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

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

RE: Docket No. 02N-0209, Request for Comment on First
Amendment Issues (67 FR 34942, May 16, 2002)

Dear Sir or Madam:

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

- 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, 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.

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- NFPA previously filed comments on this docket on July 9, 2002. NFPA appreciates the opportunity to provide additional perspective on this important matter. In these comments, NFPA addresses the majority of questions that FDA posed in its notice of May 16, 2002. As NFPA focuses on food issues, our comments address those questions that are relevant for food labeling. NFPA advances perspectives that address the issues of both prohibited speech and required speech.

Responses to FDA's questions:

1. Are there arguments for regulating speech about drugs more comprehensively than, for example, about dietary supplements? What must an administrative record contain to sustain such a position? In particular, could FDA sustain a position that certain promotional speech about drugs is inherently misleading, unless it complies with FDA requirements? Does anything turn on whether the

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speech is made to learned intermediaries or to consumers? What is the evidentiary basis of such a distinction?

The First Amendment provides strong support for regulatory reforms that attenuate the level of regulatory scrutiny for articles subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act), with respect to the actual safety and anti-deception issues presented. While substantial attention has been given to the regulation of commercial speech for foods in the context of “health claims” made in food labeling, relatively little attention has been directed toward the onerous restrictions placed on food labeling, advertising, Internet and other promotions as a result of FDA’s expansive reading of the “drug” definition set forth in section 201(g)(1)(C) of the FD&C Act. The broad interpretation of the “drug” definition operates to ban truthful claims concerning the health benefits of foods, both in the context of FDA policy distinguishing “structure-function” claims from “disease” (i.e., “drug”) claims, and also by creating an overbroad definition of “health claim,” which operates to subject claims unnecessarily to burdensome premarket approval requirements.

Under the First Amendment, truthful and non-misleading claims for conventional food products are fully protected. The FDA policy that operates in effect to ban substantiated claims simply because they mention a “disease” term cannot be justified under the commercial speech doctrine. FDA commonly issues warning letters to food companies that raise no question concerning the accuracy or substantiation supporting the claim, but rather threaten and intimidate companies into discontinuing valuable claims, by taking the position that certain terms and words simply cannot be said for an ordinary food product unless a New Drug Application (NDA) first is approved by FDA. FDA has taken enforcement action against common beverage products in the grocery store aisles arguing that these foods cannot be sold until an NDA is approved, or certain “disease” words are removed from the company website. Such actions fail to account for the First Amendment protections extended to all expressions and terms companies may wish to employ, and rely on a regulatory standard which simply cannot be justified on constitutional or public health grounds.

In *Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002), the Supreme Court struck down FDA’s ban on advertising of “compounded drugs” which operated as a condition for the exemption from NDA approval requirements for these drugs. By way of analogy, under current FDA policy interpreting the “drug” definition in section 201(g)(1)(C), “food” status is conditioned on the FDA ban of “disease” terms in food labeling, advertising, and other promotions. In both cases, FDA has defended its policy as necessary to preserve the integrity of the NDA system. In *Thompson*, while the Supreme Court recognized the value of the NDA system, it held that FDA could not carry

its burden to defend the broad advertising ban, and found the amount of beneficial speech that was prohibited by the FDA policy to be unconstitutional. The Court emphasized that, "If the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort. Yet here it seems to have been the first strategy the Government thought to try." *Id.* at 1507.

The *Thompson* decision firmly establishes that, despite the important public interests in the integrity of the NDA system, these interests cannot justify the ban of truthful information of benefit to consumers. Ultimately, we believe that FDA cannot justify imposing NDA requirements on any conventional food product that is safe under FD&C Act requirements simply because a "disease" term is used in labeling or advertising. A breakfast cereal or fruit juice product should not fall subject to NDA requirements as a condition of promoting new information on the health benefits of a food, which can be conveyed together with other well substantiated benefit statements (e.g., "now with a crunchier taste"). Taken together with the *Pearson v. Shalala* decision, it seems clear that the only standard that FDA can justify for the regulation of commercial speech for conventional food products, regardless of the vehicle (i.e., food labeling, advertising, Internet) or the terminology (i.e., health claims, disease claims, etc.), is a straightforward substantiation standard of the kind that is firmly established under the Federal Trade Commission (FTC) Act, the Lanham Act, and consumer protection laws of the 50 states.

Question 2 is not addressed in these comments.

