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VIA FACSIMILE

June 21, 2006

Food and Drug Administration  
Office of Information and Regulatory Affairs, OMB  
Attn: Fumie Yokota, Desk Officer for FDA

Re: Docket No. 2005N-0097, Experimental Study of Qualified Health Claims: Consumer Inferences About Omega-3 Fatty Acids, Monounsaturated Fatty Acids from Olive Oil, and Green Tea. 71 Fed. Reg. 29340-29342 (May 22, 2006)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the proposed experimental study of qualified health claims (QHCs) and consumer inferences about omega-3 fatty acids, monounsaturated fatty acids from olive oil, and green tea (71 Fed. Reg. 29340-29342; May 22, 2006). CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplement and over-the-counter (OTC) drug products.

Members of the CHPA Dietary Supplements Committee (DSC) applaud FDA for continuing its efforts to explore ways to help consumers distinguish between QHCs with different levels of scientific support. Our comments pertain to the use of letter grades in the report card grading scheme and to the use of qualifying language for significant scientific agreement (SSA) health claims (i.e., claims which meet the SSA standard).

CHPA DSC members question whether a report card graphic is an appropriate method for communicating the level of scientific support for QHCs to consumers. The International Food Information Council (IFIC) and Foundation conducted research that suggests a report card graphic could lead consumers to make unintended inferences about a product's safety, quality, and healthfulness. For example, results from this study, presented at the November 17, 2005, FDA Public Meeting on Assessing Consumers'

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Perception of Health Claims, indicate that some products bearing B and C letter grades in a report card graphic format were perceived by consumers to be of low quality and safety [Docket number 2005N-0413, Document Number TS6].<sup>1</sup>

CHPA DSC members are concerned it may be the inclusion of a letter grade (i.e., B, C, and D) within the report card graphic that contributed to consumer misperceptions. Personal biases, experiences, or beliefs about a specific letter grade inherent in a report card format could affect a consumer's perception about a product or ingredient. Consumers may also inappropriately attribute a grade level approved for one product ingredient to products with similar ingredients, contributing to an unintended "halo effect."

To more fully assess consumer perceptions, CHPA DSC members propose that FDA conduct the experimental study with two versions of the report card scheme, one with the letter grades and text ratings (see Attachment 1. A.) and another with the text ratings only and no letter grades (see Attachment 1. B.). Testing these variants to the report card scheme may help determine whether letter grades potentially skew the data. This research paradigm may also help correct misperceptions created by the report card schemes observed in earlier research studies.

In addition to requesting that FDA test this alternative report card scheme, we request that the Agency explore other approaches to effectively communicate the degree of scientific evidence supporting health claims. One approach could be the inclusion of qualifying language for SSA health claims that have previously only been tested against claims bearing qualifying language. Findings reported in the working paper entitled "Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims" by Brenda Derby, Ph.D., and Alan Levy, Ph.D., both of FDA, suggested that qualified B- and C-level claims were perceived to have a greater scientific certainty than SSA health claims which did not include qualifying language.<sup>2</sup> This was the perception although SSA claims have the highest level of scientific evidence.

CHPA DSC members request that FDA test the use of qualifying language consistent with the highest level of science supporting SSA health claims so that it can be determined whether the presence of a qualifier increases consumers' perceived credibility of the message. An example of qualifying language could be "Very strong, conclusive evidence shows..." This is consistent with a consumer study conducted by the U.S.

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<sup>1</sup> Kapsak, W. (2005, November). Assessing Consumers' Perceptions of Health Claims. Retrieved June 6, 2006, from <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00006-kapsak.pdf>.

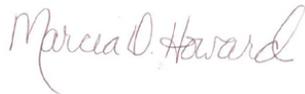
<sup>2</sup> Derby, B. & Levy A. (2005, September). Working Paper: Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. Retrieved June 6, 2006, from <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>.

Federal Trade Commission (FTC) [Docket number 2005N-0413, Document number TS5] and with language suggested by the Grocery Manufacturers Association (GMA) [Docket number 2005N-0413, Document number TS9] and presented at the November 17, 2005, FDA public meeting.<sup>3,4</sup> Please see Attachment 2 for examples of qualifying language that might be useful in developing effective disclaimers.

