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BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In The Matters of	)	
	)	
	)	Docket Nos. 91N-0384
	)	84N-0153
	)	85N-0061
	)	91N-0098
Nutrition Labeling: Nutrient Content	)	91N-0099
Claims: Health Claims; Ingredient	)	91N-0094
Labeling; Proposed Rules	)	91N-0096
	)	91N-0095
	)	91N-0219

Comments of the Staffs of
the Bureaus of Economics and Consumer Protection
of the Federal Trade Commission

February 25, 1992

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*These comments are the views of the staffs of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Anne Maher (202-326-2987), Bureau of Consumer Protection or Alan Mathios (202-326-3495), Bureau of Economics.

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I. INTRODUCTION AND SUMMARY

The Nutrition Labeling and Education Act of 1990 (NLEA)[1] requires the Secretary of Health and Human Services, through the Food and Drug Administration (FDA), to make sweeping changes in the regulations governing food labels. Under a tight time schedule, FDA has published over 500 pages of proposed regulations for food labels implementing these requirements and has requested comments on many aspects of these proposals.[2] Based on our experience in analyzing the effects of information in consumer product markets and in considering regulations that address information issues, the staffs of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission (FTC) offer the following comments to assist FDA in its deliberations.[3]

The FTC enforces sections 5 and 12 of the Federal Trade Commission Act, prohibiting deceptive or unfair practices in or affecting commerce.[4] One of the FTC's major responsibilities is

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[1] Pub. L. No. 101-535, 104 Stat. 2353 (1990)(codified in part at 21 U.S.C. §§ 343(i)(q),(r)).

[2] 56 Fed. Reg. 60,365-891 (1991)(to be codified at 21 C.F.R. Part 101, et al.).

[3] These comments are the views of the staffs of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner.

[4] 15 U.S.C. §§ 45 et seq. The FTC has jurisdiction over the advertising of food and has concurrent jurisdiction with the FDA and USDA over the labeling of food. The FTC also has statutory authority to enforce a number of laws that mandate disclosure, including the Federal Cigarette Labeling and

(continued...)

to regulate national advertising, and historically, the FTC has considered the prevention of deceptive food advertising to be of utmost importance. At the same time, the FTC appreciates that food advertising can effectively provide useful nutrition information to consumers. The FTC has developed considerable expertise in understanding the roles of advertising and labeling in providing consumers with information,[5] and regularly considers such issues in food advertising. While we recognize that there are important differences between claims on food labels and those in advertising that may require different regulatory approaches,[6] we believe our expertise has a bearing on many of the issues FDA has addressed.[7]

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[4](...continued)
Advertising Act, the Truth in Lending Act, and the Energy Policy and Conservation Act, which regulates appliance labeling, and to enforce several laws relating to standard-setting, including the Wool Products Labeling Act and the Magnuson-Moss Warranty & FTC Improvement Act. In addition, the FTC has promulgated disclosure rules, such as the R-Value Rule, which regulates thermal insulation labeling, the Used Car Rule, which requires warranty disclosures, and the Care Labeling Rule, which regulates clothing labeling.

[5] Relevant FTC staff research includes: P. Ippolito & A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market (1989); M. Lynch, R. Miller, C. Plott & W. Porter, Experimental Studies of Markets With Buyers Ignorant of Quality Before Purchase: When do 'Lemons' Drive Out High Quality Products? (1986); M. Frankena, M. Cohen, T. Daniel, L. Ehrlich, N. Greenspun & D. Keenan, Alcohol, Advertising, Consumption, and Abuse, (1985).

[6] See Letter from Federal Trade Commission to Senator Slade Gorton, September 25, 1991.

[7] Meat and poultry product labels are regulated by the United States Department of Agriculture (USDA). The USDA has proposed regulations that directly parallel the substance of the (continued...)

Our analysis is founded on the premise that consumers can improve their diets in two ways. First, they can switch from foods they are currently eating to the healthiest foods that are available (e.g., substituting vegetables and fruit for high fat desserts). Second, consumers can switch to more nutritious or more healthful versions of the foods they are currently eating (e.g., substituting lean meats or chicken for fatty meats, or margarine for butter). If, as a recent survey shows,[8] many consumers are unlikely to give up their favorite foods in order to improve their diets, then switching to healthier versions of those favorite foods may prove especially important. This comment analyzes how the proposed regulations are likely to affect consumers' ability to make more informed choices for both types of dietary change.

Another premise of this comment is that nutrient claims on a package's front label serve a different function than information on the label's nutrition panel. For example, a nutrition panel on the back of a package may provide useful information, but may be relatively ineffective in generating consumer interest in a

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[7](...continued)
FDA's regulations in most of the respects discussed in this comment. 56 Fed. Reg. 60,301-64 (to be codified at 21 C.F.R. Parts 317, 320 and 381). The USDA proposals differ from FDA's in some respects. For example, USDA proposes to adopt voluntary labeling for many raw meat and poultry products and to adopt the additional defined terms, "lean" and "extra lean." Because it appears that the USDA and the FDA are following similar courses, we will also consider here the effects of the FDA proposals on meat and poultry products, whenever appropriate.

[8] Survey of American Dietary Habits, The American Dietetic Association, (1991) at 12.

new and innovative product. Truthful nutrient claims on the front of the package, however, may be helpful in alerting consumers to more healthful products they might consider in efforts to improve their diets. Thus, this comment also examines how the proposed regulations will help consumers find better products, and how this could affect innovation in food markets.

