

Chairman of the Board
Coletta Barrett, RN, MHA, FAHA

President
Augustus O. Grant, MD, PhD, FAHA

Chairman-Elect
William D. Colledge

President-Elect
Alice K. Jacobs, MD

Immediate Past Chairman of the Board
Craig T. Beam, CRE

Immediate Past President
Robert O. Bonow, MD

Secretary-Treasurer
Robert L. Carson, Esq.

Directors
C. William Balke, MD
Claire M. Bassett
Andrew B. Buroker, Esq.
Anthony M. Fletcher, MD
Lawrence H. Frame, MD
Larry B. Goldstein, MD
Susan T. Goodreds
Richard M. Hodosh, MD
Daniel W. Jones, MD
Cindy Keitel
Karen Murray
M. Benjamin Perryman, PhD
Hon. John Edward Porter
Gary R. Saslaw, Esq.
Larry L. Swift, PhD
Mark B. Taubman, MD, FAHA
Gayle R. Whitman, PhD, RN, FAHA
Gail R. Wilensky, PhD
Benjamin A. Willingham

Chief Executive Officer
M. Cass Wheeler

Chief Administrative Officer
Nancy A. Brown

Chief Operating Officer
Gordon L. McCullough

Chief Science Officer
Rose Marie Robertson, MD, FAHA

**Executive Vice President
Science Operations**
Susan Barnett

**Executive Vice President
Corporate Operations & CFO**
Walter D. Bristol Jr, CPA

**Executive Vice President
Healthcare Markets**
Meighan Girgus

**Executive Vice President
Advocacy**
Katherine A. Krause

**Executive Vice President
Corporate Secretary &
General Counsel**
David Wm. Livingston, Esq.

**Executive Vice President
Development**
Suzie Upton

**Executive Vice President
Technology & Customer Strategies**
Michael Wilson



Fighting Heart Disease and Stroke

Office of Public Advocacy

1150 Connecticut Ave, NW, Suite #300
Washington, DC 20036
Tel 202.785.7900
Fax 202.785.7950
americanheart.org

January 23, 2004

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, room 1061
Rockville, MD 20852

**Re: AMERICAN HEART ASSOCIATION Comments on
FDA Advance Notice of Proposed Rulemaking
Docket No. 2003N-0496; Food Labeling: Health Claims & Dietary
Guidance**

The Food and Drug Administration (FDA) issued this advance notice of rule making to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements, and comments on various other issues related to health claims and the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels.

Background

In December 2002, the FDA announced the Consumer Health Information for Better Nutrition Initiative to make available more and better information about conventional foods and dietary supplements to help consumers improve their health and decrease the risk of contracting diseases by making sound dietary decisions. A notice was published in the Federal Register of July 11, 2003 (68 FR 41387) announcing the availability of two guidances entitled "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" and "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements". The notice also stated that the FDA intended to publish an advance notice of proposed rule making to solicit comments on the regulatory approaches and topics related to the Consumer Health Information for Better Nutrition initiative and the two related Guidances.

As of September 1, 2003, the FDA implemented the evidence-based ranking system and the procedures for qualified health claims on an interim basis. The FDA has stated that there is the need for transparent, long-term procedures that have the force and effect of law. Such procedures would benefit both the

2003N-0496

C8

industry and the consumer, provided they result in well-reasoned, science-based decisions that facilitate the communication of truthful and non-misleading information to the consumer. To this end, on November 21, 2003, the FDA the agency issued the advance notice of proposed rule making to solicit comment on various approaches to regulate qualified health claims in the labeling of conventional foods and dietary supplements.

American Heart Association Comments

The American Heart Association (AHA) supports the FDA's efforts to stimulate more and better nutrition information to consumers to improve their diets and health. However, the AHA has concerns about the current qualified health claims approach being initiated without the benefit of consumer research to determine the most effective manner of communicating health claim messages to consumers in the context of labeling and advertising which require short statements, and in the context of the new rules which require a combination of a health claim statement and an accompanying qualification statement. It is essential to understand what health messages consumers understand and what they do not; whether consumers will read and understand accompanying qualifiers or disclaimers; and whether consumers will correctly understand the overall intended message resulting from the combination of a health claim statement and a qualifying statement. **The AHA requests that the FDA not release any additional qualified health claims until consumer research has been done and the FDA's rules for health claims have been adjusted accordingly.**

A. Regulatory Alternatives for Qualified Health Claims

The FDA is considering three alternatives or options for regulating health claims which do not meet the SSA (significant scientific agreement) standard of evidence (i.e., qualified health claims) specified in 21 USC 343(r)(3)(B)(i). The AHA offers comments on those three options, but also expresses another alternative which represents the AHA's preferred approach.