In summary, CHPA DSC members commend FDA for seeking to further its understanding of consumer perception of the level of scientific support for QHCs, and thus ensuring the effectiveness of disclaimers and other qualifying language. As the Agency moves forward on this proposed research project, we urge FDA to test the report card graphic with and without letter grades and to include qualifying language for health claims that meets the SSA standard.

On behalf of CHPA DSC members, I thank the Agency for this occasion to provide comments. Please contact me at 202-429-9260 if there are any questions.

Sincerely,



Marcia D. Howard, Ph.D.  
Associate Director of Scientific Affairs

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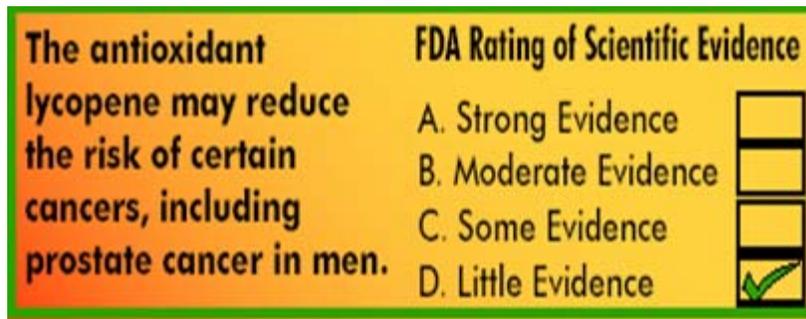
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<sup>3</sup> Ippolito, P. (2005, November). Qualified Health Claims. Retrieved June 15, 2006, from <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00005-ippolito.pdf>.

<sup>4</sup> Kretser, A. (2005, November). Statement on Assessing Consumer Perceptions of Health Claims. Retrieved June 15, 2006, from <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00009-01-vol1.pdf>.

**Attachment 1: Proposed Alternative Research Paradigm for Graphic Report Card Scheme**

A. With letter grades:



B. Without letter grades:



Modified from FDA's Graphic Report Card Scheme [Docket number 2005N-0413, Document Number TS4]<sup>5</sup>

<sup>5</sup> Derby, B. & Levy, A. (2005, November). Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. Retrieved June 6, 2006, from <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00004-Derby.pdf>.

## **Attachment 2: Examples of Qualifying Language from FTC and GMA**

### **A. FTC-Tested Claim Language<sup>6</sup>**

#### **1. Proof Claim:**

Scientists have now proven that supplements containing these same antioxidant vitamins also reduce the risk of cancer. It's a fact!

#### **2. Mildly Qualified Claim:**

Some medical studies are now suggesting that supplements containing these same antioxidant vitamins may also reduce the risk of cancer.

#### **What This Means to You**

It looks promising, but scientists won't be sure until longer term research is completed.

#### **3. Qualified Claim:**

Some medical studies are now suggesting that supplements containing these same antioxidant vitamins may also reduce the risk of cancer.

#### **What This Means to You**

It's too early to tell for sure. Some studies have failed to show that these vitamins protect against cancer. Longer term research is needed.

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<sup>6</sup> Ippolito, P. (2005, November). Qualified Health Claims. Retrieved June 15, 2006, from <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00005-ippolito.pdf>.

**Attachment 2: Examples of Qualifying Language from FTC and GMA (continued)**

**B. GMA-Proposed Language (based on a three-tier system)<sup>7</sup>**

**1. Unqualified Claim Language:**

“Very strong science demonstrates that calcium helps to reduce the risk of osteoporosis.”

**2. First Tier QHC Language:**

“Strong science suggests that nuts may help reduce the risk of heart disease.”

**3. Second Tier QHC Language:**

“Weak science suggests that green tea may help reduce the risk of prostate and breast cancer.”

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<sup>7</sup> Kretser, A. (2005, November). Statement on Assessing Consumer Perceptions of Health Claims. Retrieved June 15, 2006, from <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00009-01-vol1.pdf>.