Much of what FDA has proposed will provide valuable nutrition information to consumers. However, we are concerned that, in some respects the regulations go beyond the NLEA's statutory requirements and may have unintended undesirable effects. We believe FDA should consider changes that could enhance the regulations' effectiveness; these are summarized below and discussed in more detail in the remainder of the comment.

A. Nutrient Content Claims

As required by the NLEA, FDA defines terms that companies must use to characterize the level of a nutrient in a food.[9] The definitions for absolute nutrient content claims (those that do not refer to other products), such as "low," "high" and "free," would provide clarity and certainty through the use of simple terms that highlight foods with the lowest (or highest) levels of various nutrients. These terms should be helpful to consumers attempting to identify such foods. However, the proposed definitions for absolute nutrient content claims are

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[9] See Section 3(b)(1)(A)(iii), 104 Stat. at 2361 (regulations for the implementation of 21 U.S.C. § 343(r)).

based on uniform standards that apply across all food groups, and most foods, including many that can help consumers improve their diets, do not meet the standards in these "low" and "high" definitions.

The proposed regulations would prohibit manufacturers of food products that do not meet the "low" or "high" thresholds from simply featuring the amount of a nutrient on the front of the labels for these products. For example, claims such as "50 calories per serving" or "6 grams of fat per serving" are prohibited on the front label, even though this information appears on the mandatory nutrition label.

Such a prohibition eliminates many factual claims that could help consumers make better food choices and increase producers' incentives to improve the nutritional composition of their products. Under the proposed regulations, most cereals, fruits and vegetables could not feature the grams of fiber in the product on the front of the label, and similarly, most lean meat, poultry and fish products could not point out the grams of fat or saturated fat, or milligrams of cholesterol in the product. We believe that FDA should authorize simple statements of the amount of a nutrient in a food, unless FDA has reason to believe that in a particular circumstance such a declaration is likely to mislead consumers. In addition, we believe that FDA should authorize additional terms so that producers of healthful foods that do not meet the "low" or "high" thresholds have a simple way to display nutrient information to consumers.

Because few labels could feature simple, absolute nutrient content claims, relative claims (i.e., those that explicitly make comparisons with other products), such as "reduced" and "less" could become the most important way labels encourage dietary changes and stimulate innovation and competition on nutrition. The proposed regulations for relative claims would require lengthy disclosures, requiring that all relative claims identify the comparison food and provide several pieces of information on the characteristics of the two foods.[10] While this approach will provide added information if such claims are made, the required disclosures appear to be so extensive that they may discourage many claims, especially those that compare products on several nutrient dimensions. Since the proposed disclosures, in part, duplicate information available in the mandatory nutrition panel, we question whether the added convenience of two sources of nutrient disclosures on the product's label is worth the potential loss of truthful claims that may be discouraged by the added requirement.

The proposed regulations would also limit which products may be compared. The proposals aim to eliminate trivial or irrelevant comparisons by requiring that products achieve minimum absolute and percentage reductions before qualifying to make particular claims and by restricting the foods against which comparisons may be made.[11] These provisions may eliminate many

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[10] See 56 Fed. Reg. at 60,446.

[11] See id. at 60,445-47.

objective comparisons that could help consumers select more nutritious foods and therefore, may unnecessarily limit the flow of useful nutrition information to consumers. For example, the rules would not allow brand-to-brand comparisons (e.g., "our cola has 25% fewer calories than Coke"), comparisons across food groups (e.g., "our fruit cocktail for dessert instead of cake saves you 8 grams of fat"), or clear comparisons that are below the threshold amounts (e.g., "30 calories less than our regular brownie that contains 80 calories").

FDA requests comment on an alternative approach to relative claims that would retain the minimum absolute difference requirement and most of the restrictions on the types of foods that could be compared, but would not require the compared product to meet a minimum percentage difference.[12] We believe that eliminating the minimum percentage difference requirement is an improvement, but remain concerned that the alternative proposal still prohibits brand-to-brand comparisons, comparisons across food groups, and clearly stated comparisons for products when the differences between them are smaller than the threshold amounts. We believe that relative claims that numerically disclose the difference between products in a nonmisleading way would meet the requirements of the NLEA, allow many more truthful

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[12] Under this alternative proposal the terms "reduced" and "less" could be used interchangeably. Use of either term would require that the food be compared with an accepted reference food and that the difference in the amount of the nutrient between the reference food and the product with the claim meet or exceed the "low" threshold for that nutrient.

claims than the current proposal, and still be effective in controlling deceptive and misleading claims.

Finally, the proposed regulations require that "a nutrient content claim be, in type size and style, no larger than that of the statement of identity."[13] While we appreciate FDA's concern that single nutrients can be overemphasized, we suggest that FDA reconsider this proposal. Style and format play an important role in effective marketing, which is critical to bringing information to consumers' attention, and to successful product innovation. If particular claims mislead consumers, through excess prominence or other such means, these claims can be restricted under the overall requirement that no claim may mislead consumers.

