



January 18, 2005

**NFPA**<sup>®</sup>  
*The Food Safety People*

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

NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

[Docket Nos. 1994P-0390 and 1995P-0241] Food Labeling:  
Nutrient Content Claims, General Principles; Health Claims,  
General Requirements and Other Specific Requirements for  
Individual Health Claims; Reopening of the Comment Period  
69 Federal Register 24541, May 4, 2004.  
69 Federal Register 67513, November 18, 2004.

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following  
comments on the docket referenced above.

The National Food Processors Association (NFPA) is the voice of the \$500  
billion food processing industry on scientific and public policy issues involving  
food safety, food security, nutrition, technical and regulatory matters and  
consumer affairs. NFPA's three scientific centers and international office  
(Bangkok, Thailand), its scientists and professional staff represent food industry  
interests on government and regulatory affairs and provide research, technical  
assistance, education, communications and crisis management support for the  
Association's U.S. and international members. NFPA members produce  
processed and packaged fruit, vegetable, and grain products, meat, poultry, and  
seafood products, snacks, drinks and juices, or provide supplies and services to  
food manufacturers. In 2005, NFPA will become the **Food Products  
Association (FPA)**.

NFPA submitted one of the petitions (Docket No. 1994P-0390) that has resulted in  
the rulemaking for which FDA is now seeking new comments. NFPA has also  
submitted several comments to this docket, including comments in recent years that  
recommended that the Agency incorporate its recent First Amendment activities  
into the decade-old rulemaking, and publish final rules. During this time, NFPA  
consistently has advocated for flexibility in the expression of health claims,  
nutrient content claims, and other types of food label statements.

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## Summary of Comments

NFPA recommends that FDA develop final rules on health claims and nutrient content claims policies consistent with the arguments that NFPA advanced in our 1994 petition. Specifically,

- NFPA urges FDA to conduct a First Amendment analysis for this rulemaking, and apply First Amendment principles to the resolution of this rule;
- NFPA urges FDA to remove minimum nutrient contribution requirements from health claim provisions;
- NFPA urges FDA to replace disqualifying nutrient levels for health claims with disclosures;
- NFPA recommends that FDA consider removing the requirement for the word “may” from the expression of “significant scientific agreement” health claims;
- NFPA recommends that FDA permit unlisted synonyms for nutrient content claims, and develop flexible provisions for “anchoring” unlisted synonyms;
- NFPA urges FDA to permit abbreviated and implied health claims.

## First Amendment Considerations

NFPA is encouraged that FDA is requesting comments on the 1994 petition rulemaking at the same time that the Agency is establishing policy on qualified health claims, as it appears to signal that FDA is now considering the integration of the legal points from the *Pearson v. Shalala* decision into the health claims and nutrient content claims framework for conventional foods. NFPA urges FDA to continue forward on this promising path toward health claims and nutrient content claims reform more generous than those originally proposed in 1995. While FDA’s current request for comment focuses on the technical details of health claims policy, NFPA believes it is necessary first to discuss First Amendment issues.

NFPA notes, at the outset, that this rulemaking requires a robust First Amendment analysis. The regulations proposed by FDA in response to the 1994 NFPA petition (60 FR 66206; December 21, 1995) did not address the First Amendment requirements set forth in the petition, and as a result denied the proposed reforms without following established legal requirements. After the 1994 NFPA petition was filed, and after the December 1995 proposal, the extensive body of First Amendment case law supporting NFPA’s requested reforms expanded to include the landmark decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (*reversing* 14 F. Supp.2d 10 (D.D.C. 1998)),

*reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999). The legal analysis and reforms proposed in the 1994 NFPA petition foreshadowed the *Pearson* decision and, in our view, now require FDA to undertake actions to implement claims policy reforms of the specific kind NFPA originally put forward in its petition. The 1994 NFPA petition outlined the inconsistencies with First Amendment policies that resulted from FDA rules implementing the Nutrition Labeling and Education Act of 1990 (NLEA), and proposed concrete remedial reforms. The 1994 petition was accompanied by a white paper prepared by NFPA counsel, Covington & Burling, which provided an extensive analysis of the First Amendment protections of commercial speech, and responded to each point that FDA had argued regarding the First Amendment application to the regulations implementing the NLEA.

The steps FDA must take to abide with the requirements of the First Amendment, in NFPA's view, fully support both the public health and the concept of truthful, substantiated claims. Nevertheless, the First Amendment sets clear and firm boundaries on the regulatory methods that FDA would choose to employ as the means to implement nutrient content claims and health claims policies. These boundaries require FDA to respect the rights of those who wish to communicate true and substantiated health information of value to the public. The First Amendment requires FDA to employ flexible regulatory approaches to permit a wide range of truthful, substantiated health representations on labels and in labeling, and not just those claims that the Agency has the resources to address.