Preferred Alternative:

The AHA strongly recommends another option besides the three identified by the FDA. That alternative is to retain the current regulatory framework and process permitting only unqualified health claims.

Even though the AHA comments on the FDA's three identified options, the AHA recommends that no additional qualified health claims should be approved in

the absence of needed consumer research. Before the FDA expands qualified health claims, adequate consumer research needs to be undertaken to assure that a reasonable consumer can sufficiently understand the health statement and its accompanying disclaimer or qualifying statement. Based on the AHA's consumer research showing that consumers do not correctly distinguish between three levels of qualified health claims, if the FDA decides to authorize qualified health claims, then the AHA recommends that there be just two levels of health claims: an unqualified health claim and only one qualified health claim rather than 3 levels of qualified health claims.

Based on its consumer research, the AHA further recommends that a heart symbol on a food label be reserved only for unqualified health claims based on SSA.

Option 1: Codify the current interim procedures and evidence-based ranking system into a regulation, or codify a variation of these. This process does not include the notice-and-comment rulemaking, but the petition to the FDA which requests a qualified health claim and its supporting data would be made available for public comment.

The AHA supports maintaining the pre-market clearance system that provides for FDA review of qualified health claims and supporting data.

On the presumption that consumers do not adequately distinguish between the three levels of qualified health claims based upon the AHA's consumer research, the AHA recommends that unqualified health claims be maintained and that only the "B" level of qualified health claims be approved.

Regarding the proposed Option 1, the AHA has a concern about the opportunity for public participation without the customary notice-and-comment rulemaking procedure. Specifically, more clarification is requested regarding the process for making the requested qualified health claim and supporting data available to the public for comment, and the specific location or accessibility of the proposed claim and supporting data. Additionally, clarification also is desired regarding whether the FDAMA process would be available to request qualified health claims. A concern is that proposed claims with lesser science support could avoid public comment.

Option 2: Require each qualified health claim to undergo notice-and-comment rulemaking, which is the statutorily prescribed process for health claims for conventional foods. This approach would require the FDA to reinterpret the SSA standard to apply to the claim (including any disclaimer) instead of the underlying substance-disease relationship.

Thus, the FDA's focus would be on whether the words of the claim accurately reflect the data supporting it (e.g., "limited and preliminary scientific research suggests ..."), rather than whether there is SSA supporting the substance-disease relationship.

Of the three offered options, the AHA supports this option over the other two. While it requires more time, it also assures a more comprehensive scientific evaluation of the proposed claim, which benefits consumers.

Regarding the reinterpretation of SSA to apply to the claim, the AHA suggests that the evidence considered regarding SSA should be evidence-based and published in peer reviewed journals. Randomized blinded trials would be desired whenever feasible. Additionally, clarification is sought whether the FDA's suggested reinterpretation of the SSA standard to apply to the claim instead of the underlying substance-disease relationship would be limited to qualified health claims and the SSA would continue to be applied to unqualified health claims as it historically has been where there is a substantiated substance-disease relationship.

Option 3: Treat qualified health claims as outside the NLEA and regulate them on a post-market basis under section 403(a)(1) of the Act which provides that food is misbranded if its labeling is false or misleading.

The AHA does not support a post-market basis for administering qualified health claims. This would have the unfortunate result of the FDA only being able to evaluate a claim after it appears on the product label.

The FDA, unlike the FTC, does not have an administrative subpoena power allowing the FDA to obtain a company's substantiating data and to take enforcement action with relative speed. This will result in the FDA not being able to promptly take enforcement action. The adverse consequence is that an unsubstantiated, false or misleading qualified health claim would be on the market for some time before effective enforcement action could be taken, thus misinforming or confusing the public as to the claims made by a particular food product or food supplement.