B. Health Claims

We agree with FDA that claims that truthfully relate the health reasons for better food choices are potentially very important to consumers, and that developing regulations for health claims are among the most important challenges in FDA's efforts to redefine the regulations governing food labels. We believe, however, that there are a number of ways in which the proposed regulations could be modified to enhance their ultimate success. We are concerned that the proposed regulations are more restrictive than is necessary to comply with the NLEA's mandate and in several ways could prevent truthful health claims for many

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[13] 56 Fed. Reg. at 60,424.

products the consumption of which has been encouraged for health reasons by dietary authorities.

Under the proposed regulations, many foods may be labeled with relative nutrient content claims, but may not bear health claims. Nonetheless, FDA Diet and Health surveys[14] and the FTC staff's study of the cereal market[15] indicate that relative nutrient claims alone are unlikely to educate consumers about diet and disease relationships. Consumers who do not know why a particular nutrient is important appear less likely to react to nutrient content claims than consumers who understand the disease implications of the particular nutrient. Moreover, FDA surveys show that even many highly educated consumers lack knowledge of the most basic diet-disease relationships.[16]

FDA has proposed "disqualifying nutrient levels" for total fat, saturated fat, cholesterol and sodium. A product that exceeded the disqualifying level for any of these nutrients on the basis of serving size, reference amount, or per 100 grams of food) could not bear a health claim about any diet-disease

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[14] These are national telephone surveys directed by the FDA in collaboration with the National Heart, Lung, and Blood Institute (NHLBI). For a detailed description of the survey see Levy and Stephenson (1990), "Nutrition Knowledge Levels About Dietary Fats and Cholesterol: 1983-1988:" Draft, Division of Consumer Studies, FDA.

[15] Ippolito & Mathios, supra note 5.

[16] See id.

issue.[17] FDA further proposes that foods also must satisfy the definition of "low" or "high" for the nutrient involved in the claim.[18]

Many foods that can improve diets, including foods that dietary authorities recommend to consumers, could not meet one or more of the thresholds proposed for health claims, and thus labels for these products could not explain the health reasons for considering them. Several aspects of the proposed regulations raise concerns, because they could inadvertently serve to undermine the goals that underlie FDA's health claims policy, many of which we share.

First, the proposed cholesterol disqualifying level appears to be based on behavioral assumptions about consumption patterns that are not borne out by USDA consumption data. Thus, health claims for some foods that would otherwise meet the NLEA requirements may be excluded unnecessarily.

Second, no food may exceed <u>any</u> of the disqualifying levels: (a) per serving size; (b) per reference amount; and (c) per 100 grams of food. This last requirement is intended to prohibit foods with small serving sizes on a weight basis from making health claims if they contain relatively high concentrations of

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[17] These levels implement the NLEA's requirement that health claims be used only for a food that does not contain any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related, taking into account the significance of the food in the total daily diet. 21 U.S.C. § 343(r)(3)(A)(ii).

[18] This additional provision does not appear to be required by the NLEA.

the targeted nutrients. USDA data suggest, however, that the addition of this 100 gram criterion disqualifies foods such as cereals and breads, which dietary authorities recommend for increased consumption and which typically are not consumed in 100 gram amounts per serving. Accordingly, we suggest that FDA reconsider whether its proposed 100 gram requirement is likely to be successful in identifying foods that raise the risk of disease, taking into account the significance of the food in the total daily diet.

Third, we believe there are important reasons for the Secretary of HHS to use the discretion afforded him under the NLEA to allow health claims for some foods that exceed the disqualifying levels in particular nutrients, in cases where such claims would assist consumers in maintaining healthy dietary practices.[19] Most importantly, under the proposed regulations the entire category of cooking oils would be prohibited from bearing claims that mention the health reasons for choosing oils that are lower in saturated fat, since all oils are above the fat disqualifying level. The same issues are raised in the margarine market. While FDA's concern about not allowing misleading claims that would encourage increased fat consumption is appropriate, it also is important to allow truthful claims to convey to consumers the importance of focusing on the type of fat in the fats they do consume. This issue is particularly compelling because, as FDA recognizes in its review of the science, the evidence linking

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[19] See 21 U.S.C. 343(r)(3)(A)(ii).

saturated fat consumption to heart disease is among the strongest evidence connecting diet to health risks.

Fourth, the proposed regulations exceed the requirements of the NLEA and require foods to meet the "low" or "high" thresholds for the nutrient in the claim if they are to bear health claims. This proposed requirement would prevent producers of many foods from explaining how their product could help consumers realize improvements in diet. For example, this requirement would prohibit the lowest fat meat, fish and poultry products from having labels that explain why consumers should switch from higher fat products to lower fat alternatives. Under the proposals, manufacturers of the vast majority of foods in the American diet will be prohibited from displaying product label messages urging consumers seeking to improve their health to care about the fat, saturated fat, cholesterol, sodium or calcium content in their diets. For these reasons, we suggest that FDA not require foods to meet the "low" or "high" thresholds in order to bear a health claim. Instead, we suggest that FDA consider allowing truthful, nondeceptive comparative health claims for foods that could help consumers identify substitutions that might improve their diets and their health.

Fifth, the proposed regulations would permit health claims for four diet-disease relationships: calcium and osteoporosis, lipids (fats) and cancer, lipids and heart disease, and sodium and hypertension. We suggest that FDA not limit its consideration of diet-disease relationships to narrowly construed

"nutrient-disease" claims. Instead, because consumers could benefit from this information, FDA might also consider permitting other claims relating diet to health provided they meet the NLEA-required standard of significant scientific agreement. For example, we recommend allowing claims linking diets with high levels of fiber-rich foods and a reduced risk of cancer, if FDA concludes that the required scientific support for this claim exists. Moreover, we recommend that properly qualified claims should also be permitted where there is the NLEA level of scientific agreement.

