



July 9, 2002

NFPA

The Food Safety People

Daniel E. Troy
Associate General Counsel (GFC-1)
Food and Drug Administration
5600 Fishers Lane
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NATIONAL

FOOD

PROCESSORS

ASSOCIATION

RE:

Docket No. 94P-0390, Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims.

Docket No. 02N-0209, Request for Comment on First Amendment Issues

John R. Cady

President and

Chief Executive Officer

Dear Mr. Troy:

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I am writing on behalf of the National Food Processors Association (NFPA) to draw your attention to matters involving First Amendment principles of interest to NFPA. The National Food Processors Association is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, 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.

First, I wish to express our appreciation for the recent FDA Request for Comment on First Amendment issues (67 FR 34942; May 16, 2002). NFPA intends to file responsive comments on this notice.

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In addition, I would like to bring to your immediate attention the pending final rule on the rulemaking proceeding initiated in response to the NFPA citizen petition filed in 1994, which proposed reforms of FDA nutrient content claim and health claim regulations of the kind necessary to bring FDA policy into compliance with First Amendment requirements (Docket No. 94P-0390; October 25, 1994). The regulations proposed by FDA in response to the 1994 NFPA

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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. NFPA understands the final rules on this rulemaking are pending review by your office. In view of the recent FDA request for comment, NFPA wishes to renew the request it has made to the Agency in prior submissions, that the Agency promptly reopen its consideration of the First Amendment reforms proposed in the 1994 NFPA citizen petition.

Since the 1994 NFPA petition was filed, the extensive body of First Amendment case law supporting the proposed reforms has 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 compel FDA to take seriously its obligation to embrace reforms of the specific kind NFPA has proposed.

While the *Pearson* decision has attracted some controversy, NFPA rejects the mischaracterizations of the law being employed by critics relying on the politics of fear, and not the law, in warning that the First Amendment obligations of the Agency cannot be fulfilled without threatening the public health. These warnings are groundless. The First Amendment protections provided to those manufacturers engaged in sharing substantiated health information with consumers in no way diminishes the legal responsibility of manufacturers under the FD&C Act to ensure that the food products that are presented for sale to consumers are safe and accompanied by accurate labeling. Likewise, the First Amendment protections in no way diminish the legal authority of FDA under the FD&C Act to take enforcement action against food products that are unsafe, or deceptively labeled.

The steps FDA must take to abide with the requirements of the First Amendment fully support public health. There is no question that FDA has been charged with critically important responsibilities for regulating food to protect the public health. At the same time, there can no longer be any question that the First Amendment requires FDA to become more disciplined in the regulatory methods it chooses to employ as the "means" for serving the "ends" of public health protection. The First Amendment sets clear and firm boundaries on Agency authority, and these require FDA to accept the limits of its own knowledge, experience, resources, and perspective, and to respect the rights and values of others who wish to share substantiated health information of interest and value to the members of the public. The First Amendment does not permit FDA to employ regulatory methods that abolish all expressions of health information by manufacturers except for those the Agency has the capacity and resources to endorse.

In our 1994 citizen petition, NFPA presented for FDA consideration a broad and concrete proposal for reconstructing the regulations FDA adopted in implementing the health claim and nutrient content claim provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). As our petition discussed, no benefit to public health can result from the arbitrary obstacles codified in FDA rules 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. By opening the channels of communication in the ways the First Amendment requires, the creative energies of responsible food manufacturers can be put to work exposing the truth about the ways in which the ordinary food choices consumers make in the grocery store aisles can make a powerful difference in their personal health status. The reforms the First Amendment requires would better equip food manufacturers 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 wisdom and efficacy of the First Amendment as a matter of public health policy comes through the ability of consumers at the "grassroots" to make well-informed decisions concerning their personal health. 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.

The 1994 NFPA petition proposed concrete reforms of FDA policy which would go a long way in addressing First Amendment concerns. These proposals include systemic reforms of FDA's health claims policy which anticipated and are responsive to the court's First Amendment ruling 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 1994 NFPA petition detailed the indisputable and persistent violations of the First Amendment that have resulted from the FDA policies implementing the 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 fully rebutted each defense FDA offered for its choice to ignore First Amendment requirements in the regulations implementing the NLEA.

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. 60 Fed. Reg. 66206 (December 21, 1995). 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 at page 7 [Docket No. 94P-0390 and 95P-0241].

In a letter to FDA Commissioner Jane Henney, MD submitted on April 4, 2000, NFPA again urged FDA to take the First Amendment obligations presented in the 1994 NFPA petition seriously, and objected to FDA’s legally groundless policy to exclude conventional foods from the food labeling reforms adopted in response to the *Pearson v. Shalala* decision.