3. May FDA distinguish claims concerning conventional foods from those relating to dietary supplements, taking into account limits on claims that can be made about foods in the Nutrition Labeling and Education Act, 21 U.S.C. 301, 321, 337, 343, 371? What must an administrative record contain to sustain or deny claims on food labels? How can information best be presented in a succinct but non-misleading fashion? To what extent do assertions in claims need qualifications or disclaimers added to the label to avoid any misconceptions that consumers may draw? Is there a basis to believe that consumers approach claims about conventional foods and dietary supplements differently?

NFPA believes that this question is best answered through a focus on the context of FDA's strategy, articulated in past years, for implementing the *Pearson v. Shalala* decision. FDA's implementation strategy has focused on dietary supplements to the exclusion of conventional foods, even though the violative FDA policy addressed in *Pearson* applies squarely to conventional foods. FDA's strategy is particularly frustrating since there has been pending, since 1997, an FDA rulemaking on conventional food health claims that was initiated specifically in response to a 1994 NFPA citizen petition (Docket No. 94P-0390), which sought health claim policy reforms on the same First Amendment grounds now required by the court in *Pearson*. NFPA has already commented with respect to the issues raised in our

1994 petition and the current FDA request for comments on First Amendment issues (comment submitted July 9, 2002, Docket No. 02N-0209).

Both conventional foods and dietary supplements should benefit equally from the principles advanced through the *Pearson* decision. FDA's announced strategy to implement the *Pearson* decision improperly treats the holding of that case as though it applies only to dietary supplements. The basic First Amendment concerns expressed by the *Pearson* court did not turn on the fact that the health claims issues were raised by dietary supplement marketers. Three of the four health claims sub-regulations invalidated by the court (21 CFR §101.71(a), (c), and (e)), as well as FDA's interpretation of its general health claims regulation (21 CFR §101.14) apply equally to dietary supplements and conventional foods. The *Pearson* court explicitly noted that FDA regulates health claims for dietary supplements and conventional foods using the same substantive standard for authorization and procedure for evaluating a claim's validity. *Pearson v. Shalala*, 164 F.3d at 653 note 2.

As noted in the *Pearson* decision, the actual First Amendment violation arose directly from FDA's policy under the "significant scientific agreement" standard, which FDA applies equally to conventional foods and dietary supplements. We see no way that FDA can remedy the First Amendment violation found in *Pearson* and limit its consideration to dietary supplement health claims alone. This approach is plainly inconsistent with FDA's long-standing policy and practice of regulating health claims for conventional foods and dietary supplements identically. In the preamble to FDA's final rule on health claims for dietary supplements, the Agency stated that "applying the same standard and procedure to health claims on dietary supplements as that which applies to foods in conventional food form ... will subject all segments of the food industry to regulation in a fair and consistent manner." (59 FR 395, at 403; January 4, 1994). This is a position the government continued to take in District Court argument in the *Pearson* case. *Pearson v. Shalala*, 14 F. Supp. 2d 10.

NFPA believes that the principles of the *Pearson* decision should apply to all classes of foods, including both conventional foods and dietary supplements, and should extend beyond the scope of health claims. In general, FDA should permit, even encourage, the communication of all forms of truthful, non-misleading, and well substantiated statements on the labels and labeling of food products. This approach would enable FDA better to meet its obligations under the First Amendment, and would in fact allow FDA to maintain public health protection while not constraining the right to speech. NFPA believes that, as currently applied, FDA's practices regarding the regulation of speech are in conflict with the First Amendment.

FDA should replace its policy of prohibiting and otherwise restricting speech with a new policy that broadly permits and encourages all forms of truthful, non-misleading speech. The *Pearson* decision fundamentally pronounced that more speech is of greater benefit to consumers than prohibition of speech, and that more speech may remedy speech that is potentially misleading. Following this tenet reduces the debate to a discussion of what constitutes truth, what is a non-misleading statement, and what is required to substantiate a representation. In this context, a health claim may be evaluated in the same manner as all other label statements, consistent with the authorities in the FD&C Act.

NFPA believes that FDA should alter its framework for pre-clearance of health claims on foods and dietary supplements by making room for all health claims that are supported by scientific evidence providing a reasonable basis for the specific claim that is made. This approach would be consistent with the *Pearson* decision. Reforms are needed to minimize the need for claim-by-claim premarket clearance, and to eliminate prescriptive requirements with respect to the expression of claims. Without such reforms, the First Amendment standards of *Pearson* are unlikely to be satisfied. NFPA believes that significant headway can be made through "safe harbor" regulations which provide guidance to manufacturers concerning the construction of substantiated health claims, but do not prescribe the specific requirements concerning the expression of such claims. Regulatory approaches that attempt to confine the content of expression are inherently suspect under the First Amendment and should be avoided by the Agency.

