

7/7/03

**Memorandum of Meeting**

**Date:** July 7, 2003  
**Place:** Harvey W. Wiley Federal Building, College Park, MD  
Room 2B047  
**Subject:** Health Claim Petition- International Tree Nut Council  
Nutrition Research and Education Foundation  
(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)

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

James Hoadley, Ph.D., Special Assistant to the Director, Division of Nutrition Labeling and Programs (HFS-830)

Paula Trumbo, Ph.D., Supervisory Team Leader, 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)

Claudine Kavanaugh, Ph.D., Biologist, Division of Nutrition Labeling and Programs (HFS-830)

Craig Rowlands, Ph.D., Regulatory Review Scientist, Division of Nutrition Labeling and Programs (HFS-830)

Office of Scientific Analysis and Support

Steven Bradbard, Ph.D., Leader, Consumer Studies Team  
Division of Market Studies (HFS-727)

Brenda Derby, Ph.D., Statistician, Consumer Studies Team  
Division of Market Studies (HFS-727)

**International Tree Nut Council Nutrition Research and Education Foundation**

Guy Johnson, Ph.D., Johnson Nutrition Solutions

Maureen Ternus, M.S., R.D., Nutrition Coordinator, International Tree Nut Council Nutrition Research and Education Foundation

This meeting was held at the request of representatives of the International Tree Nut Council Nutrition Research and Education Foundation (INCNREF). The purpose was to share with FDA the results of quantitative consumer research that the INCNREF conducted in cooperation with Kraft Foods. The research addressed alternative language for a qualified health claim with regard to a health claim petition submitted on behalf of

**02P-0505**

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the INCNREF. This 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 on the label or in the labeling of certain whole or chopped nuts (i.e., peanuts and nine tree nuts) and certain nut-containing products.

An INCNREF representative discussed the objectives and findings of this consumer research, and offered to send electronically the slide presentation for this meeting. The representative further stated that he planned to submit the research findings formally as part of the public docket for their petition. An FDA representative discussed the submission of this research in relation to the agency's making a final decision about the language for a qualified health claim.

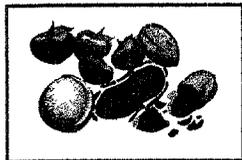
In addition, the INCNREF representative stated that INCNREF is still interested in pursuing a health claim for nuts that would be based on the significant scientific agreement standard, and indicated an interest in engaging FDA in a dialogue about what the design of a long-term study should look like. An FDA representative responded that the agency appreciates this interest and discussed possible ways in which FDA and other DHHS agencies might provide support.

/s/

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

cc: FDA meeting participants

## A Qualified Health Claim for Nuts – Consumer Research



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### Background

- Unqualified claim proposed – August 27, 2002  
“Diets containing one ounce of nuts per day can reduce your risk of heart disease.”
- Qualified claim tentatively proposed – March 14, 2003  
“Nuts [including *name of specific nut*], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive. See nutrition information for total fat and saturated fat content.”

### Background

- Alternative qualified claim language developed  
“...the petitioner would need to demonstrate, based on a fair review by scientific experts of the totality of publicly available scientific information, that the “weight of the scientific evidence” supports the proposed claim.”  
“For a claim that meets the “weight of the scientific evidence” standards, the agency would decline to initiate regulatory action, provided the claim is qualified by appropriate language so consumers are not misled as to the degree of scientific uncertainty that would still exist.”
- Consumer Research fielded – June, 2003
- Current resolution date for the claim – July 17, 2003

Source: 67 FR 78902, 78903, December 20, 2002

### Research Objectives

- The perceived clarity of the alternate claims
- How well each of these claims communicates the desired message
- The degree of certainty associated with nut/heart disease link

### Alternate Claim Language

- “Uncertainty remains”  
“Nuts may reduce the risk of heart disease when eaten as part of a diet low in saturated fat and cholesterol. FDA has determined that although some scientific uncertainty remains, the weight of the evidence supports this conclusion.”
- “Data limited”  
“Eating nuts regularly as part of a diet low in saturated fat and cholesterol may reduce your risk of heart disease. FDA has concluded that while the scientific data are limited, the majority of available evidence supports this statement.”

