



May 23, 2001

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NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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

[Docket No. 01D-0058] Guidance on Applying the
Structure/Function Rule; Request for Comments
66 Federal Register 11172, February 22, 2001.

Dear Sir or Madam:

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

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202-639-5900

NFPA commented in September 1998 on a related docket, 98N-0044, Regulations
on Statements Made for Dietary Supplements Concerning the Effect of the
Product on the Structure or Function of the Body, the proposed rule that resulted
in the January 6, 2000 final rule (65 FR 1000), which is the subject of the
contemplated guidance.

NFPA is the voice of the \$460 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's 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 believes that FDA should promulgate guidance to explicate acceptable and unacceptable structure/function claims, in order to provide interpretation for 21 CFR §§101.93(f) and (g).

The preamble to the January 6, 2000 final rule (65 FR 1000) is extensive and sufficiently complex. Consequently, there is merit to extracting the examples of acceptable and unacceptable structure/function claims that permeate that preamble and convert those examples into guidance. As a general rule, preambles to final rules present a discussion of the comments received on the proposal, as well as the Agency's decisions regarding amendments and requests for clarification put forward in those comments. Only through careful review of an entire preamble can one discern the practical examples that are compatible, and incompatible, with the Agency's regulatory decisions. The preamble to the January 6, 2000 final rule runs for 49 pages in the Federal Register. FDA would do a great service to the food and dietary supplement industries by condensing into a single, compact guidance document the numerous examples of structure/function claims and "disease" claims interspersed through that text.

NFPA further believes that a guidance that includes many examples of acceptable and unacceptable structure/function claims will enrich the general understanding of the Agency's views on the definition of "disease." To this end, the examples in the guidance should be accompanied by a brief summary of the basis for the Agency's determination that a particular example likely is, or is not, an acceptable structure/function claim; or whether it is, or is not, likely a "disease" claim. NFPA further believes that the examples that FDA includes in the guidance should include illustrations of what the Agency considers to be implied "disease" claims, as well as expressed claims.

NFPA also requests that FDA provide examples of structure/function claims from the Agency's current review of the statements submitted through notification by dietary supplement manufacturers and marketers. Some current statements submitted through the notification process have not been acceptable to FDA, yet appear to conform to §§101.93(f) and (g). If the theoretical constructs used in the current rule do not readily translate to acceptable statements, NFPA believes that it is evident that useful guidance is necessary. It would enhance the industry's understanding of acceptable structure/function claims if realistic examples are explained.

NFPA suggests that illustrations of the types of acceptable and unacceptable structure/function claims should follow the general structure of the final rule at 21 CFR §§101.93(f) and (g). Following this structure would necessitate developing guidance on the citation of a publication or a reference implying the treatment or prevention of a disease, as this is the subject of §101.93(g)(2)(iv)(C).

NFPA further suggests that FDA elaborate upon the use of specific words that might be employed to construct structure/function claims. For example, in the January 6, 2000 preamble, FDA notes that "helps promote digestion" likely would be an acceptable structure/function claim, while "promotes low blood pressure" would not be acceptable (66 FR 1000 at 1006). Both claims use the verb "promote" in different ways. Thus it is clear that the choice of verb alone is not an indicator of a "disease" claim, unless the selected verb is "diagnose," "prevent," "treat," "cure" or "mitigate" (65 FR 1000 at 1011).

It is clear from parts of the preamble to the January 6, 2000 final rule that duration of symptoms may be a critical factor in determining whether a statement may be an acceptable structure/function claim or a "disease" claim. The Agency cites, for example, "for relief of occasional constipation" as an acceptable structure/function claim under §101.93, while statements of an effect on chronic constipation may be suggestive of treatment of a symptom of serious disease (65 FR 1000 at 1015). NFPA urges FDA to include in its guidance further examples of this nature, which could include explanation of structure/function claims addressing occasional restlessness, occasional forgetfulness, occasional fatigue, or occasional difficulties with joint flexibility.

Likewise, severity of symptoms appears to be an additional critical concept in structure/function claims, evidenced by FDA's differentiation of mild and severe abnormalities associated with several conditions. The Agency noted that such differentiation could apply to conditions such as mild menstrual dysfunctions versus cyclical depression, characteristic skin and scalp changes associated with aging versus the more serious chronic diseases of aging, and mild adolescent acne versus cystic acne (65 FR 1000 at 1020). NFPA believes that the guidance on structure/function claims should include clear illustrations that reflect the relative severity of symptoms on acceptable and unacceptable statements.

NFPA believes that a systematic review of the preamble to the January 6, 2000 final rule is likely to produce a wealth of examples of acceptable and unacceptable structure/function claims. These examples will be useful not only for dietary supplements as regulated under the Dietary Supplement Health and Education Act, but will be of great assistance as the food industry explores the possibility of using structure/function claims on conventional foods. NFPA notes that the Agency has articulated "FDA advises, however, that for consistency, the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements" (65 FR 1000 at 1034). NFPA therefore encourages FDA to develop guidance on structure/function claims for dietary supplements.

NFPA strongly believes that elaborating such guidance is likely to be useful not only in the domestic food labeling environment, but will also be of assistance in an international

National Food Processors Association

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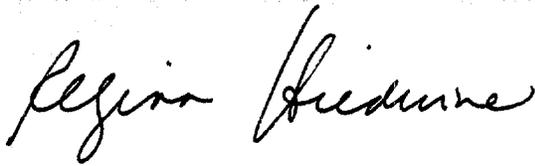
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context, especially as Codex Alimentarius develops guidelines on the use of health and nutrition claims in food labeling, which include concepts analogous to structure/function claims.

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

Sincerely,

A handwritten signature in cursive script, reading "Regina Hildwine". The signature is written in black ink and is positioned above the typed name and title.

Regina Hildwine
Senior Director, Food Labeling and Standards
Regulatory Affairs