As we argued in our 1994 petition, FDA should provide for means other than health claims pre-approved through petitions to encourage the expression of statements on the disease risk reduction of certain foods and diets. NFPA believes that FDA would be well served by adopting an adjudicatory modality, rather than a prior approval modality, for the evaluation of such health benefit statements. Under an adjudicatory modality, FDA would take enforcement action against foods in interstate commerce that contain label statements that are false or misleading, but would otherwise permit all health claims that are supported by scientific evidence providing a reasonable basis for the specific claim that is made.

NFPA believes that FDA could foster well-supported health claims through the development of guidance of the kind the Federal Trade Commission (FTC) has issued from time-to-time, which articulates the principles that must be considered in determining whether a specific claim is substantiated by scientific evidence providing a reasonable basis for the claim. Such guidance can be readily developed, since these principles form the foundation of the anti-deception provisions of the FTC Act, Lanham Act, and the consumer protection laws of the

50 states. There is no need for FDA to duplicate those existing provisions. NFPA advocated this type of approach in our 1994 petition.

Under a FTC-type standard, FDA could establish a policy that food companies making representations on food labels assemble the scientific evidence providing a reasonable basis for the specific claim that is made. The expression of the representation should be qualified to reflect the nature and weight of the scientific evidence supporting the specific claim that is made, and in appropriate circumstances may include such expressions as “preliminary research suggests that ...” or “while inconclusive, new research tends to indicate that ...” or “although all scientists do not agree with these findings, recent studies have shown that ...” Thus, the wording of the claim itself would include all elements needed to ensure that the claim is non-misleading.

FDA should not prescribe any statement 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. 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.

NFPA believes that substantiation of a claim must be developed and maintained by the firm making the claim. Submission of this information to FDA should not be required. If FDA has questions regarding the substantiation of a label representation, the Agency should make a showing that it has reason to believe the speech is false, misleading, or inadequately substantiated. FDA should bear in mind that, under the First Amendment, the burden is on the government to prove that speech is false or misleading.

Having made such a showing that it has reason to believe a label representation is false, misleading, or inadequately substantiated, FDA should allow the firm to demonstrate the substantiation to support the claim. FDA should proceed with an enforcement action to ban a health claim only where the Agency can establish that the claim is misleading. The First Amendment places the burden of proof on the Agency to establish that the speech it wishes to restrict is not protected under the *Central Hudson* test, as reflected in the *Pearson* decision.

4. Should disclaimers be required to be in the same (or smaller or larger) size of type and given equal prominence with claims? Is there any relevant authority or social science research on this issue?

NFPA notes that issues surrounding the prominence of label statements relate to whether such label statements are misleading. It is the responsibility of food

companies that market to consumers to ensure that label representations are non-misleading. NFPA sees no need for FDA to prescribe prominence requirements for disclaimers. It would be sufficient for FDA to limit its intervention to guidance that notes that disclaimers should be reasonably related in prominence to the claim. In an evaluation of prominence, the context of the entire label must be taken into consideration. NFPA believes that any unreasonable requirements with respect to label element prominence likely would itself be in conflict with the First Amendment.

5. How can warnings be made most effective in preventing harm while minimizing the chances of consumer confusion or inattention? Is there any evidence as to which types of warnings consumers follow or disregard?

It is the responsibility of the company marketing foods to ensure that any warnings are non-misleading. Companies in the regulated industry also take into account product liability issues, which will tend to ensure that any warning statements are clear to the consumer.

FDA regulations have required certain warning statements on food labels. NFPA believes that these regulated warning statements should be frankly recognized as required speech. With respect to required speech, FDA carries substantial burdens: first, in establishing a scientific basis that justifies a required statement; second, in determining that the required statement is the best approach to advance the government's interest in a specific matter; and third, in determining that the specific wording of a required statement explicitly communicates the intended message in a manner that most effectively and efficiently advances the government's interest in a matter.

