

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



February 13, 2004

141 Northwest Point Blvd
Elk Grove Village, IL 60007-1098
Phone: 847/434-4000
Fax: 847/434-8000
E-mail: kidsdocs@aap.org
http://www.aap.org

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

Re: Docket No. 2003N-0496

Executive Committee

President

Carden Johnston, MD, FAAP

President-Elect

Carol D. Berkowitz, MD, FAAP

Executive Director

Joe M. Sanders, Jr, MD, FAAP

Board of Directors

District I

Eileen M. Ouellette, MD, JD, FAAP
Newton Center, MA

District II

Robert M. Corwin, MD, FAAP
Rochester, NY

District III

Alan E. Kohrt, MD, FAAP
Philadelphia, PA

District IV

David T. Tayloe, Jr, MD, FAAP
Goldsboro, NC

District V

Ellen Buerk, MD, MEd, FAAP
Oxford, OH

District VI

Kathryn Piziali Nichol, MD, FAAP
Madison, WI

District VII

Gary Q. Peck, MD, FAAP
New Orleans, LA

District VIII

Jon R. Almquist, MD, FAAP
Federal Way, WA

District IX

Burton F. Willis, MD, FAAP
Huntington Beach, CA

District X

Charles W. Linder, MD, FAAP
Augusta, GA

Immediate Past President

E. Stephen Edwards, MD, FAAP

To whom it may concern:

On behalf of the 57,000 members of the American Academy of Pediatrics (AAP), I offer the following comments regarding the Advance Notice of Proposed Rulemaking, *Food Labeling: Health Claims; Dietary Guidance* published in the *Federal Register* on November 25, 2003 (68 FR 66040).

The AAP is the national professional organization representing physicians who provide health care to our infants, children, adolescents, and young adults. In that role, the AAP has developed extensive policy guidelines regarding adequate and safe diets for these age groups.

First, as a general comment, the AAP believes that the US Food and Drug Administration (FDA) must consider the ramifications of food claims on *all* children. The unique dietary needs of infants, children, adolescents, and young adults are not addressed in the November 2003 document. Further, the effect of these changes, if implemented, on the regulations of infant formulas and infant foods is not clear. Although infant formula manufacturers are not permitted to market new infant formulas without first being approved by the FDA, the health claims of infant foods and formulas are less strictly governed.

Second, the AAP - like the American Medical Association (AMA) - opposes the use of qualified health claims in the labeling of conventional foods." If this labeling practice continues despite the concerns of the medical community, the FDA should not lower the "significant scientific agreement (SSA) standard" to the "weight of the scientific evidence standard", as detailed by the FDA. The effects of such a change would be potentially confusing to consumers, especially parents who will not have any basis upon which to apply specific food standards towards the health of their children.

With respect to the **specific alternatives for regulating health claims** that do not meet the SSA standard of evidence (i.e., qualified health claims) required to evaluate the scientific validity of health claims detailed in the November 2003 announcement, the Academy offers the following comments:

2003N-0496

C12

- 1) The Academy applauds the Task Force on Consumer Health Information for Better Nutrition Initiative (“Task Force”) for recognizing that its discussions were enriched by partnerships with sister public health agencies and others in the medical community. We encourage the Task Force to continue these relationships and look forward to working with the FDA on this and other important health matters.
- 2) The Academy supports Option 1 (“incorporate the interim procedures and evidence-based ranking system into a regulation under notice-and-comment rulemaking”) as the most efficacious and best option of the three that are provided. A pre-market clearance system appears to be the most prudent to help prevent potential mishaps, and the ability to “readily revise its decision about a qualified health claim if subsequent data were to indicate the need to do so” is appealing. However, the Academy is concerned about the use of a “clarifying disclaimer”. If these are used, the Academy suggests close regulation, including approval of disclaimers that are employed in any product label.
- 3) The Academy believes that Option 2 (“reinterpret the SSA standard to apply to the accuracy of the characterization of the evidence supporting the claim, instead of the underlying substance-disease relationship, and subject qualified health claims to notice-and-comment rulemaking”) is less desirable than with Option 1 for several reasons. Most notably, the phrasing of a qualified health claim becomes problematic, since much is left open for subjective interpretation. Phrases such as “limited and preliminary scientific evidence suggests...” could allow for almost any claim based on minimal data. This process is also described as “burdensome” to the FDA and may potentially be subject to challenge according to the first amendment.
- 4) The Academy believes that Option 3 (“treat qualified health claims as wholly outside the Nutrition Labeling and Education Act of 1990 [NLEA] and regulate them solely on a post market basis, if they are false or misleading”) should not be pursued as it potentially exposes the public to products that could be mislabeled. Additionally, FDA control would be difficult under Option 3, as actions might not occur until months or years following complaint or adverse events reports.

