

National Milk Producers Federation

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National Milk Producers Federation • 2101 Wilson Blvd., Arlington, VA 22201 • 703-243-6111 FAX 703-841-9328

Agri-Mark, Inc.
Arkansas Dairy Cooperative Association
Associated Milk Producers, Inc.
California Dairies, Inc.
Cass-Clay Creamery, Inc.
Continental Dairy Products, Inc.
Cooperative Milk Producers Assn.
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Dairy Lea Cooperative Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
First District Association
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers, Inc.
Manitowoc Milk Producers Coop.
MD & VA Milk Producers Cooperative Association, Inc.
Michigan Milk Producers Assn.
Mid-West Dairymen's Company
Niagara Milk Cooperative, Inc.
Northwest Dairy Association
Prairie Farms Dairy, Inc.
St. Albans Cooperative Creamery, Inc.
Scioto County Co-op Milk Producers' Assn.
Select Milk Producers, Inc.
Southeast Milk, Inc.
Swiss Valley Farms, Co.
Tillamook County Creamery Assn.
United Dairymen of Arizona
Upstate Farms Cooperative Inc.
Zia Milk Producers

February 25, 2004

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

Re: Food Labeling: Health Claims; Dietary Guidance
Docket No. 2003N-0496
68 Federal Register 66040 (November 25, 2003)

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) submits the following comments on the docket referenced above. NMPF, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 32 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 60,000 dairy producers on Capitol Hill and with government agencies.

NMPF appreciates the opportunity to provide comments in response to the advance notice of proposed rulemaking (ANPR) that the Food and Drug Administration (FDA) published to address health claims and dietary guidance for conventional food and dietary supplements [1]. Specifically, NMPF submits comments on selected sections of the ANPR related to regulating qualified health claims in the labeling of conventional foods and dietary supplements and on the appropriateness and nature of dietary guidance statements.

I. Health Claims

A. Options for Regulating Qualified Health Claims

FDA is considering three alternatives (i.e. options) identified in the report by the Task Force on Consumer Health Information for Better Nutrition (the Task Force) [2] for regulating health claims that do not meet the "significant scientific agreement" (SSA) standard of evidence (i.e. qualified health claims) required in 21 CFR 101.14(c) to evaluate the scientific validity of health claims. The options being considered are: Option 1 – incorporate the current interim procedures and evidence based ranking system into a regulation under notice-and-comment rulemaking; Option 2 – reinterpret the SSA standard to apply to the accuracy of the characterization of the evidence supporting the claim and require each qualified health claim to undergo notice-and-comment rulemaking similar to the process for health claims for conventional foods; and Option 3 – treat

¹ 68 Fed. Reg. 66040, 66048 (November 25, 2003)

² Task Force Final Report, Attachment A: "Possible Regulatory Frameworks for Qualified Health Claims" Internet addresses: www.fda.gov/oc/mcclellan/chbn.html or www.fda.gov/ohrms/dockets/default.htm

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Jerry Kozak, President/Chief Executive Officer

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Charles Beckendorf, Chairman

qualified health claims as wholly outside the NLEA and regulate them solely on a postmarket basis, if they are false or misleading.

NMPF believes that science strongly supports the technical rationale for the prenotification process that FDA has been using in its current interim procedures and evidence-based ranking system for evaluating qualified health claims. To achieve the best public health outcomes, FDA should retain this approach and codify these procedures, with the modifications suggested below:

1. Filing of a qualified health claim premarket notification should be published as a Federal Register notice that provides time for technical review and public comment, and that the final FDA determination of premarket notification should also be published in the Federal Register. Additional information would also be appropriate for posting on the FDA website. The Federal Register publication of the filing of the premarket notification and the final decision on the qualified health claim petition will assure the most widespread public notice.