Finally, we recommend that the regulations treat references to dietary guidance from public health authorities (e.g., the National Institutes of Health and the Surgeon General) not as health claims, but as claims analyzed under FDA's general regulatory requirement that a label claim be truthful and nonmisleading. Public health organizations can be more effective in reaching consumers with valuable advice, if products that fit into their recommendations are free to display this information on their labels. Additionally, consumers are more likely to notice and appreciate the significance of dietary recommendations, if they come from respected public health organizations.

II. ABSOLUTE NUTRIENT CONTENT CLAIMS

FDA's proposed regulations govern two types of nutrient content claims on labels. The first type is absolute nutrient content, such as "low fat" and "cholesterol free," which do not refer to other food products. The second type is relative nutrient content claims, such as "less fat" and "reduced cholesterol," which make comparisons with other products. This section comments on absolute nutrient content claims. Section III addresses relative claims.

The NLEA requires that FDA mandate certain nutrition information on food labels,[20] and further requires that FDA prohibit any claim that characterizes the level of a nutrient, unless the claim uses terms that are defined by FDA regulation.[21] FDA proposes to implement these statutory requirements by establishing the elements required to appear on the nutrition panel and by defining several absolute terms, including "low," "high," "source" and "free." Defining these absolute terms appears to reflect an intention to provide simple claims to highlight foods with the lowest (or highest) levels of important nutrients. These claims should be helpful to consumers attempting to identify these foods.

Further, FDA prohibits all quantitative nutrient statements (e.g., "5 grams of fat per serving" or "50 calories per serving") unless the food meets the relevant definition for "low" or

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[20] 21 U.S.C. § 343(q)(1).

[21] 21 U.S.C. § 343(r)(2)(A)(i).

"high."[22] Our examination of USDA food data indicates that only a limited set of foods meets the definitions of "low" and "high." Most foods, including many entire food categories, do not meet the standards in these "low" and "high" definitions and, as a result, could not display truthful statements on the front label about the quantities of key nutrients contained in them. This aspect of the regulations eliminates many factually correct statements that could help consumers make better food choices and increase producers' incentives to improve the nutritional characteristics of their products. Most cereals and nearly all fruits and vegetables could not report their fiber content. For example, an apple contains approximately 3 grams of fiber but cannot have a label that displays this fact, because it does not meet the 5 gram threshold for "high" fiber. Similarly, broccoli cannot have labels displaying fiber content since a serving of broccoli contains approximately 3 grams of fiber. Additionally, most lean chicken and fish products and most lower fat cheeses could not report their fat, saturated fat, or cholesterol content. For example, broiled haddock contains approximately 4 grams of fat per serving but would not be able to have a label

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[22] See 56 Fed. Reg. at 60,426. FDA adopts this interpretation from the NLEA provision which states that the agency "shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined [by FDA]," Pub. L. No. 101-535, 104 Stat. 2353,2361. See 56 Fed. Reg. at 60,426. This interpretation assumes that all amount and percentage statements are misleading or inconsistent with defined terms for foods that do not meet the FDA's definitions of "low" or "high."

that displays this fact since the "low" threshold is 3 grams of fat.

For these reasons, we suggest that FDA consider approving other terms for labels and, in particular, reconsider its decision to ban from labels simple numerical claims of nutrient quantities for foods that do not meet the "low" or "high" definitions. Indeed, these claims might well be so useful to consumers in making improved food choices that consideration be given to making them presumptively legal and prohibited only in specific cases where such declarations are likely to be false or to mislead consumers.[23]

In addition, since effective communication helps consumers' absorb information from packages on crowded supermarket shelves, the proposed restrictions that would limit the size and distinctiveness of nutrient claims might make it more difficult for consumers to notice more healthful and improved products. Consequently, we also believe FDA should consider not restricting

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[23] In some circumstances factual content declarations can mislead. For example, if it can be determined that a statement such as "contains 10 milligrams of cholesterol" leads consumers to believe erroneously that the product is low in saturated fat and can help reduce serum cholesterol, some form of regulation may well be warranted. A triggered disclosure of the saturated fat content of the product, with an appropriate context, however, would appear not to discourage dissemination of truthful information. Such a triggered disclosure, therefore, might be a more appropriate and effective solution than a ban in such cases. We believe that this approach is more consistent with the NLEA, which provides, for example, that "high fiber" claims on products that do not meet the "low fat" definition trigger a grams of fat disclosure. 21 U.S.C. § 343(r)(2)(A)(v). See 21 U.S.C § 343(r)(2)(A)(iii-iv).

the type size and style used by firms to present FDA-approved claims.

The remainder of this section describes the proposed FDA regulations governing absolute nutrient content claims and provides the underlying basis of our recommendations.

A. Overview of the Proposed Regulations

1. Mandatory Label

In accordance with the NLEA, FDA proposes to require that, with few exceptions, all product labels contain a mandatory nutrition panel.[24] For each product, the panel requires disclosure of the numerical quantity of several nutrients, vitamins and minerals. Table 1 lists the key mandatory items included on the panel.