NFPA maintains that this is a heavy burden that FDA seldom shoulders. While some label statements required by regulation are built on a scientific basis, others are not, such as the required statement regarding use of ionizing radiation to treat food. FDA typically does a questionable job in proving that a required statement is the best approach to advancing the government's interest. This can be illustrated by drawing a parallel between the two FDA-permitted options for the labeling of food that has been treated with ionizing radiation – “Treated with radiation” or “treated by irradiation” – as expressed at 21 CFR 179.26(c)(1), with the array of statements for the labeling of meat and poultry products that have been irradiated, under the more flexible regulation adopted by the Food Safety and Inspection Service of the U.S. Department of Agriculture (9 CFR 424.22(c)(4)(iv); 64 FR 72149, December 23, 1999). That Agency has evaluated and permitted such statements as : “Treated with irradiation for your food safety,” “Treated with irradiation for food safety,” “Treated with irradiation to improve food safety,” “Treated with irradiation to reduce the potential for foodborne

illness,” “Treated with irradiation to reduce *E. coli* bacteria,” “Treated with irradiation to reduce pathogens such as *E. coli* and *Salmonella*,” “Irradiated for your food safety,” and “Irradiated for food safety.”

Seldom if ever does FDA determine that a required label statement explicitly communicates the intended message in a manner that most efficiently advances the government’s interest in a matter. To meet this burden, FDA should determine conclusively that a required statement **and no other** is the most effective in communicating the intended message to consumers. If other language is equally effective in communicating the message, FDA must permit other expressions of the required concept. FDA should make such a determination even if the statute prescribes a required statement, as the burden of proof with respect to required speech would not have been satisfied through the legislative process. FDA has an obligation to implement and enforce the law in a manner that is consistent with the First Amendment.

6. What arguments or social science evidence, if any, can be used to support distinguishing between claims made in advertisements and those made on labels? Does the First Amendment and the relevant social science evidence afford the Government greater latitude over labels?

NFPA reminds FDA that the Agency itself, in 1995, conducted consumer research on health claims and nutrient content claims, in the context of the Keystone National Policy Dialogue on Food, Nutrition and Health (final report, 1996). NFPA believes that the results of this research reinforce the perspective that companies that market products to consumers are responsible for ensuring that specific claims are truthful and non-misleading. NFPA is unaware of any social science evidence providing a reason to give the government greater latitude over labels than over advertising. In fact, substantiation and anti-deception principles are very much case-specific and are handled in line with First Amendment principles when marketers are held responsible for ensuring the truthfulness of their claims, but not for adhering to limited and preconceived claim formats, regardless of whether the vehicle of speech is a label or an advertisement.

Nevertheless, First Amendment considerations would prevail over any social science evidence in the communication of truthful, non-misleading information, on food labels. NFPA notes that there is a greater chance that a label claim will be truthful and non-misleading if that specific claim is substantiated by scientific evidence providing a reasonable basis for the claim as expressed. This substantiation policy, which NFPA strongly advocates, would allow for the presentation of truthful, non-misleading label statements that resonate with consumers.

Question 7 is not addressed in these comments.

8. Do FDA's speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?

It is NFPA's belief, as we noted in our 1994 petition, that **no** benefit to public health can result from the arbitrary obstacles, embedded 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, as expressed in the proposed Regulatory Impact Analysis for mandatory nutrition labeling rules (56 FR 60856, November 27, 1991), that the Agency itself recognizes that the public health benefit promised by the NLEA can only be attained by opening the channels of communication of health information in food labeling to consumers in ways that are genuinely effective and motivating. NFPA equally believes that barriers to truthful, non-misleading, and well-substantiated speech **impede**, rather than advance, communications to consumers on public health subjects.

These impediments are not limited to communications comparable to health claims. NFPA believes that one of the reasons that food irradiation is not widely used by food processors is that irradiated food products are required to bear labeling designed to communicate to consumers a message comparable to a warning. The required food irradiation label statement tends to steer consumers away from accepting this important food safety technology, and thereby impedes advancement of the public health.

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 delivering truthful messages about the ways in which the food choices that 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 individual consumers to make well-informed decisions concerning their personal health. The First Amendment assures that the people themselves have direct access to information they determine to be of greatest value and importance in making everyday food choices affecting their personal health. In the aggregate, these personal choices determine the public's health.

9. Are there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?

There are numerous FDA regulations, policies and guidance documents related to food labeling that run afoul of the First Amendment. NFPA has assembled some examples of FDA regulations, policies, and guidance documents related to food labeling, and the following table illustrates examples of First Amendment problem areas. The table should be understood to be a broad indicator, rather than an exhaustive iteration, of the regulations and policies that FDA should change in the light of governing First Amendment authority. NFPA has not included those areas of health claims and nutrient content claims regulations for which we petitioned for amendments in 1994. NFPA notes that the problematic labeling regulations and policies illustrated in the table appear in several different areas of FDA's food regulations, including standards of identity and food additive rules, as well as in food labeling regulations themselves. In most instances, the examples illustrate regulations and policies that require a particular form of speech and do not accommodate or encourage alternate means of presentation.

