol lowering with the Keys equation is similar to the actual results of a well-controlled clinical study. In addition, cholesterol lowering with a peanut/peanut butter diet, peanut only diet, peanut butter only diet or mixed nuts diet, is similar according to each of the Keys and Hegsted equations.

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Nut Consumption in the U.S.

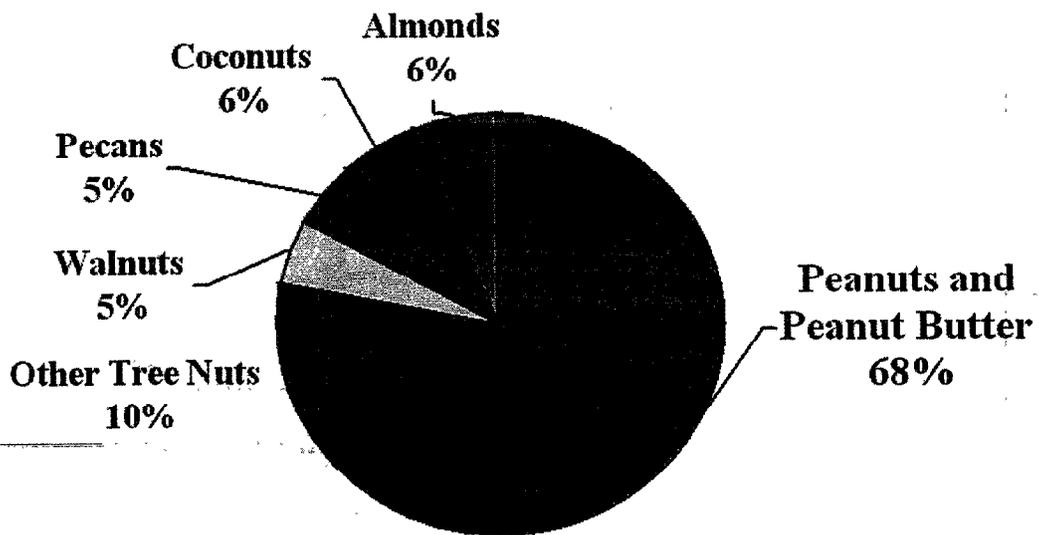


Figure 2

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Annual Per Capita Consumption of Peanut and Tree Nut Products

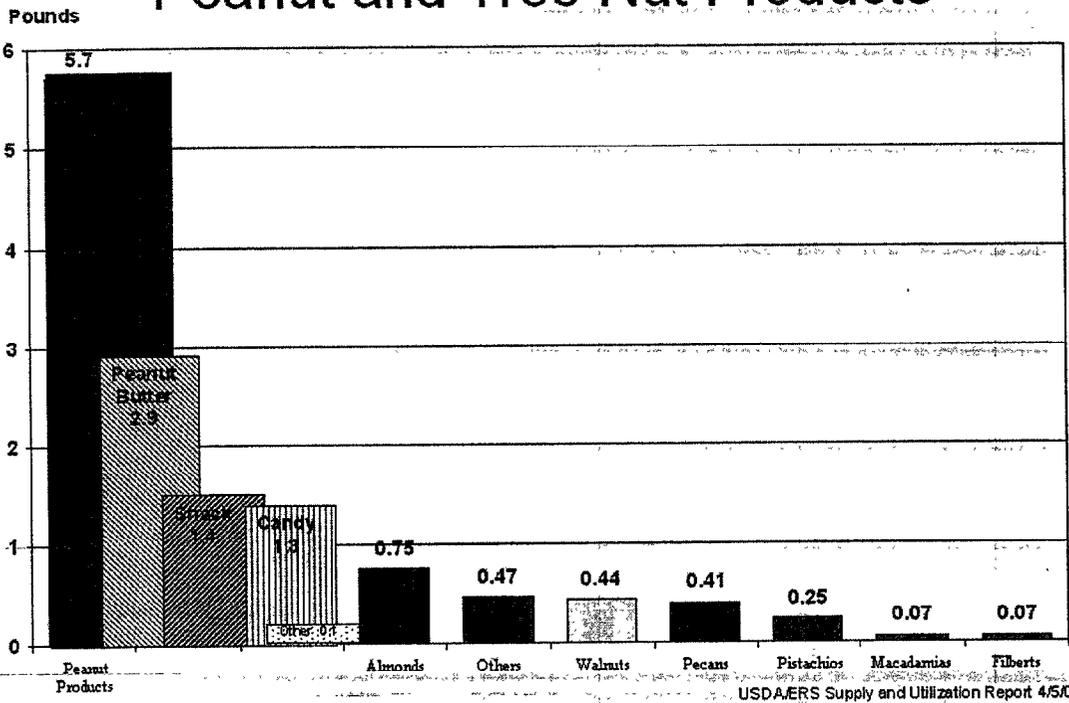


Figure 1