As our 1994 petition discussed, no benefit to public health can result from arbitrary obstacles to the creative expression of well-founded health information by food processors. FDA's own rulemaking record on health claims makes clear that the Agency itself recognizes that the public health benefit promised by the NLEA can only be gained by opening the channels of communication of health information in food labeling to consumers in ways that are genuinely effective and motivating, and can help improve consumers' personal health status. The reforms required by the First Amendment would better equip food producers to communicate well-founded health information to the consumers they know and serve each day, in the ways that are most meaningful to those consumers. The First Amendment assures that the people themselves have direct access to the information they determine to be of greatest value and importance in making the everyday food choices affecting their personal health, and in the aggregate these personal choices determine the public's health.

NFPA acknowledges that health-related representations made to consumers must be truthful and substantiated; this is consistent with First Amendment requirements. However, the health claims and nutrient content claims reforms proposed by FDA in 1995 would continue to maintain barriers against these types of health-related communications. The 1994 NFPA petition proposed concrete reforms of FDA policy

which would go a long way in addressing First Amendment concerns. In response to the 1994 NFPA petition, FDA issued proposed regulations that would make narrow amendments to certain regulations, but rejected most of the broad reforms proposed by NFPA, including revision of the health claim policies at issue in the *Pearson v. Shalala* decision. Notably, FDA declined entirely to address the First Amendment concerns presented in the NFPA petition. In response to the FDA proposal, NFPA offered the following comment:

*“Notably absent from FDA’s proposal is any response to the constitutional concerns raised in [our counsels’ Memorandum of Law]. It appears that the Agency’s continuing failure to come to grips with the constitutional requirements that must guide NLEA implementation has prevented the Agency from proposing adequate reform of its regulations. While NFPA welcomes FDA’s willingness to reconsider some of the more restrictive elements of the nutrient content and health claims provisions, the Agency would have to take much bolder steps than those offered in this proposal to respond satisfactorily to the constitutional concerns the NFPA petitions raises. . . . [T]he proposal fails to assure reasonable protection of truthful, non-misleading nutrient content and health claims.”*

(NFPA Comments, Docket Nos. 94P-0390 and 95P-0241, July 18, 1996, at page 7).

NFPA urges FDA to remedy the deficiencies in the 1995 proposed rule, and to advance health claim and nutrient content claim policies that reflect the Agency’s current approach to such communications. NFPA believes that such an approach would result in claims regulatory policy that is both less restrictive than was proposed in 1995 and more consistent with First Amendment standards.

The remainder of NFPA’s comments address the specific subjects on which FDA is seeking comment regarding nutrient content claim and health claim policy. In these comments, NFPA espouses these overarching considerations: that any regulatory limitations on health claims and nutrient content claims should be exceptions to claims policy, rather than pre-conditions for expressing claims; and that claims rules should be crafted so that it is necessary to impose restrictions case-by-case rather than grant exemptions case-by-case.

NFPA also advocates that all label elements must be considered together, and that the entire context of the label must convey a consistent message to consumers. NFPA believes that evaluation of the total food label should reflect an environment in which maximum flexibility is provided for presentation of any label statement which is intended to communicate meaningful health information to consumers.

NFPA points out that any speech restriction FDA may wish to impose on a particular type of claim, either through prohibiting speech or compelling speech, must be approached carefully, so that First Amendment standards are respected fully. Coerced or compelled speech requirements cannot be justified under the First Amendment except where necessary to alleviate a concrete speech-induced harm that otherwise would occur as a result of the particular representation. A concrete speech-induced harm would mean that the expressed claim would be actually misleading to reasonable consumers without the restriction, and not just potentially misleading. NFPA believes that the burden lies with the government to demonstrate that reasonable consumers are actually misled in the absence of the specified restriction. NFPA believes that FDA should demonstrate why our reasonable suggestions for more meaningful label communications should not be granted, rather than requiring the food industry to prove why they should be granted.

#### **Minimum Nutrient Contribution Requirement (“Jelly Bean” Rule) for Health Claims**

The current health claim requirement for minimum nutrient contribution would require that any food, in order to make a health claim, must contain not less than 10% Daily Value per serving of at least one of vitamin A, vitamin C, calcium, iron, protein or fiber, prior to any nutrient addition. In proposed §101.14(e)(6), FDA would amend the minimum nutrient contribution rule to exempt fruits and vegetable products composed solely of fruits or vegetables, and certain grain products, from this requirement. Other foods, including those which contain principally fruit or vegetable ingredients (e.g., canned fruits and vegetables), must meet the minimum nutrient contribution requirement.