Regarding the **issues raised in the Task Force Report**, the Academy offers the following comments:

- 1) The Academy concurs with eliminating the word “may” from unqualified health claims to eliminate the uncertainty about the science underlying claims that meet SSA. Claims should be based on SSA and show effect; otherwise they should not be made. A qualification might be useful, such as a footnote that further scientific studies are needed to determine the interaction of the specific nutrient with other nutrients in the diet. In addition, the FDA might consider qualifying the available data: (e.g., Level 1: SSA confirms the claim; Level 2: SSA is suggestive of a claim but does not account for potential nutrient-nutrient interactions; Level 3: SSA does not confirm the claim and the claim cannot be made.)

- 2) The Academy suggests not using the interim final rules (IFR) process, as safety should be the primary concern - especially with children. An IFR format could allow manufacturers to avoid obtaining further data unless their claim and/or product was later deemed inaccurate and/or unsafe. Further, the IFR process could lead to development of habits of usage and nutrient ingestion that might create problems should the claim be disallowed at a later date.
- 3) The Academy is concerned that the use of such phrases as "FDA authorized" could lead to consumer confusion. The Academy is also concerned about the applicability of qualified claims and dietary recommendations on labels, as these would not be appropriate for children.
- 4) The Academy agrees that consumer education should be an integral part of the FDA's work concerning qualified health claims. We are available to assist the FDA in educating parents and older children/adolescents, as well as health care providers to pediatric patients on the use of health claims and diet and health matters.
- 5) The Academy suggests that the FDA commission specialty groups to review the SSA pertaining to areas of expertise within each group. The Food Advisory Committee (FAC) could either assist with the selection of these groups of experts or work with the FDA to provide final approval of a review by a specialty group pertaining to a specific claim or product. The FDA could seek the opinion of various specialty groups, including the AAP, to help with this process.

Pertaining to issues related to **dietary guidance**, the AAP offers the following comments:

- 1) The Academy suggests distinguishing guidelines from recommendations or claims made regarding specific foods or nutrients. Thus, the example given of claims made based on a dietary guideline to justify all grains in the diet should not extend to mean that claims for each specific grain be made on labels. The FDA should specifically require each food substance rather than a "broad category of food" to be appropriately labeled and tested to meet the claim that is being made.
- 2) The Academy believes that statements that make a claim based on a substance would appear to be easier to justify and support with SSA than food-specific claims. The latter would require testing of each food, a process that would seem almost impossible to accomplish. However, as noted above, maybe a footnote leading to a statement that the nutrient should be considered in the context of a whole food or diet.
- 3) The Academy strongly advises that the FDA not engage in recommending food substitutions or replacements. This is a complicated process that involves consideration of each individual's nutritional requirements and genetic predispositions that would potentially influence which foods would be recommended in place of others. This process seems better suited towards the education of the public, as suggested above, and could involve the Academy to help educate the public directly and through pediatric care providers.
- 4) The Academy notes that dietary guidelines are established by other agencies and as such do not need to be reinvented by the FDA. Specifying dietary guidelines on labels seems

on the surface to be helpful. However, the Academy is concerned that certain parties might use the dietary guidelines to promote specific products. For example, a low fat diet might be the only piece of the recommendations placed on a label to justify a high carbohydrate/low fat product that otherwise would not be the most healthful choice in an overall diet of a child (who might need additional calories for growth, might need fewer calories due to overweight, or for a child under 2 years of age who should not have fat restricted). If this policy is implemented, however, we encourage the FDA to partner with the Academy to consider implications of the labeling for children and to consider appropriate criteria that evaluate the scientific validity of guidelines as applied in children.

Finally, with respect to any future analysis of benefits and costs, the Academy notes that infants, children and adolescents have different nutritional and therefore dietary requirements that must be considered in determining health claims and their subsequent effects. Questions such as "What effects do health claims have on consumer purchases of foods and dietary supplements?" and "What effects do health claims have on the total diet?" must be asked - and answered - from a pediatric perspective. Similarly, issues concerning consumers' willingness to buy products with various health claims must be examined from a pediatric point of view.

The Academy welcomes the opportunity to comment on this important matter. Please contact me or Molly Hicks in the Academy's Washington Office (202/347-8600) if we can be of any further assistance.

Sincerely,



Carden Johnston, MD, FAAP
President
American Academy of Pediatrics

CJ:ptk