B. Issues Raised in the FDA Task Force Report.

The FDA also seeks comment on additional topics raised in its Task Force report:

1. Data and research on a substance/disease relationship, including incentives for SSA. Although the FDA intends to provide for the use of

qualified health claims, it remains interested in authorizing unqualified health claims by regulation under the SSA standard. FDA specifically requested comments on how to provide incentives for manufacturers to develop the data needed to obtain SSA for an unqualified health claim, and comments on how to more effectively develop public-sponsored research on substance/disease relationships.

Regarding how to provide incentives for manufacturers to develop the data needed to obtain Significant Scientific Agreement for an unqualified health claim, the AHA suggests both positive and negative incentives for consideration: Potential positive incentives could include a tax incentive or tax deduction for costs of underlying research to obtain SSA, or granting a period of marketing exclusivity for a qualified health claim when the manufacturer undertakes the research or activities necessary to obtain the SSA for that unqualified health claim. Potential negative incentives include a strict enforcement approach for all non-complying qualified health claims which would emphasize the need for manufacturers to get appropriate approvals for their claims. Another possible incentive would be to establish a time limit for qualified health claims, at the end of which time period either the qualified health claim must be converted to an unqualified health claim based on development of an acceptable SSA or, at the very least, the substantiation for the qualified health claim must be reassessed for continuing validity.

2. Revised Claims Language for Unqualified Health Claims. The Task Force suggested that the FDA remove the requirement for the word “may” from unqualified health claims to eliminate uncertainty on the part of consumers about the science underlying claims that meet SSA. FDA intended the word “may” to alert consumers that there is no certainty that risk of disease will be reduced for each individual, however, it seems to the agency that in common practice the word “may” often is misinterpreted as a reflection of the science supporting the claim rather than the certainty about the ability of a dietary practice to affect any one consumer. Thus, the word “may” leads to uncertainty about the science behind the claim. FDA requests comments on whether the agency should make this change, whether there are alternatives to this change, and whether such a change would assist consumers in identifying the level of science supporting such health claims.

The AHA would accept deleting the word “may” from unqualified health claims but, also, suggests that the word “might” should be required for qualified health claims.

Alternatively, since the use of the verb “may” makes sense in the statement that a food substance “may reduce the risk” of a specified disease, the verb “may”

should be retained in unqualified health claims, but the FDA and other government agencies should undertake an education program regarding the meaning of qualified and unqualified health claims of consumers. This also could include a requirement for minimum commitments on the part of those manufacturers making health claims to include such educational messages in a minimum amount of their advertisements or promotional materials. Further, this issue is appropriate for consumer research to provide information about what consumers understand.

3. Interim Final Rules for Unqualified Health Claims. The Task Force recommended that FDA solicit comment on whether FDA should authorize unqualified health claims through interim final rules (IFRs) to expedite the availability of the health claim in food labeling.

The AHA supports the use by the FDA of the Interim Final Rule process to authorize some unqualified health claims. The AHA finds that the three unqualified health claims authorized pursuant to the IFR process (plant sterol/stanol esters and reduced risk of CHD, soluble fiber from whole oat sources and reduced risk of CHD, and dietary sugar alcohols and dental carries) are appropriate.

The AHA supports this approach only for unqualified health claims, not qualified health claims.

4. Use of the phrase “FDA authorized” or “FDA approved” in qualified and unqualified health claims. The agency has for decades discouraged or prohibited use of such phrases as “FDA authorized” or “FDA approved” in labeling. All products of a type were FDA approved so that a label statement regarding one product implied a difference that did not exist; or “approval” terminology was not appropriate because FDA did not approve any individual or specific product. FDA requests comments on whether a phrase indicating FDA authorization (e.g., “FDA says ...”) would encourage consumers to have more confidence in a claim it accompanied than in a claim without the phrase.

The AHA recommends that consumer research be undertaken to determine whether or not such a phrase conveys an inappropriate message implying a difference between products that does not exist or implying FDA approval of a specific or individual product versus an appropriate message suggesting FDA authorization for the health claim link between a food substance and disease, which would encourage more consumer confidence in health claims.

5. Consumer Education. The FDA Task Force report noted growing evidence of a public health gap in knowledge and behavior with respect to substance/disease relationships. Even when the scientific evidence for substance/disease relationship does not meet the standard of SSA, there may be considerable evidence of a relationship between the substance and the disease which consumers may find useful in planning their diets. The FDA requests comments on how the agency could best educate consumers about the role of qualified health claims on food labeling, and how such claims may be used by consumers to advance their own understanding of diet and health matters.