The proposed regulations also require that the mandatory nutrition panel contain the Recommended Daily Intake (RDI) or Daily Reference Values (DRV) for each nutrient for which one of these is defined. This provides a context for consumers to assess the significance of the product's nutrient content or nutrient claims.[25] Table 1 provides the applicable RDI or DRV for each of the mandatory nutrients on the panel and lists other key information also required to appear thereon. We agree with FDA that the elements of the mandatory panel are important, in

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[24] 56 Fed. Reg. at 60,367.

[25] Id. The DRVs are FDA-specified values for maximum daily intake level for eight nutrients which are not vitamins or minerals. The RDI is analogous to the Recommended Daily Allowance (RDA) currently in use for vitamins and minerals.

TABLE 1

Major Requirements for Nutrition Label and Related Definitions

Mandatory Nutrients	DRV or RDI[1]	Other Required Information
Total fat (g)[2]	75	Serving Size
Saturated fat (g)	25	Servings per container
Cholesterol (mg)	300	Calories
Total Carbohydrates (g)	325	Calories from fat
Complex Carbohydrates (g)	NA	
Sugars (g)	NA	
Dietary fiber (g)	25	
Protein (g)	50	
Sodium (mg)	2400	
Vitamin A (mg RE)	875	
Vitamin C (mg)	60	
Calcium (mg)	900	
Iron (mg)	12	
Other approved nutrients if added as supplement or if claim is made.		

Definitions of Label Terms

"Reference Amount"	FDA-specified quantities of food customarily consumed for over 100 categories of products to be used as a basis for determining labeled serving size.
"Serving size"	Amount to be listed on label developed from reference amount, as specified in FDA regulations, e. g., for products in discrete units, the number of units closest to the reference amount for the product category.
"Daily Reference Value" (DRV)	FDA-specified values for maximum intake level of eight nutrients, i.e., fat, saturated fat, unsaturated fat, cholesterol, carbohydrates, fiber, sodium and potassium.
"Reference Daily Intakes" (RDI)	Recommended amounts for protein and 26 vitamins and minerals for five age groups.

SOURCE. FDA Proposed Labeling Rules, *Federal Register*, Vol. 56, November 27, 1991.

NOTES. [1] RDI listed is for adults and children 4 or more years of age for the specified vitamins and minerals. DRVs apply to the eight nutrients listed in the definition of DRV. NA is not available, that is, not defined by the FDA.

[2] Required units of measure are grams (g), milligrams (mg) and retinol equivalents (mg RE), as noted.

part, because they provide the background information on the label against which other label claims can be considered by consumers.

2. Absolute Nutrient Content Claims

FDA proposes to implement the NLEA requirements for absolute claims by establishing nutrient thresholds that must be met before a product may use approved terms such as "low," "high," "source," or "free," on labels, as shown in Table 2.[26] FDA would also define all claims that expressly or implicitly relate to any nutrient as claims that characterize the level of a nutrient, and thus, make such claims subject to FDA regulation under the NLEA.[27] Under this definition, FDA would prohibit all percentage claims for which it has discretion,[28] unless the food meets the "low" or "high" definition. All claims stating the amount of any nutrient would also be prohibited, unless the product meets the "low" or "high" definition for the nutrient in question,[29] as would all ingredient claims that could relate to

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[26] See, e.g., id. at 60,432-45.

[27] See, e.g., id. at 60,423-27.

[28] See id. at 60,426. Statements that describe the percentage of a vitamin or mineral in the food in relation to the RDI are not included here, because these statements are specifically exempted from FDA regulation by the NLEA.

[29] See id. In some circumstances, the NLEA or the FDA requires the disclosure of the amount of particular nutrients for products that are not "low" in the nutrient. For example, a product with a "high fiber" claim is required to disclose its fat content in grams in close proximity to the fiber claim, if it is not "low" in fat, see 21 U.S.C. § 343(r)(2)(A)(v), even though it would not be allowed to disclose its fat content in the absence of the fiber claim.

TABLE 2

Basic Requirements for Proposed Absolute Nutrient Claims[1]

Claim	Requirements	Amounts
"Low Fat"	3 grams fat or less*	
"Low Cholesterol"[2]	20 mg cholesterol or less*	
	2 grams sat. fat or less*	* [Per Serving Size and Per Reference Amount and Per 100 grams of food
"Low Sodium"	140 mg sodium or less*	
"Low Calories"	40 calories or less*	
"Low Saturated Fat"[2,3]	1 gram sat. fat or less+	
	15 percent calories or less from saturated fat	+ [Per Serving Size and Per Reference Amount
"High Fiber"[2]	5 grams fiber or more+	
"High Calcium"	180 mg or more+	

Other Absolute Nutrient Claims and Requirements

All claims trigger a half-sized, bold-faced statement "See [appropriate panel] for nutrition information," with specific mention of any nutrients that exceed disclosure levels.

Numerical or percentage claims (e.g., "5 grams fat/serving") allowed only for foods that meet "low" or "high" definition for that nutrient.

"X percent fat-free" claims allowed only for "low fat" foods.

"High" claims for other approved nutrients only if contain 20 percent of the RDI or DRV for the relevant nutrient per reference amount and per serving size.

"Source" claims only if contains 10 percent or more of the RDI or DRV for the relevant nutrient per reference amount and per serving size.

SOURCE. Proposed FDA Labeling Regulations, Fed. Reg., Vol. 56, Nov. 27, 1991.