“FDA’s strategy for implementing the Pearson v. Shalala decision excludes conventional foods, even though the violative FDA policy addressed in Pearson applies squarely to conventional foods. FDA’s strategic decision is particularly disappointing since there is a pending FDA rulemaking on conventional food health claims which was initiated specifically in response to a 1994 NFPA Citizen Petition . . . seeking health claim policy reforms on the same First Amendment grounds now required by the court in Pearson . . .

Our intention with this comment was to advise FDA of its responsibility to implement general reforms required under the Pearson decision with respect to health claim policies for conventional foods, and to do so promptly in the context of the Agency’s rulemaking in response to the 1994 NFPA Citizen Petition. We must emphasize, however, that we

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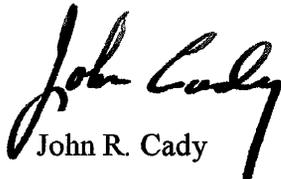
would object to FDA publishing a final rule without providing for full consideration of the First Amendment issues in the context of the pending rulemaking. These issues no longer can be ignored by FDA under Pearson.

NFPA believes most strongly that the Pearson decision applies to health claims for conventional foods. To implement the Pearson decision fully, FDA must ensure that the policy reforms needed to protect truthful, nonmisleading health claims from unconstitutional regulation extend equally to both conventional foods and dietary supplements.”

While the administrative record before the Agency documenting the need for First Amendment reforms of FDA food labeling regulations surely will be strengthened and expanded in response to the recent FDA notice, the record already established in connection with the 1994 NFPA citizen petition amply supports the reforms the NFPA petition proposed. A summary of the NFPA proposals and the FDA response is presented in Attachment A to this letter.

The still-pending 1994 NFPA citizen petition provides the Agency with an important opportunity to address the First Amendment issues presented by the *Pearson v. Shalala* decision and the related body of First Amendment case law in a manner that is systematic and fair. FDA can achieve real progress through a rulemaking proceeding that reopens consideration of the 1994 NFPA citizen petition and addresses the critical First Amendment issues presented there, which FDA has unlawfully ignored.

Best regards,


John R. Cady

Actions requested in 1994 NFPA Citizen Petition
to FDA on Health Claims and Nutrient Content Claims Policy
[Docket No. 94P-0390]
and FDA Response

A. Enhanced Flexibility for Synonyms and Implied Nutrient Content

1. 1994 NFPA Citizen Petition: Proposed that FDA issue regulations authorizing the use of synonyms and implied nutrient content claims that are not specifically defined in FDA regulations but are reasonably understood by consumers to have the same meaning as a defined term. The NFPA proposal would require such claims to be “anchored” through the use of the corresponding defined term in product labeling.

2. FDA Proposal: Would amend regulations to permit the use of “anchored” synonyms that have not been defined by FDA regulation, but would require the defined term to be used immediately adjacent to the anchored claim, and would prohibit claims modifying defined terms (e.g., “source”). NFPA comments on the FDA proposal objected to the burdensome restrictions of the FDA proposal, arguing that the proposal failed to provide the relief requested even for claims specifically mentioned in the NFPA petition (e.g., “great source of calcium”). In recent enforcement actions, FDA has continued to maintain an expansive interpretation of its authority to regulate nutrient content claims, strictly enforcing current policy prohibiting undefined synonyms and implied claims in ways that plainly violate the First Amendment.

B. Jelly Bean Rule and Disqualifying Levels

1. 1994 NFPA Citizen Petition

a. Jelly Bean Rule: Proposed regulations to allow health claims to be made for foods that contain less than 10 percent of the Daily Value for protein, fiber, vitamin A, vitamin C, calcium, or iron; require any food bearing a health claim that refers to a nutrient that has been added to the food to disclose the nutrient addition;

b. Disqualifying Levels: Proposed regulations that would convert disqualifying levels to disclosure levels of the kind required for nutrient content claims where the presence of a nutrient is not directly related to the disease to

which the health claim refers. The regulations would require only disclosure by an appropriate referral statement in conjunction with the health claim. The proposal would require disqualification only where the nutrient was found in another health claim regulation to be directly and adversely related to the disease mentioned in the claim.

2. FDA Proposal:

a. Jelly Bean Rule: Proposed to maintain jelly bean rule except for “dietary supplements, fruit or vegetable products composed solely of fruits and vegetables, enriched grain products [and bread] that conform to a standard of identify”

b. Disqualifying Levels: Denied NFPA request.

C. Mechanisms for Streamlining FDA Approval of Health Claims

1. 1994 NFPA Citizen Petition: Proposed that FDA adopt regulations authorizing health claims where the scientific basis for any such claim is affirmed by the findings of a qualified panel of experts and a premarket notification is submitted to FDA. The petition included a similar proposal for nutrient content claims.

2. FDA Proposal: Denied Request.

Based on an authoritative statement of scientific body of the Federal Government, a modified version of the NFPA proposal was adopted in the 1997 FDAMA Amendments.