

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Food Labeling: Nutrient Content Claims,)
General Principles; Health Claims,)
General Requirements and Other)
Specific Requirements for Individual)
Health Claims; Reopening of the Comment)
Period)
_____)

Docket Nos. 94P - 0390
and 95P - 0241

Comments of

Center for Science in the Public Interest

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Division of Dockets Management
5630 Fishers Lane
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Re: Docket Nos. 1994P-0390 and 1995P-0241

The Center for Science in the Public Interest (CSPI) is filing these comments on proposed changes to FDA's nutrient content and health claims regulations.¹ These comments supplement those filed by CSPI on March 20, 1996 and address issues that have arisen with the advent of the Consumer Health Information for Better Nutrition Initiative.

In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA) with widespread bi-partisan support. The bill, a product of two years of negotiations and compromise, was greeted enthusiastically by both consumer and public health groups, as well as the food industry. More than 13 years later, an examination of marketplace data and consumer behavior surveys provide clear evidence that the NLEA has been a success. Consumers are using food labels to select more healthful foods.²

¹ 69 Fed. Reg. 24541 (May 4, 2004), 60 Fed. Reg. 66,106 (Dec. 21, 1995).

² Consumers who use nutrition labels consistently consume fewer calories from fat, cholesterol and sodium and consume more fiber. Dr. Rodolfo M. Nagaya, Professor, Dept. Of Agricultural Economics at Texas A& M University, 2003. *Do Nutritional Labels Affect Caloric Intakes and Diet Quality?* Prepared for the FDA Workshop: Exploring the Link Between Food Labeling and Weight Management. Base brands have significantly increased their levels of positive nutrients, while brand extensions have reduced their levels of negative nutrients. Christine Moorman, *Market-Level Effects of Information: Competitive Responses and Consumer Dynamics*, Journal of Marketing Research (Feb. 1998) at 82-89. Base brands are the regular

Despite the success of the NLEA, the food industry has continually pressured FDA to weaken some of its rules implementing the Act. We understand the Agency's need to be responsive to the industry it regulates and to correct any unintended problems created by its regulations. However, the FDA's primary responsibility is to protect the public's health and to ensure the welfare of consumers. Therefore, we urge FDA to move cautiously and conservatively in its review of the labeling rules to ensure that any changes are truly in the best interest of the public.

I. FDA Should Not Undermine the Consumer Protection Provisions for Health Claims in the NLEA.

Health claims are an extremely powerful marketing tool that have a great potential for misleading consumers. Although health claims can also be educational, this can only occur if they are regulated properly. For this reason, we urge the Agency to proceed with great caution in revising its health claim rules. Caution is particularly important at this time because FDA has reduced the evidentiary requirements necessary to support health claims by exercising its enforcement discretion to permit qualified health claims.

Some members of the food industry have argued that FDA's health claim regulations are so strict that virtually no claims are being made. In fact, we estimate that hundreds of brand-name products already bear FDA-approved health claims.³ Considering that many major food

versions of products, that is not reduced fat, reduced calorie etc. Brand extensions are nutritionally improved versions of the base brands.

³ Data from FDA's 2000-2001 Food Labeling and Packaging Survey (FLAPS) indicate that 56 out of 1,281 products surveyed included a health claim stating the relationship between a component of the product and a disease. The top product groups for health claims were: hot cereals, 75.5%; refrigerated juices/drinks, 66.2% and frozen juices/drinks beverages, 41.9%. The survey did not include products sold in less than 10% of the retail market, or food products sold in

companies are making health claims under FDA's current regulations, the Agency should require that any changes in the rules be supported by data clearly demonstrating that the proposed change will benefit consumers.

A. FDA Should Retain the 10-Percent Nutrient Contribution Requirement for Health Claims.

CSPI strongly supports the 10-percent requirement, although we support exemptions for particularly healthy foods including:

- Fruits and vegetables that are processed or prepared with nutritionally insignificant amounts of oil, sodium, or sugar. Such products should not contain a significant amount of sauce, syrups, or similar ingredients.
- Whole grain breads, cereals, pasta, pancakes, crackers and other whole grains.

One goal of the NLEA is to help consumers improve their health by eating a better diet.

Encouraging the consumption of foods – like candy and soda – that provide calories but few nutrients, fiber or phytochemicals does nothing to further this goal and, in fact, undermines it.

The 10-percent nutrient requirement is aimed at prohibiting these less-than-nutritious foods from making health claims and must be maintained.

B. FDA Should Retain Disqualifying Nutrient Levels for Health Claims

CSPI strongly supports FDA's decision not to replace disqualifying levels for health claims with disclosure levels. We believe that such a change would violate the spirit, if not the letter, of

retail stores other than supermarkets. Lori LeGault, Mary Bender Brandt, et. al., *Perspectives in Practice, 2000-2001 Food Label and Package Survey: An Update on Prevalence of Nutrition Labeling and Claims on Processed, Packaged Foods*, Journal of the American Dietetic Association (June 2004). These findings indicate that a median average size supermarket stocked with 22,000 products may contain more than 960 food items that bear health claims. (Calculation is based upon Nielsen survey finding of 22,000 SKUs. *Facts, Figures, & the Future*, A.C. Nielsen (May 10, 2004) available at http://www.factsfiguresfuture.com/archive/may_2004.htm#top.

the NLEA. The Act expressly provides that health claims can be made for "a food that does not contain . . . any nutrient in an amount which increases . . . the risk of a disease."⁴ This general provision is accompanied by a narrow exception, which allows a food that contains a risk-increasing nutrient to make a health claim, based on a specific finding regarding that particular nutrient.⁵