NFPA continues to oppose any minimum nutrient contribution requirement, as it creates arbitrary and unfair biases against food products that make valuable contributions to the diet. For example, all forms of fruits, vegetables, and grain products contribute to a healthful diet, and individual foods in these categories should not be excluded from the health claims available to fruits, vegetables, and grains simply because they do not constitute a “good source” of any arbitrarily specified nutrients. NFPA thus opposes the narrow exemption from the minimum nutrient contribution requirement that FDA proposed. NFPA believes that our view has been supported in the years intervening since the 1995 proposal, as FDA has permitted additional exemptions from the minimum nutrient contribution requirement: in 21 CFR 101.80, the health claim for non-cariogenic carbohydrate sweeteners and reduced risk of dental caries; in 21 CFR 101.83(c)(2)(iii)(C), in the interim final rule for the health claim on stanol esters and sterol esters and reduced risk of cardiovascular disease; and in the recently authorized Qualified Health Claims on walnuts and reduced risk of heart disease, and on monounsaturated fat from olive oil and reduced risk of heart disease.

FDA should examine this issue prospectively, as well. The Agency is increasingly likely to be presented with proposed Qualified Health Claims for foods that do not meet the minimum nutrient contribution requirement. These claims undoubtedly will necessitate additional exemptions from the minimum nutrient contribution requirement, as foods that are candidates for such claims may not contain appreciable amounts of any of the nutrients vitamin A, vitamin C, calcium, iron, protein or fiber.

The NFPA petition requested that minimum nutrient contribution requirement be eliminated and that foods be permitted to qualify for health claims on the basis of fortification. NFPA recommends that FDA craft health claims rules so that a series of exemptions is not needed to permit any claim. If a health claim needs to be restricted because absence of the restriction would cause the claim to be misleading, FDA should justify such a restriction and impose it specifically on the relevant food.

#### **Disqualifying Nutrient Levels for Health Claims**

FDA's 1995 proposal would maintain disqualifying levels for total fat, saturated fat, cholesterol, and sodium, which would prevent use of any health claim, except for foods for which the Agency has issued a specific exemption. FDA also proposed (in §101.70(f), B) a procedure whereby manufacturers could seek exemptions for foods on a case-by-case basis by filing an extensive health claim petition. The proposal lists the criteria the Agency would consider in determining whether an exemption would be granted, but these criteria suggest that exemptions would be granted only rarely. FDA has attempted to justify this proposal on the grounds that disqualifying levels are necessary to assist consumers in constructing daily diets that meet the *Dietary Guidelines for Americans*. FDA argues that the policy underlying NLEA is to reserve health claims for foods that contribute generally to a healthful diet.

NFPA opposes this approach, as it characterizes foods as "good" or "bad," depending on specific nutrient profiles. In particular, §101.70(f), B.4., which would require a petitioner to discuss the public health need for waiving disqualification requirements, is overly restrictive. NFPA believes the clear label disclosure of the public health implications of consuming a food which may exceed any defined levels of specific nutrients should be sufficient to support the government's interests.

In the classic case that argues against disqualifying nutrient levels, whole milk on occasion can be part of a diet that complies with the *Dietary Guidelines for Americans*, and such a diet will also assist in reducing risk of osteoporosis. In many instances, foods that exceed the current health claim disqualifying nutrient levels contribute to healthful diets. In fact, since the 1995 proposed rule, FDA has exempted foods from disqualifying nutrient levels several times: with respect to total fat in foods that qualify for the stanol

esters/sterol esters health claim interim final rule, and in the Qualified Health Claims for nuts, walnuts, DHA and EPA omega-3 fatty acids in fish, and monounsaturated fatty acids from olive oil. All of these Qualified Health Claims relate to reduced risk of heart disease. The approach that NFPA petitioned would require the disclosure of fat, saturated fat, cholesterol and sodium, in a label statement consistent with that for nutrient content claims, when they exceed certain levels.

With respect to health claims for disease risks that are already accommodated in regulations, we note that FDA has received a recommendation from the Nutrition subcommittee of the FDA Food Advisory Committee that the health claim disqualifying level for total fat should not apply to health claims on reduced risk of heart disease. NFPA supports this recommendation. NFPA believes it is appropriate generally to replace this disqualification level with a disclosure requirement, consistent with our 1994 petition. Finally, any future health claims that relate to specific fatty acids also are likely to require such an exemption.

