



Council for Responsible Nutrition

1828 L Street, NW, Suite 900 • Washington, DC 20036-5114
(202) 776-7929 • fax (202) 204-7980 • www.crnusa.org

February 25, 2004

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

RE: DOCKET NO. 2003N-0496, FOOD LABELING: HEALTH CLAIMS AND DIETARY GUIDANCE

The Council for Responsible Nutrition (CRN) welcomes this opportunity to comment in response to the Advance Notice of Proposed Rulemaking (ANPR) for Food Labeling: Health Claims and Dietary Guidance. CRN, a science-based trade association founded in 1973, is one of the dietary supplement industry's leading trade associations representing ingredient suppliers and manufacturers. CRN members adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices.

CRN supports this initial action by FDA toward rulemaking on health claims and dietary guidance on labeling that will incorporate procedures for the communication of truthful and non-misleading information to consumers through health claims on all foods, including conventional foods and dietary supplements. Correspondingly, consumer confidence in and understanding of health claims should be a goal for both industry and FDA, and we are pleased that FDA is engaged in ongoing consumer testing of health claim language.

CRN supports the development of science-based regulations for qualified health claims, and provides comments and recommendations at this time, primarily on the proposed options for regulating qualified health claims.

HEALTH CLAIMS

FDA has proposed three options for the regulation of health claims which do not meet the significant scientific agreement (SSA) standard of evidence for FDA-authorized (i.e., "unqualified") health claims and has requested comments on the strengths and weakness of each option. CRN's evaluations and recommendations are as follows:

Option 1 (i.e., codification of the current interim procedures). CRN recommends this option but with some significant modification.

We concur with the FDA that the current practice in which the data supporting qualified health claims are evaluated by the Agency prior to authorization is consistent with the tone of the Nutrition Labeling and Education Act of 1990 (NLEA). Moreover, this process establishes common scientific standards and standardization of the health claims across the entire food industry and allows for public input into FDA's decisions on health claims. We are also in support of the use of enforcement discretion letters but believe that the term "enforcement discretion" is not appropriate as it falsely implies that the claim is illegal. Other wordage, such as "is allowed" or "not opposed" by the Agency, would be preferable and more accurate. CRN believes the current approach provides the most efficient, flexible, and rapid mechanism by which FDA can revise a decision based on emerging scientific evidence. Furthermore, we recommend that Option 1 be modified to permit parties interested in developing qualified health claim language that promotes consumer understanding, the option of working in conjunction with the Agency.

We believe that if the Agency had originally implemented NLEA by focusing on the scientific support for the claim as stated, with sufficient rigor to prevent the claim from being false or misleading, the confrontation between FDA and the industry before the Courts over this issue would have been avoided.

We support the following approaches by which FDA may provide for a reasonable timeframe for review:

1. As proposed by FDA, review of petitions for a new qualified health claim will be completed within 270 days after receipt of the petition and qualified health claims could be used after 270 days unless the FDA concludes within the 270-day review period that the data do not support the proposed health claim.
2. We proposed that, in addition, priority review and a shorter approval time within the 270-day period (such as 120 or 180 days), should be given to those petitions that include competent and reliable scientific data and an assessment of those data by qualified experts (similar to a GRAS panel).
3. For existing claims, we propose that modifications to the qualifying language, based on new scientific data submitted to the Agency, can be used 90 days after the submission of the new data unless FDA objects to such modification.

Of utmost importance to the dietary supplement industry is that the FDA establish and adhere to reasonable time frames for review and approval. The above-mentioned modifications will facilitate a more timely review of qualified health claim petitions while providing the Agency with sufficient time to review the data supporting the claim prior to its use in labeling.

Option 2 (i.e., require each qualified claim to undergo notice and comment rulemaking).

This option is not acceptable because it requires too long a review period for emerging scientific evidence. CRN supports Option 1.

Option 3 (i.e., treat qualified health claim as wholly outside NLEA). This option is not acceptable and CRN questions whether FDA has the authority to decline the implementation of the health claims provisions of the NLEA in this manner.

While Option 3 would help educate the public about important new health benefits, CRN is concerned about FDA's limited resources to allow for appropriate enforcement to stop or remove unsupported qualified health claims. Because each individual company would determine the standard of scientific evidence it deems necessary and sufficient to support each type of qualified health claims it makes, the lack of FDA review and standardization has the potential to allow qualified health claims that are confusing to the consumer.

While Option 3 has some merits?avoiding a time-consuming preclearance process?there are several issues that argue against this approach. These include problematic enforcement, possibility of consumer confusion, and the lack of premarket review of qualified health claims.

TASK FORCE REPORT ISSUES

The FDA is seeking comment on several additional issues that were raised by the Task Force. CRN offers the following comments and recommendations on certain issues that seem manageable without additional consumer research.

Data and Research on Substance/Disease Relationship

How can FDA provide incentives for manufacturers to develop the data needed to obtain SSA for an unqualified health claim?

CRN supports the use of incentives for manufacturers to undertake research and development of high quality scientific data deemed necessary to obtain the SSA to support an unqualified health claim. The development of data to support a conclusion of SSA will require substantial resources both in terms of clinical cost and personnel, therefore, the sponsor who provides the data should be afforded a period of marketing exclusivity (at least 12- to 24-months). As an incentive, data submitted in support of the unqualified health claim should be confidential until the end of the 12- to 24-month market exclusivity period, after which any party may use the unqualified health claim.

This approach does not restrict another petitioner from submitting its own data to support an unqualified health claim, but would require independent development of that evidence. All possible encouragement for research to support health claims that can be provided without patent law change should be identified and made available. However, regardless of exclusivity issues, CRN strongly advocates additional research on substance/disease relationships.

CRN encourages the Agency to consider greater flexibility in how unqualified health claim language is used on the product label. Alternative language, which may include simpler statements, should be permitted as long as it conveys the same message to consumer.

Revised Claim Language for Unqualified Health Claims

Should FDA remove the word “may” from unqualified health claims? Are there alternatives to this change and will these changes assist the consumer in identifying the level of science supporting such health claims?

CRN strongly supports the removal of the word “may” from unqualified health claims. The word “may” is, itself, a qualifier and can be confusing to consumers, especially for unqualified health claims where an SSA has been established for the substance/disease relationship. Unqualified health claims that are written in appropriate layman’s terms will be best understood by the consumer. For example, the statement “calcium reduces the risk of osteoporosis” clearly indicates the disease/substance relationship and should be permitted on product labeling if the other requirements of the health claim also appear on the label. Indeed, the phrase “reduces the risk” is a sufficient qualifier of this level of scientific evidence. There is no discernable evidence that a consumer will misinterpret the phrase as “eliminates the risk.”

CONCLUSION

CRN believes FDA should continue with rulemaking on qualified health claims, without necessarily waiting for completion of the consumer research needed to effectively address the many other issues outlined in the ANPR.

CRN looks forward to continued cooperation with the FDA in the development of a regulatory process for qualified health claims. We encourage development of a process that is transparent, flexible to the needs of emerging science, prevents unfair market advantages, and provides review of the petitions on a timely basis. We welcome the opportunity to work with the Agency and other interested parties towards this end.

Sincerely,

A handwritten signature in black ink that reads "Annette Dickinson". The signature is written in a cursive, flowing style.

Annette Dickinson, Ph.D.
President