Type of Speech Restriction: Required label statement, no alternate language provision

Issue	Description	Citation
Irradiation Labeling	Labeling of foods in package form treated with ionizing radiation. "Treated with radiation" or "treated by irradiation." Additional presentation requirements.	21 CFR 179.26(c)(1)
Olestra Labeling	Labeling of food products containing Olestra. "This Product contains olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added." Additional label presentation requirements.	21 CFR 172.867
Aspartame Labeling	Labeling of foods containing aspartame. Label must bear on PDP or information panels the statement "PHENYLKETONURICS: CONTAINS PHENYLALANINE"	21 CFR 172.804(d)

Sugar Alcohol Labeling: Mannitol	Labeling of foods containing mannitol, statement required when anticipated daily ingestion is 20g or more. "Excess consumption may have laxative effect."	21 CFR 180.25
Sugar Alcohol Labeling: Sorbitol	Labeling of foods containing sorbitol, statement required when anticipated daily ingestion is 50g or more. "Excess consumption may have laxative effect."	21 CFR 184.1835
Polydextrose Labeling	Labeling of foods containing polydextrose, a single serving of which would be expected to exceed 15 grams of the additive, must bear the statement "Sensitive individuals may experience a laxative effect from excessive consumption of this product."	21 CFR 172.841(d)
Warning Labels for Unpasteurized Juice	Labeling of juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens shall bear the following statement: "WARNING: This juice has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Additional label presentation requirements.	21 CFR 101.17(g)(2)
Labeling of Sell Eggs	The label of all shell eggs must bear the following statement "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly." Additional presentation requirements.	21 CFR 101.17 (h)
Nutrient Content Claim Disclosure Statements	Disclosure statements for nutrient content claims on foods that exceed specified nutrient levels.	21 CFR 101.13(h)

Type of Speech Restriction: Excessively Restrictive Standard

Issue	Description	Citation
Implied "Disease" Claims	Structure-function claims determined to be "implied" disease claims.	21 CFR 101.93
Standard for Health Claims	Guidance on "significant scientific agreement" standard notes that the standard is met when the validity of the substance/disease relationship is not likely to be reversed by new and evolving science, and when the validity of the relationship is supported by the conclusions of federal government scientific bodies. The guidance notes that conclusions of independent, expert bodies may also be relevant, but appears to be not as strong a criterion as federal government acceptance.	Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, December 22, 1999
Internet Representations	FDA approach to Internet representations for foods would deem some statements to be considered food labeling .	Letter of Margaret M. Dotzel, FDA Associate Commissioner for Policy, to Washington Legal Foundation, November 1, 2001.

Type of Speech Restriction: Required statement based on potentially trivial differences with comparison food

Issue	Description	Citation
"Imitation" Labeling	Labeling of "imitation" foods named with a standardized term, yet "nutritionally inferior". Nutritional inferiority may include trivial differences in nutrient content, as low as 2% Daily Value.	21 CFR 101.3(e)

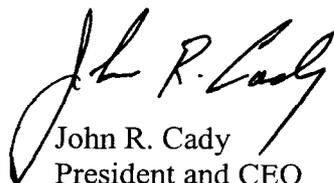
Type of Speech Restriction: Required label statement, the need for which is eliminated by general regulations

Issue	Description	Citation
Identity of Standardized Food	Standard of identity, canned prune juice, name of food "Prune juice – a water extract of dried prunes." Naming convention is rendered unnecessary by such general regulations as : 21 CFR 101.4, 21 CFR 101.30, 21 CFR 102.33, 21 CFR 130.11	21 CFR 146.187(c)

In addition to these examples, NFPA believes that FDA has exceeded First Amendment authority in the issuance of certain warning letters. Several warning letters issued in June 2001, by the FDA Office of Nutritional Products, Labeling and Dietary Supplements, interpret the term "with" as an undefined synonym for the nutrient content claim "contains." NFPA notes that FDA did not justify its assertion in any of the June 2001 warning letters. NFPA recommends that FDA develop enforcement strategies that are consistent with the First Amendment, and preserve Agency resources to enforce the enforceable.

NFPA thanks you for consideration of these comments, anticipates an opportunity to respond to FDA's regulatory proposals, and welcomes the challenge of working with FDA towards an improved environment for communicating truthful, non-misleading information on food labels.

Sincerely,



John R. Cady
President and CEO
National Food Processors Association