The AHA suggests that manufacturers which intend to use qualified health claims should be required to undertake a public education campaign, dedicating an appropriate amount of their advertising or promotional expenditures, space or activities. Additionally, the FDA and other appropriate government agencies should undertake a public education campaign, whether alone or in conjunction with organizations such as the American Heart Association, American Dietetic Association or others.

6. Evaluations of Outside Scientific Groups. The FDA has been requested on several occasions to consider accepting evaluations of outside scientific groups as representing scientific consensus that could justify health claims, such as the American Heart Association or the American Dietetic Association. The Task Force asked FDA to consider the recommendations of such groups as evidence of the strength of the science underlying a health claim. However, to make such a system work fairly to the benefit of all, the FDA would need to have confidence in the scientific validity of the group's conclusions about the particular claim in question. The FDA is not aware of a mechanism for evaluating them fairly and accurately, and requests comment on whether the evaluations of non-governmental groups should be given weight in evaluating the strength of the science supporting a health claim and, if so, how should this weight be determined?

The AHA recommends that the evaluation or positions of such organizations should be given weight, but there must be an appropriate standard to assure scientific reliability or quality of their positions such as, for instance, an evaluation of peer-reviewed research results by experts in the field. The opinions of qualified organizations would be useful on the appropriateness of a health claim and assessment of the supporting science underlying a health claim. There is consumer value in the evaluations or conclusions of independent and qualified health organizations.

7. Competent and Reliable Scientific Evidence. The FDA's interim evidence-based ranking system presupposes that FTC's requirement of "competent and reliable scientific evidence" to substantiate a claim related to health or safety has been met. The Task Force recommended that FDA consider scientific evidence only if it is competent and reliable. FTC defines "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence" based upon the expertise of professionals in the relevant area, that has been "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted" in the profession to "yield accurate and reliable results." FDA requests comments on the meaning and/or relevance of "competent and reliable scientific evidence" for the purposes of supporting a qualified health claim within the specific context of qualified health claims.

The FTC definition is acceptable. The AHA stresses that acceptable research must be "objective". One approach is to have the research published in a peer reviewed journal, especially for research sponsored by a food or dietary supplement company. Also, the AHA stresses that "competent and reliable" scientific evidence includes peer reviewed published evidence, preferably from randomized blinded trials rather than observational studies.

C. Issues for Future Consideration. Although the regulatory alternatives discussed previously focus primarily on assessing scientific data as a basis for qualified health claims, the FDA Task Force recognized that there may be merit in developing greater flexibility in other areas of health claim regulation. More flexibility in regulating the use of health claims would further advance the use of reliable diet and health information to consumers via food labels. The Task Force recommended that FDA solicit comments on two issues, in particular: (1) disqualifying nutrient levels, and (2) minimum nutrient content requirements.

1. Disqualifying Nutrient Levels.

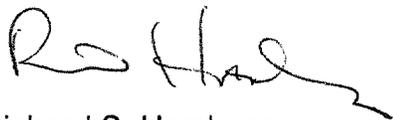
The current health claim regulations do not permit a health claim when the food contains more than a specified or disqualifying level of fat, saturated fat, cholesterol or sodium. The AHA recommends that a disqualifying level for an excessive amount of added sugars be implemented which would prevent health claims for food products that have excessive added sugar. The AHA recognizes that the first step would be to add the required disclosure on the Nutrition Facts panel for added sugars.

2. Other Comments.

Additionally, the AHA suggests that the concept of substitution be an element of health claims when appropriate, for instance, a statement clarifying that nuts can substitute for meat. Information about one food substituting for other foods, even across food groups, hopefully can support a message of moderation and substitution in constructing a healthy diet instead of erroneously suggesting a message of additional foods and calories. A focus on total calorie intake is increasingly important in view of the alarming rates of obesity.

Further, the FDA should encourage food companies to provide labeling and advertising messages regarding portion size, the appropriate balance between intake and expenditure of calories, trans fats and added sugars, and overall diet composition to help consumers create a healthier overall diet.

Submitted on behalf of the American Heart Association,



Richard S. Hamburg
Director, Government Relations