NOTES. * and + refer to the amounts in the "amounts" column on which requirements must be met.

[1] Meal-type products must meet the standards per 100 grams of food only. The threshold for "low calorie meal" claims is 105 calories or less per 100 grams. "Free" claims generally require inconsequential quantities of the nutrient and "free," "no added," "very low" and "low sugars" claims are not addressed here.

[2] Triggers fat disclosure in grams and other disclosures in some circumstances.

[3] Triggers cholesterol disclosure (mg) if not a "cholesterol free" product.

a nutrient.[30] These prohibitions do not appear to be required by the NLEA.

Table 2 summarizes the proposed requirements for the use of the terms "low" and "high" for the nutrients addressed by FDA, as well as other absolute nutrient claims. For example, to use the term "low fat," a product would be required to have 3 grams of fat or less per serving, as well as per reference amount and per 100 grams of food. All other absolute nutrient claims not using terms defined by FDA would be prohibited.[31]

As required by the NLEA, firms making any permitted nutrient content claims would be required to include the statement "See [appropriate panel] for nutrition information."[32] FDA also proposes to establish "disclosure levels" for fat, saturated fat, cholesterol and sodium, namely, 11.5 grams of fat, 4 grams of saturated fat, 45 milligrams of cholesterol and 360 milligrams of sodium.[33] Foods that exceed any of these levels per reference amount, per serving size, or per 100 grams of food must include a reference to the affected nutrient in the triggered statement, "See [appropriate panel] for information about [nutrient

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[30] See id. at 60,423. FDA provides examples of ingredient claims that are related to nutrients, including "contains no tropical oils," "made with 100 percent vegetable oil," and "contains no palm oil." Id.

[31] The regulations also provide a petition process through which firms can request authorization of additional terms.

[32] 21 U.S.C. § 403(r)(2)(B).

[33] 56 Fed. Reg. at 60,425-26.

requiring disclosure] and other nutrients."[34] Additionally, FDA would require all nutrient claims to be in the same style as and in a size no larger than the statement of identity of the food.

B. Considerations Relating to Authorizing Additional Terms, Simple Quantitative Nutrient Statements and Nonmisleading Ingredient Statements for More Healthful Foods

FDA proposes to adopt a very broad definition of the statements it will regulate as "claims that characterize the level of a nutrient," and explicitly includes statements about ingredients and the amount or percentage of a nutrient in this proposed definition.[35] The agency then proposes to define a few terms that can only be used on a very narrow range of foods -- those that contain the ideal amount of the particular nutrient -- and proposes to authorize amount and percentage statements for only these foods.

This restriction appears to be based on FDA's assumption that all statements about the amount or percentage of a nutrient in a food imply to consumers that the food is "low" or "high." Whether a factual statement about the amount of a nutrient implies that a product is "low," however, is difficult to ascertain without examining the claim in the context of particular food groups and particular settings that may affect its meaning to consumers.

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[34] Id. at 60,426.

[35] 56 Fed. Reg. at 60,301.

Moreover, the assumption that such quantitative statements imply that the food is "low" appears to be inconsistent with certain provisions of the NLEA. For instance, the NLEA requires that a "high fiber" claim be accompanied by a numerical disclosure of the grams of fat if the product does not meet the definition of "low fat," to correct the potential misunderstanding that it is "low" in fat.[36]

The effect of these two proposed requirements would be to prohibit even the simplest nutrient or ingredient information on the front label and elsewhere on the package for the vast majority of foods in the U.S. diet. The issues relating to simple quantitative and ingredient statements are analyzed in more detail below.

1. Limitations on Disclosing Numerical Quantities of Product Nutrients

There are two ways for consumers to improve their diets.[37] First, they can switch from foods that do not meet the proposed FDA thresholds for "low" in some nutrient (e.g., fat, cholesterol, or sodium) to those that do meet the standards (e.g., substitute broccoli for a high fat meat). A second method is to choose foods that do not meet the "low" standard, but that nonetheless are better than the foods currently eaten (e.g., substitute lean meat or fish for high fat meat)..

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[36] 21 U.S.C. § 343 (r)(2)(A)(v).

[37] For simplicity, we focus on nutrients that most consumers would benefit from reducing; the principle is largely the same for those nutrients that we should increase.

Survey evidence indicates that many consumers are reluctant to give up their favorite foods to improve health.[38] If these data are accurate, prohibition of simple quantitative statements may adversely affect consumers if many products that could feature this information are foods that could play an important role in consumer efforts to improve diet.

To establish whether the excluded foods are useful components of healthy diets, it is necessary to assess the nutritional characteristics of a broad database of foods that represents the range of food products consumed by Americans. For this purpose, food data from the USDA's 1986 National Food Consumption Survey were used. This survey includes relatively current information on the types of foods consumed by American women aged 19-50 years.[39] Table 3 indicates the percentage of

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[38] A recent survey by the American Dietetic Association attempts to examine the reasons Americans eat the way they do. The survey respondents were shown several possible reasons that individuals would not want to improve their diets. They were then asked "please tell me if this is a reason for you not doing more to achieve balanced nutrition and a healthy diet. For each statement, please tell me if it is a major reason, a minor reason, or not a reason for you personally." The survey results indicate that 38 percent of consumers report that the major reason they do not improve their diets is that they do not want to give up their favorite foods. See Survey of American Dietary Habits, The American Dietetic Association (1991) at 12.