#### **Use of the Word “May” in Unqualified Health Claims**

In its request for comments, FDA states that the word “may” in unqualified health claims describes the relationship between a substance and a disease or health-related condition, and reflects the multi-factorial etiology of most chronic disease states. NFPA disagrees with this statement, and we recommend that FDA use greater precision in this characterization.

Health claims, in fact, are required to be expressed in terms of the total diet. Health claims thus reflect a diet characterized by a substance to achieve the claimed health effect. There is no need for language that suggests that cause of disease is multi-factorial, because health claims are expressed in the context of the diet.

With respect to “significant scientific agreement” (SSA) health claims, NFPA believes that, in an era of Qualified Health Claims, such claims should not be characterized as “unqualified.” NFPA observes that all of the currently authorized health claims are qualified claims, to some degree. Every health claim, whether regulated as a 21 CFR subpart E health claim, or established under the notification procedures of the FDA Modernization Act, states that a specific type of diet emphasizing a particular substance “may” “reduce risk” of a particular disease. Each statement is conditional, is stated as risk reduction, and is expressed in the context of the total diet. This may be minimal qualification, but it is not appropriate to suggest that such statements are “unqualified.” It is the degree of qualification that is salient. NFPA would prefer that FDA characterize the body of health claims established by regulation in 21 CFR Subpart E and through FDAMA notifications as SSA health claims.

NFPA believes that FDA should consider removing the word “may” from the requirements for expression of a SSA health claim. NFPA notes that the current standard language required for a SSA health claim expresses that the claimed substance in the diet “may reduce risk.” Reducing risk is, in itself, a qualification for the claim. Stating “may reduce risk” qualifies the health claim to two degrees. For a SSA health claim, one degree of qualification, expressed as risk reduction, should suffice. Thus, stating that the substance, in the context of the diet, “reduces risk” of a disease or health-related condition should be sufficient to communicate truthfully the scientific support for the “significant scientific agreement” claim. The simplest language that communicates truthfully and clearly to consumers should be permitted.

NFPA does not suggest that the term “may” should be prohibited from expression of SSA health claims. We recognize that the term is currently in use on all labels that express SSA health claims, and food processors should not be required to change their labels to remove the word “may.” NFPA recommends that the word be permitted, but not required, for SSA health claims.

### **Unlisted Synonyms for Nutrient Content Claims**

NFPA supports §101.13(r)(2)(i), the 1995 FDA proposal that a nutrient content claim using an unlisted synonym be non-misleading, and that it should, in the context of the entire label, be understood by consumers to be synonymous with the defined term. If a dictionary definition or thesaurus entry can demonstrate that the terms are synonymous, that alone should suffice to demonstrate compliance with the intent of the rule.

NFPA believes that presence of an undefined synonym in a current dictionary or thesaurus, in the context of the characterizing word of the claim, is adequate substantiation for consumer understanding. Terms do not appear in dictionaries or thesauruses until their meaning is accepted in language. Since language changes constantly, presence of terminology in dictionaries or thesauruses means that the sense is well established; terminology in a current dictionary or thesaurus should be regarded as “General Recognition of Meaning.”

Since language evolves continuously, some claims synonyms may be too current to be incorporated in a dictionary or thesaurus. In these instances, if a marketer wishes to utilize contemporary idiom as a synonym for a defined claim term, that marketer may need to conduct consumer research to ensure that the meaning intended is the meaning taken. This should be the only instance where consumer research may be required to substantiate a nutrient content claim synonym.

Some undefined synonyms may be very colloquial in expression, and may appeal only to the intended consumers of the food. For example, one can imagine reading the claim "loaded with fiber" as a synonym for "high in fiber" on a breakfast cereal. This may appeal to specific segments of the population that are motivated by colloquial expressions on food labels. In such an instance, any substantiation that the intended population of consumers understands the terms to be synonymous with a defined term should be sufficient to permit use of the synonymous term.

FDA requested comment on whether the time frame to petition for a nutrient content claim synonym is burdensome to industry. The time frame for such a petition, as described in 21 CFR 101.69(n), allows FDA 105 days to evaluate the petition, and additional time as may be needed for the Agency to draft a rule. This would be added to any time the petitioner required to develop the petition. A total of six months from petitioner's concept to final rule might seem realistic, but it would also reflect half a year when a marketer could not communicate truthful, non-misleading, synonymous terms to consumers, and this would constitute an unreasonable restriction on the marketer's commercial speech rights.

FDA should not need to define a full range of nutrient content claim synonyms; FDA is not in the position to regulate the entire English language. Industry experts in communicating to consumers have a strong and proven history of succinct, effective language that is well understood and motivating to consumers. NFPA believes that marketers must have the freedom to be responsive to the changing perspectives of consumers, and the content of truthful, non-misleading expressions must not be confined by a rigid regulatory approach.