### Alternate Claim Language

- “Evidence suggests”  
“New scientific evidence suggests, but does not yet prove, that eating nuts may help reduce your risk of heart disease when eaten as part of a diet low in saturated fat and cholesterol.”
- “Emerging evidence”  
“The weight of emerging scientific evidence suggests that nuts may reduce the risk of heart disease as part of a diet low in saturated fat and cholesterol.”

## Methodology

- What:** Communications test of Heart Healthy Nut claims
- Who:** Approximately 400 interviews with a broad random sample of adults 21-70 (50% Female/50% Male); Age quotas were set to match census.
- How:** Central location interviews
- Where:** 16 geographically dispersed markets
- When:** May-June, 2003



## Methodology

- Each respondent was exposed to 3 claims – the FDA approved claim plus 2 of the alternatives
  - Following exposure to each claim they were questioned regarding the clarity, believability and main point of the claim before going on to the next claim.
  - Order of exposure to the claims and the specific combination viewed were rotated so that all claims had an equal chance of being in 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> position.
- Following the interviewing phase, data were weighted to ensure that those exposed to each claim had similar demographic and nut usage profiles

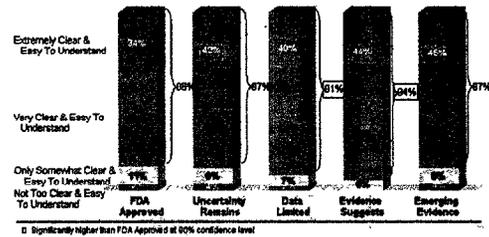


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## Clarity/Understandability of Statement



## Main Point of the Statement

	FDA Approved	Unapproved Reasons	Limited	Evidence Suggests	Emerging Evidence
Heart disease	68	71	55	64	70
Reduce the risk of heart disease	42	45	38	42	44
Nuts reduce/lowers the risk of heart disease	13	10	12	8	15
Nuts reduce heart disease	8	10	6	8	6
Nuts help to reduce the risk of heart disease	3	1	3	5	2
Nuts help reduce the risk of heart disease	2	2	2	2	2
May reduce the risk of heart disease	17	22	14	23	27
Nuts may reduce/lowers the risk of heart disease	3	2	8	4	4
Nuts may reduce heart disease	3	2	8	4	4
Nuts may help reduce/lowers the risk of heart disease	2	1	1	2	2

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## Main Point of the Statement

	FDA Approved	Unapproved Reasons	Limited	Evidence Suggests	Emerging Evidence
Scientific proof does not conclusively prove science/proof	44	36	37	28	28
Scientific evidence is not conclusive	13	9	9	8	8
It is inconclusive	5	9	4	11	3
They have no proof to back their claim	4	4	4	3	3
There is uncertainty/nut's sure about their claim	4	6	9	3	3
Scientific evidence suggests but doesn't prove their claim	4	4	4	3	3
They have scientific evidence that suggests their claim is true	9	9	14	10	21
They have solid evidence	2	3	3	5	10
They have scientific evidence that suggests their claim is true	40	42	31	39	40
New scientific evidence	8	1	1	6	3
Nuts are good for you	30	36	26	34	33
Nuts are good for your health	9	12	13	17	10
Nuts are healthy	8	8	13	17	4
Nuts are low in cholesterol	6	6	8	13	6
Nuts can help to reduce/lowers your cholesterol	6	5	8	7	6
Nuts are good for your heart	3	1	3	1	3
Good to eat nuts in moderation	7	7	13	7	8
Low in fat	11	10	14	7	13
Low in saturated fats	7	7	7	5	8
Low in fat	2	2	3	2	4

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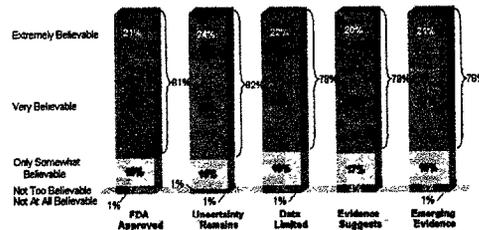


