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February 25, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
Docket #: 2003N-0496
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Re: Food Labeling; Health Claims; Dietary Guidance; Advance Notice of
Proposed Rulemaking
68 Fed. Reg. 227 (November 25, 2003) [Docket No. 2003N-0496]

The California Walnut Commission/Walnut Marketing Board (CWC) is a nonprofit organization that represents the California walnut industry, which is made up of over 5,000 walnut growers and processors. The CWC was petitioner for the walnut/heart disease health claim [Docket No. 02P-0292], the first qualified health claim FDA authorized for a whole food under the applicable First Amendment standard. CWC has substantial experience conducting and interpreting market research aimed at assessing the "consumer climate" affecting how nutrition and health information is received, evaluated, and understood by real people in the diversity of contexts and cultures which exist in the real world marketplace of ideas competing for attention and impact. CWC appreciates the diligent steps the Food and Drug Administration is taking to implement health claims policies which are aimed at promoting the important public health objectives of the Federal Food, Drug, and Cosmetic Act in conformance with First Amendment standards, and welcomes this opportunity to respond to the agency's request for comment on the health claim policy issues set forth in the above titled Advance Notice of Proposed Rulemaking (ANPR).

CWC commends the agency for assigning substantial priority to the complex considerations of human psychology and health behavior in its further evolution of health claims policy. Indisputably, as the First Amendment standards governing health claims evidence, there are no "one size fits all" methods for effective human communications. The dynamic patterns of existing knowledge, misconceptions, and motivations of persons influence how health communications, regardless of source, influence their capacity to attend, process, and respond to health information in specific and hugely diverse

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contexts. While CWC is encouraged by the direction of FDA health claims policy developments, ultimately, the public health can be advanced only to the extent FDA policy encourages the communication of responsible health information in creative ways that have meaning, credibility, and motivational value for the real people receiving the information in the real world.

While the ANPR requests comment on a large and complex range of issues of great importance, CWC offers these concise comments to stress the importance of a single, overarching principle which we believe must anchor all others: there is no evidentiary basis for concluding that any standardized government-devised formula can be successful in communicating health information effectively to meet consumer needs, or conforming with First Amendment standards. To communicate information effectively, marketers must be free to construct, reframe, and update messages as needed to stay connected and responsive to consumers and their needs.

In this regard, CWC urges the agency to reject policy options that would burden health claims with formulaic government-issue expressions or lockstep qualifiers. Based on CWC's consumer research experience, CWC believes that the standardized qualified health claim expressions that the agency embraced initially, cannot be justified on public health or legal grounds, and chill the development of more creative expressions that communicate the material information consumers want and require of marketers effectively. While FDA's goal of providing the public with meaningful information to encourage wise food choices laudable, the standardized qualified health claim language put forward may be ineffective in supporting that goal. Combining a positive health claim statement with boilerplate qualifications and caveats inevitably detracts from the clarity and informational value of the message. A crucial question is whether formulaic qualifying language diminishes consumer understanding or irreparably undermines the value of a health claim's basic message. As the past history of FDA health claims policy shows (21 C.F.R. Part 101, Subpart E), authorizing only rigid health claim expressions which lack genuine informational value in the consumer marketplace have little more public health value than claims that have been banned entirely.

Food labeling constitutes an important vehicle for communicating important health information in a time, place, and manner that is sensitive and responsive to consumer needs and motivating for healthy food choice behaviors. CWC is strongly supportive of rigorous science-based health claim substantiation standards to ensure that health claims are factually accurate and supported by appropriate scientific evidence. At the same time, CWC believes that for the benefits of such diet/health research to be translated into gains for people's health, marketers must have substantial freedom of expression to communicate in the best way possible for the given context.

CWC commends the agency for the important steps being taken to strengthen FDA health claims policy. Thank you for the opportunity to comment on these important issues.

Sincerely,

A handwritten signature in black ink that reads "Dennis A. Balint". The signature is written in a cursive style with a large, looped initial "D".

Dennis A. Balint
CEO
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