The structure of this provision of the NLEA supports the view that FDA should rarely invoke its authority to permit a health claim when a disqualifying level is exceeded. FDA should grant this exemption only when virtually all foods containing required levels of a vital nutrient would be disqualified.⁶

Rather than seeking a wholesale change in FDA's disqualifying rule for health claims, food companies should be taking advantage of the petition process set up by the NLEA to permit a particular claim containing more than the qualifying level of a particular nutrient. Through this process, manufacturers of salad dressings and spreads were able to obtain permission to exceed the disqualifying level for fats on products otherwise qualifying for the use of claims for plant stanol and sterol esters and the reduction of coronary heart disease.⁷

C. FDA Should Prohibit Use of the Word "May" in Unqualified Health Claims

CSPI believes that FDA should eliminate the use of the word "may" in health claims

⁴ Section 3(A)(ii) of the NLEA.

⁵ *Id.*

⁶ As an example, we suggested in our February 1992 comments that an exemption would be appropriate if FDA permitted health claims for fish oils, and if the only good source of the oils were fish that exceeded the disqualifying level for fat and/or cholesterol.

⁷ 21 C.F.R. § 101.83.

supported by significant scientific agreement and should reserve its use for qualified health claims.

In issuing the 1993 regulations governing health claims based upon significant scientific agreement (SSA), FDA predicted that most claims would be qualified by the word “may” because “absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial.” Thus, regardless of the healthfulness of a person’s diet, certain individuals may be predisposed to developing particular diseases. The Agency, therefore, concluded that “health claims must be free to use the term ‘may’ with respect to the potential to reduce the risk of the disease.”⁸

In the intervening years and with FDA’s acquiescence to the use of qualified health claims, the term “may” has been reinterpreted by consumers to refer to the uncertainty surrounding the science supporting the claim as opposed to the unknown effect of a diet on a particular individual. For example, the Task Force on Consumer Health Information for Better Nutrition Initiative recommended that FDA seek comments on removing the “may” from health claims that meet SSA, so that the uncertainty surrounding claims such as ‘calcium may reduce the risk of osteoporosis’ is eliminated.”

In light of the FDA’s position that qualified health claims are legal⁹ and the fact that the term “may” is now being interpreted to cast doubt on the validity of unqualified health claims, we

⁸ 58 Fed. Reg. 2478, 2504 (Jan. 6, 1993).

⁹ CSPI believes that permitting the use of qualified health claims violates both the substantive and procedural requirements of the NLEA. CSPI and Public Citizen are challenging the legality of claims not meeting the significant scientific agreement standard. *Center for Science in the Public Interest, et.al. v. FDA* (case No. 03-cv-01962 D.D.C.)

believe that health claims supported by SSA should no longer contain the word “may.” Instead, the claims could state “_____ reduces the risk of -----.” The word “may ” should only be used in qualified claims (in the event that a court rules they are permissible under the Act – an event we believe is unlikely occur), in addition to other qualifiers, to indicate the uncertainty of the science behind the claim.¹⁰

D. FDA Should not Allow “Split” Health Claims Health Claims

CSPI does not object to FDA's tentative decision to make optional some of the elements that it currently requires to be included in health claims. We agree with the FDA that, once these revisions are finalized, claims already approved by the Agency will be brief enough to permit their use on the principal display panel.

However, we do not agree with the Agency's tentative decision to allow the splitting of longer and more complex claims, such as the health claim for calcium and osteoporosis. FDA is proposing to allow the separation of those elements necessary to ensure that the claim is truthful and not misleading from those elements that are necessary to understand the significance of the claim in the context of the total daily diet. We believe that this distinction is an artificial one, which is not supported by the law. We believe that FDA should allow the splitting of a health claim only when it is necessitated by the small size of the package.

If FDA allows the splitting of certain health claims, then it must not approve a split until it has received data demonstrating that the new abbreviated claims are not in use and that splitting the claim will not significantly decrease the likelihood that consumers will read the full statement.

¹⁰ A claim that promises to “reduce the risk” of a disease does not promise to *prevent* the illness. Rather, it promises to lower the odds, or risks, that the disease will occur.

II. Nutrient Content Claims: FDA Should Prohibit the Use of Unapproved Synonyms

As we stated in our 1996 comments, CSPI strongly opposes allowing the use of unapproved synonyms for defined terms used in nutrient content claims. The proliferation of illegal low-carbohydrate claims strengthens our belief that nutrient content claims language must be closely regulated. In the absence of FDA action to define carbohydrate claims, manufacturers have developed a series of synonyms, , e.g., carb counting, carb smart, carb aware, carb control, carb conscious and carb options, to convey the impression that the products are low in carbohydrates. Furthermore, these claims are often based on different methods of calculating carbohydrate content declared as net carbs, impact carbs or similar terms on the label. These claims are confusing to consumers and thwart the NLEA goal of developing a “limited lexicon” of terms that consumers can rely on to understand the nutrient content of the foods they eat.

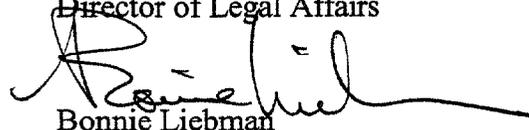
III. Conclusion

CSPI appreciates this opportunity to comment on proposed changes to FDA’s food labeling regulations, and looks forward to working with the Agency in the future to ensure that the goals of the NLEA are achieved.

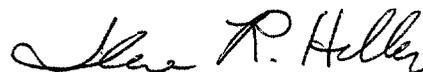
Respectfully submitted,



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