2. The weight of the scientific evidence in support of a particular claim will not always fit neatly into the four-category Evidence Based Ranking System as proposed by FDA. Consequently, the standardized qualifying language suggested in the interim guidance procedures [3] as appropriate for a particular category of qualified health claim cannot be applied rigidly by FDA for several important reasons. First, the First Amendment to the United States Constitution requires that FDA permit the use of any explanatory or qualifying terms that accurately convey the weight of the scientific evidence and are not misleading. Second, where the weight of the scientific evidence falls midway between any two of the FDA categories, it will be necessary to fashion appropriate qualifying language that reflects the weight of the scientific evidence rather than just using the standard phrases set forth by FDA in the interim guidance. In short, the focus must always be on the accuracy, truthfulness, and nonmisleading nature of whatever claim is presented in a premarket notification, and not upon the use of some standardized terminology offered by FDA.

At most, the standardized qualifying language suggested by FDA in the interim guidance might serve as a "safe harbor" that could, in the discretion of the person submitting the premarket notification, be adopted without the need for further discussion. Where a premarket notification submits different terminology that is consistent with the scientific evidence, however, FDA must consider it in the light of First Amendment principles and cannot deny it absent empirical evidence that it is false or misleading. It is highly likely that companies with expertise in communicating to consumers can configure better messages than those suggested. These messages would have qualifying language that meets FDA requirements of truthful and non-misleading while maintaining the ability to effectively connect and communicate with consumers.

3. The letter grading system that FDA proposes to assign to qualified health claims, based upon the level of scientific evidence supporting them, are likely to confuse rather than inform consumers. Consumers will very likely interpret these grades as indicative of the health value or overall quality of the food product, rather than the level of scientific evidence supporting the claim. There is concern that such

³ Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements: (Internet addresses: <http://www.cfsan.fda.gov/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.html>)

confusion will discourage companies from petitioning FDA for use of a qualified health claim and, thus, FDA's intent to share more truthful nutrition information with consumers more rapidly may not occur. To avoid this outcome, FDA could eliminate the letter grade designations it has proposed, and recognize the constitutional right of companies to develop equivalent alternatives to the agency's model qualifying language. If the existing ranking system remains in place, it threatens to undermine the value of the information that it seeks to promote. Option 1 should also be modified to clarify that the focus of any rating system is the relationship of the scientific evidence to the proposed health claim, and *not* to the underlying substance-disease relationship [4].

Option 2 does not seem practical because it would require each qualified health claim petition to undergo notice-and-comment rulemaking and would require excessive FDA and industry resources resulting in unwarranted excessive delays of up to 540 days to communicate important health information to consumers. If modified as proposed, Option 1 would represent the best means of promoting communication of truthful, accurate, and non-misleading qualified health claims.

B. Issues Raised in the Task Force Report

In its report, the Task Force recommended that FDA seek comment on several additional topics related to health claims.

1. Revised Claim Language for Unqualified Health Claims

FDA regulations require unqualified health claims to state that the substance "may" reduce the risk of the specified disease or health related condition [5]. As FDA has indicated, the word "may" leads to uncertainty about the science behind the claim because, as further noted by FDA, consumers are likely to interpret the word "may" 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." [6]. The Task Force's suggestion to remove the qualifier "may" from unqualified health claims makes good sense so that the uncertainty surrounding claims such as "calcium may reduce the risk of osteoporosis" is eliminated.

2. Interim Final Rules (IFRs) for Unqualified Health Claims

The Task Force recommended that FDA solicit comments on whether FDA should authorize unqualified health claims through IFRs to expedite the availability of health claims in food labeling. FDA reliance upon interim final rules (IFRs) for unqualified health claims has been essential to promoting enhanced communication regarding the health benefits of food. Accordingly, FDA should continue to use IFRs to expedite the availability of all health claims.

3. Evaluations of Outside Scientific Groups

FDA should consider the findings, conclusions, and recommendations of outside scientific groups for making important contributions to understanding the relationship between diet and health or disease. The scientific value and credibility of contributions made by outside scientific groups should be evaluated on the basis of standard scientific criteria -- the training and expertise of the individuals involved, the thoroughness of the evaluation that they have undertaken, the quality of the report they have produced, the scientific data and information on which they rely, and other

⁴ In Option 2, FDA acknowledged that this view is consistent with section 403(r)(1)(B) of the FD&C Act. 68 Fed. Reg. At 66042.

⁵ 69 Fed. Reg. At 66043 (citing 21 C.F.R. 101.14(d)(2)(ii)).