### Main Point of the Statement

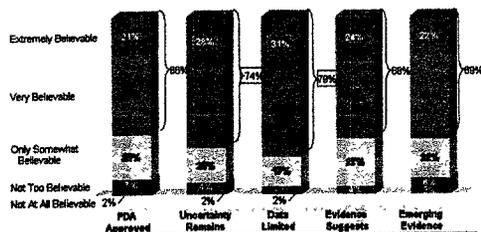
	FDA Approved	Uncertainty Remains	Data Limited	Evidence Suggests	Emerging Evidence
Importance of your diet	23	21	18	19	19
Note as part of a diet	28	29	17	17	16
As part of a low-fat diet	16	12	15	16	8
Note as part of a diet that is low in fat	5	6	3	3	3
Note as part of a diet low in saturated fats	5	6	3	2	3
Note as part of a diet low in cholesterol	5	4	2	4	2
FDA reference/recommendation	7	13	12	3	2
Based on what the FDA says	7	7	5	3	1
To eat nuts and get the healthiest nuts	8	9	12	9	7
To buy/eat nuts	7	9	10	6	6
Statement, link to the link	6	6	7	7	7

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### Believability of Statement

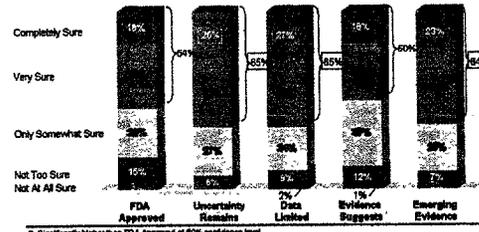


### Believability in linking nuts to reducing CHD risk



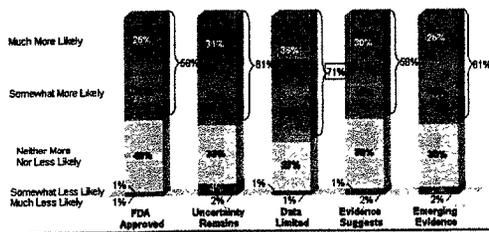
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### How sure authors are that nuts help reduce CHD risk



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### Likelihood to buy/eat more nuts



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### Summary of Key Measures

	FDA Approved	Uncertainty Remains	Data Limited	Evidence Suggests	Emerging Evidence
Clarity/Understandability Of Statement					
Extremely/very clear & easy to understand	86	87	88	84	87
Extremely clear & easy to understand	34	62	40	44	46
Believability Of Statement					
Extremely/very believable	81	82	78	79	79
Extremely believable	21	24	22	20	21
Believability to Linking Eating Nuts To Reducing Heart Disease Risk					
Extremely/very believable	65	74	79	68	69
Extremely believable	21	29	31	24	22
How Sure Authors Are That Nuts Help Reduce Heart Disease Risk					
Completely/very sure	54	66	66	50	64
Completely sure	19	38	37	16	23
Likelihood To Buy/Eat More Nuts Based On Statement					
Much/more likely to buy/eat more nuts	59	61	71	59	61
Much more likely	26	31	39	39	26

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### Conclusions

- All claims are equally believable on a generic basis
- "Emerging evidence" and "Evidence suggests" are similar to the FDA claim with respect to communicating the nut/CHD message
- "Emerging evidence" and "Evidence suggests" are more clear and easy to understand than the FDA claim
- "Emerging evidence," "Evidence suggests" and "Uncertainty remains" are similar to the FDA claim with respect to the likelihood to buy/eat more nuts
- "Emerging evidence" and "Evidence suggests" are closest to the FDA claim in communicating scientific uncertainty

### Recommendations

Quantitative consumer research shows that "Evidence Suggests" does the best job of all claims in communicating clear and understandable information about the role of nuts in reducing the risk of CHD without misleading consumers about the degree of scientific uncertainty that still exists. We therefore, recommend that FDA move swiftly to "authorize" this language for the qualified claim. A second alternative that is most powerful in communicating a believable message, is "Emerging Evidence."