In sum, NFPA supports the aspect of FDA's 1995 proposal that a nutrient content claim using an undefined synonym be non-misleading, and that, in the context of the entire label, it should be understood by consumers to be synonymous with the defined term. NFPA urges FDA to recognize that dictionary definition, thesaurus entry, or consumer research should be more than adequate to determine a synonym for a nutrient content claim.

NFPA supports FDA's intention, expressed in the 1995 proposal, to undertake rulemaking to define synonyms if the Agency finds that undefined claim synonyms are not being employed consistently, or if equally credible but different meanings are attached to an undefined claim synonym.

In proposed 21 CFR §101.13(r)(2)(ii)(A) and (B), FDA would authorize the use of unlisted synonyms for nutrient content claims only when the claims are anchored to a defined nutrient content claim. According to the proposal, anchoring may occur in two

ways: 1) the defined claim appears “immediately adjacent” to the most prominent use of the unlisted synonym and appears at least half as prominently, or 2) the defined claim is more than twice as prominent on the label as the unlisted synonym.

NFPA opposes the approach proposed in §101.13(r)(2)(ii)(A) as overly restrictive. It would provide little incentive for the use of unlisted synonyms, especially in brand names. NFPA urges FDA to reconsider the approach put forward in our 1994 petition, which would authorize the use of unlisted synonyms, provided the defined claim appears in the product labeling and the undefined synonym is non-misleading and is understood as synonymous with a defined term.

NFPA believes the context of the entire label should be adequate for determining that undefined synonyms and defined claims are anchored to each other. In terms of consumer perception, in the context of the entire label, it is unlikely that conflicting messages of identical meaning could be communicated on the same label, regardless of type size or placement of the undefined term on the label, since such internal conflict would be likely to mislead consumers.

NFPA believes that anchoring of defined and undefined terms in immediate proximity to each other, as FDA has proposed, is unnecessary, and could result in absurd nutrient content claims, such as “chock full of calcium - high in calcium” as a required label message. In our 1994 petition, NFPA made the point that the message on the label regarding the nutrient should be consistent between the defined term and the undefined synonym, and that consumers would understand both parts as a single message, in the context of the entire label.

### **Abbreviated and Implied Health Claims**

In §101.14(d)(2)(iv), FDA proposed to simplify the required presentation of health claims. NFPA notes that FDA failed to accommodate health claims that are truncated or presented in implied forms, as in attention-getting bursts or slogans (e.g., “heart healthy,” “be cancer smart,” “help reduce risk of brittle bones”), if the full health claim appears prominently on the label, and if the truncated or implied claim is not misleading in the context of the entire label or labeling. NFPA had requested consideration of this approach in our 1994 petition. Proposed §101.14 (d)(2)(iv)(B) would permit certain abbreviated health claims when specifically authorized, as is the case for the dental caries health claim on small packages.

NFPA opposes this restrictive approach to abbreviated health claims. In its petition, NFPA had advanced a perspective that abbreviated and implied health claims, including health claims communicated by symbols, should be authorized by permitting a shortened

or implied claim to be accompanied by a referral statement directing the consumer to the label panel where the complete health message appears. This would replace the current requirement that the entire health claim appear in one place on the label. NFPA believes that both symbols and brief slogans should benefit from the ability to use a brief notation, with a referral statement to the complete health claims elsewhere on the label. This approach is consistent with the recognition that the entire label is regulated and constitutes the area of communication to consumers.

NFPA urges FDA to give full consideration to the issues that we presented in our 1994 petition on health claims and nutrient content claims policy, and promulgate final rules on this rulemaking.

In sum, NFPA recommends that FDA develop final rules on health claims and nutrient content claims policies consistent with the arguments that NFPA advanced in our 1994 petition. Specifically,

- NFPA urges FDA to conduct a First Amendment analysis for this rulemaking, and apply First Amendment principles to the resolution of this rule;
- NFPA urges FDA to remove minimum nutrient contribution requirements from health claim provisions;
- NFPA urges FDA to replace disqualifying nutrient levels for health claims with disclosures;
- NFPA recommends that FDA consider removing the requirement for the word "may" from the expression of "significant scientific agreement" health claims;
- NFPA recommends that FDA permit unlisted synonyms for nutrient content claims, and develop flexible provisions for "anchoring" unlisted synonyms;
- NFPA urges FDA to permit abbreviated and implied health claims.

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

Sincerely,



Regina Hildwine  
Senior Director, Food Labeling and Standards