[39] The latest USDA consumption data that are available are from 1987/88 and contain data for men and women. However, questions about the low response rate in the 1987/88 data led us to use the 1986 data. Our examination of the 1987/88 data indicates that our results are not sensitive to this choice, because the range of foods eaten by men and women is very similar. All food items eaten by at least one person in the survey (each USDA food item number such as "Chicken Breast, Roasted, without skin") were examined to determine if the food

(continued...)

TABLE 3

Percent of Foods Eligible to Make "Low" or "High" Claims Using Proposed FDA Criteria

Food Category (N)[1]	"Low" Claims					"High" Claims	
	Fat	Sat. Fat	Chols.	Sodium	Calories	Fiber	Calcium
Poultry (170)	2	7	2	36	1	0	0
Fish (94)	12	26	0	15	0	0	4
Meat (206)	0	5	1	35	0	3	1
Franks/Lunch Meat (74)	1	3	3	0	0	0	3
Mixed Foods (Grain) (102)	10	31	25	9	2	3	30
Bread (107)	39	70	34	9	0	8	1
R-T-E Cereal (84)	67	86	93	11	0	17	0
Pasta/Rice/Cooked Cereal (54)	63	80	87	44	0	13	6
Soups (61)	44	41	67	3	39	13	5
Milk (47)	40	17	36	49	0	0	68
Cream & Substitutes (14)	0	21	21	86	0	0	7
Cheese (46)	9	9	9	22	0	0	46
Yogurt (11)	45	9	45	45	0	0	100
Eggs (23)	9	9	4	17	4	0	0
Fats/Gravies/Dressings (65)	12	31	26	22	3	0	0
Muffins/Sweet Breads (39)	3	5	5	0	0	3	3
Cakes (58)	5	5	3	22	0	0	0
Pies (27)	0	0	0	4	0	0	0
Cobblers, etc. (18)	0	11	33	17	0	0	6
Frozen Desserts, Pudding (45)	4	7	11	16	0	0	0
Cookies (49)	0	27	4	16	0	0	0
Crackers/Salty Snacks (44)	7	64	70	20	0	0	0
Nuts, Nut Butters (27)	0	4	4	52	0	19	0
Candy (59)	20	20	20	54	0	0	0
Jams, Jellies, Sweet Sauces (31)	77	100	100	90	13	0	0
Vegetables/Fruit/Legumes (420)	75	80	88	61	26	5	2
Coffee, Tea, Soft Drinks, Alcoholic Beverages (131)	97	88	100	97	50	1	2

DATA. All food items reported in the 1986 Continuing Survey of Food Intakes by Individuals, Women 19-50 Years and Their Children 1-5 Years, 1 Day, U. S. Department of Agriculture, Human Nutrition Information Service.

NOTES. [1] N is the number of items in the category consumed by at least one person.

items within each food category that meets the various definitions of "low" and "high", and thus, the percentage of the foods in each category that could feature basic nutrient information on the label under the proposed regulations.

The results in Table 3 clearly show that many foods that are useful to consumers attempting to maintain healthy dietary practices do not meet FDA's proposed definitions. For instance, the vast majority of items, including the leanest meats, chicken and fish entrees could not state their fat, saturated fat, or cholesterol levels on the front of the package under these regulations. As illustrated in the health claims section infra, these characteristics vary greatly within and across these food categories, and consumers could significantly improve their diets by making different and more healthful choices within these groups. Prohibiting these products from using simple quantitative claims to communicate their nutrient content would make it more difficult for consumers to identify the more healthful versions of these foods.

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[39](...continued)
met the "low" and "high" thresholds per reference amount and per 100 grams of food. The proportions of various food groups that met the various definitions were computed. A complete list of the USDA food item codes that make up each food group are available upon request. For a detailed description of the 1986 CSFII, see CSFII Documentation, National Food Consumption Survey, Continuing Survey of Food Intakes by Individuals, Human Nutrition Information Service, USDA, Report 86-1, 1986.

Similarly, only 9 percent of cheese entries would meet the "low" definitions for fat, saturated fat and cholesterol.[40] Thus, these foods would be prohibited from featuring this information on their packages, despite the substantial range for these nutrients in cheese products and their substitutes. For example, many cheese products, such as Swiss and American cheese, contain over 7 grams of fat per 2/3 of an ounce slice. The lower fat versions of these products often contain less than 3 grams per slice.

Table 3 also indicates that very few foods could report calories on the front of the label. In 19 of the 26 food categories examined, none of the items meets the "low" calorie threshold. Only the food categories Soup, Beverages, Vegetables, and Jams have more than 5 percent of the items meeting the "low" calorie threshold. Given the importance placed by dietary authorities on limiting calories in the American diet, we believe that more foods should be able to feature this information on the front of the label with a simple quantitative statement (e.g. 100 calories per serving).