⁶ *Id.*

similar factors. In short, each recommendation of an outside scientific group must be evaluated on the merits of the work, not on the general merits of the organization.

4. Competent and Reliable Scientific Evidence

It is apparent that competent and reliable evidence is credible, and credible scientific evidence is competent and reliable. This is a semantic distinction without a substantive difference. The standard of credible scientific evidence can be satisfied by any scientific study that meets long-established principles of scientific investigation, *e.g.*, a written protocol that describes the investigation in adequate detail, informed consent of study subjects, documented methodology, statistical analysis of results, and a written report reviewing the investigation and containing its conclusion. Such evidence may include *in vitro* data, results of animal experimentation, data on the mechanism of action involved in any nutrient-disease relationship, epidemiology, clinical studies and any other form of scientific information. The evidence need not be published or peer-reviewed. The specific wording of the claim would determine the type and quantity of evidence required to support it and the results of consumer testing could be considered as part of the supporting information.

II. Dietary Guidance

The Task Force recommended that FDA also seek opportunities to promote the development and use of more dietary guidance statements on foods in order to assist and encourage Americans to make better food choices and establish healthier eating patterns. FDA acknowledges the importance of dietary guidance statements and points out that although these types of statements are not health claims (58 FR 2478 at 2487 and 59 FR 395 at 418) and do not require regulatory review or approval before use, however such statements, when used in labeling for foods must still be truthful and nonmisleading. Accordingly, FDA has recognized the need to identify and agree upon dietary guidance that is appropriate for food labels and how such guidance may be used.

A. Regulatory Distinctions Between Dietary Guidance and Health Claims

There is substantial merit in FDA's distinction between health claims and dietary guidance statements as noted in the ANPR which indicated that "Unlike health claims, which target a specific substance and a specific disease or health-related condition, dietary guidance statements focus instead on general dietary patterns, practices, and recommendations that promote health". FDA also noted that dietary guidance statements may make reference to a disease or substance, but not both. These criteria, however, cannot be imposed in such rigid manner as indicated in the preamble to the final rule regulating health claims for conventional foods [7]. Companies have the right to make dietary guidance statements that make reference to both a disease and a substance that would not necessarily trigger health claim status if such statements are truthful, accurate, and nonmisleading with respect to the recommended dietary pattern that may reduce the risk of a specific disease or a health related condition and also communicate the general nutritional significance of the foods or food groups associated with that dietary pattern. For example, the Dietary Guidelines for Americans, 2000 recommends: "Eat fruits and vegetables. They are naturally low in salt and calories. They are also rich in potassium, which may help decrease blood pressure." [8]. In this case, "...rich in potassium, which may help decrease blood pressure" constitutes an integral part of the intended overall dietary pattern and, in the spirit the Dietary Guidelines recommendations, constitutes a dietary guidance statement.

⁷ 58 Fed. Reg. 2478, 2487 (January 6, 1993).

⁸ US Department of Agriculture and US Department of Health and Human Services: "Nutrition and Your Health: Dietary Guidelines for Americans," 5th ed. Home and Garden Bulletin No. 232. Washington DC: US Government Printing Office, 2000. Website: www.ars.usda.gov/dgac/

B. Issues Relating to Dietary Guidance

1. Definitions

There is substantial merit in FDA's current distinction between a health claim and dietary guidance with generic modifications that address the example noted in part II.A above.

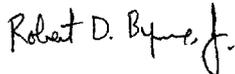
2. The Substance as the Subject of a Health Claim

Companies possess a First Amendment right to make any claim that is truthful, accurate, and non-misleading. Unless FDA can demonstrate that a food-specific health claim (e.g., "Yogurt reduces the risk of osteoporosis") is inaccurate or inherently misleading, it may not prohibit its use. FDA may require the use of a qualifying statement if empirical evidence demonstrates that it is needed to cure a potentially misleading statement.

Industry is better able than FDA to determine how best to communicate with consumers regarding the health benefits of its products. Scientific communications will be best served if FDA explicitly recognizes that companies have unique expertise in fashioning health-related messages that can best inform consumers.

Thank you for the opportunity to comment on this important rulemaking.

Sincerely,



Robert D. Byrne, PhD
Vice President
Regulatory Affairs