Table 3 indicates that relatively fewer foods are prohibited from disclosing the sodium content on the label than the other nutrients, since a greater number of foods meet the "low sodium" threshold. Again, however, in some food categories very few

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[40] Under the FDA criteria, cheese must contain no more than .85 grams of fat, .28 grams of saturated fat, and 5.7 mg of cholesterol per ounce (approximately 1 slice) to qualify for the "low" claims respectively, because 100 grams is approximately 3.5 ounces.

products could report their sodium content despite the significant reductions in sodium intake that could be achieved by switching among foods within the category. For example, because they do not meet the threshold on a 100 gram basis,[41] most cereals cannot highlight their sodium content on the label. Thus, despite the significant variation in sodium content across cereals, many of the lower sodium cereals cannot disclose their sodium level in this convenient way. For example, many ready-to-eat cereals contain over 250 milligrams of sodium per ounce while many other cereals contain less than 120 milligrams of sodium per ounce.

Finally, Table 3 indicates that very few foods could highlight the amount of fiber or calcium in the product. Importantly, only 5 percent of the products in the Vegetables/Fruit/Legumes category could disclose fiber content on the front label. While these products do not have at least 5 grams of fiber per serving (the required amount to qualify for a "high fiber" claim), consumers might significantly increase their fiber consumption if information about the fiber content of these foods is made more accessible.[42]

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[41] In order for a cereal to meet the "low sodium" threshold of 140 milligrams, it must contain less than approximately 45 milligrams per serving, since there are approximately 3 servings per 100 grams of food.

[42] Some of these products will be able to use the statement "source of fiber" though they cannot list the amount of fiber on the front of the label.

Appendix A contains several examples of prominent nutrition content disclosures that appear inconsistent with the proposed regulations. These examples illustrate the type of information that would be prohibited on the front of food labels. The first, on page A-1, shows labels for two brands of cheese. On each of these labels, the amounts of fat, cholesterol and calories are prominently featured on the front of the label. These products do not meet the respective "low" definitions, and thus these nutrient content disclosures would be illegal under the proposed FDA regulations.[43] The second page of the appendix includes another example of a simple nutrient statement that would be prohibited. In this case, a nonfat yogurt displays that it contains "100 calories." Again, this information would be prohibited, because 100 calories is not less than the 40 calorie threshold for "low calorie" claims.

2. Ingredient Claims

FDA proposed regulations also would prohibit ingredient claims (e.g. "made from whole wheat flour") if such a claim implies "that a nutrient is absent or present in a certain amount."[44] While some ingredient declarations may mislead consumers, the assumption that all, or even many, ingredient claims that relate to nutrients are misleading and therefore should be prohibited is troubling. The proposed regulations

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[43] These examples are for illustration purposes only. In using them, we express no opinion on the accuracy of these labels or the compliance of these disclosures with existing regulations.

[44] 56 Fed. Reg. at 60,423-24.

governing ingredient claims presume that such a prohibition is appropriate. It is not clear from the proposals whether statements such as "contains no lactose," "contains no MSG," "contains no wheat flour," would be permitted because they may imply something about the presence of sugar, sodium or fiber. To preclude use of these statements would raise serious concerns, because among other things, they provide useful, indeed, sometimes vital, information to consumers who are allergic to lactose, MSG, or wheat flour.

C. Featuring Claims Increases the Effectiveness of Labeling

FDA's proposals appear to go beyond the NLEA in limiting the ways in which producers can use approved terms on product labels. The terms would have to appear on the label in style and size no larger than the product's statement of identity.[45] FDA is concerned that permitting manufacturers to feature claims might lead to undue emphasis on one aspect of the food. While overemphasis of individual nutrients is possible in some circumstances, style and format are likely to play an important role in the marketing of food products by making it easier for consumers to notice product changes or existing desirable features.

Featuring claims may be especially important for new products and reformulated products. As consumers become aware of the array of products in the supermarket and establish their

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[45] See 56 Fed. Reg. at 60,424-25. The statement of identity is the FDA approved name of a food item.

purchasing patterns, new food products must differentiate themselves so that the consumer who would value the characteristics of the new product notices them enough to consider purchasing it. An innovative product with less fat than a standard food product, for example, may have little chance for success in the crowded supermarket unless it can get enough consumers who value this change to notice that the product has reduced fat levels.

Similarly, when a producer reformulates a product or introduces an alternative version of an existing product, it must alert the consumer to the change. For example, if a pastry producer introduces a fat-free version of its products, it must make clear to consumers that there are now two versions of its pastries on the supermarket shelf. These distinctions likely are made considerably more difficult without the ability to feature them, and a predictable result would be that the new product will be slow to sell. That, in turn, would likely discourage manufacturers from developing and introducing new and more healthful products.

Appendix A provides examples of current claims on labels. One example, on page A-3, is the back panel of a Healthy Choice frozen dinner. This label uses large pie charts to compare the nutritional characteristics of its product with daily recommendations. These pie charts are larger than the statement of identity, "chicken enchilada dinner," and therefore apparently would be prohibited under the proposed regulations. The two

cheese labels, on page A-1 of the appendix, prominently feature numerical disclosures of fat, cholesterol, and calories, and the yogurt label, on page A-2, prominently displays its 100 calorie content. The requirement that all of these claims be no larger or more prominent than the product's statement of identity would be likely to reduce the effectiveness of such claims.

In sum, FDA's proposed restrictions on type size and prominence may limit the effectiveness of claims and the incentives for manufacturers to use them. This, in turn, may effect manufacturers' incentives to innovate and improve their food products.

III. RELATIVE NUTRIENT CONTENT CLAIMS

The second part of the proposed regulations for nutrient content claims deals with relative claims, i.e., claims that compare nutritional characteristics of products with those of other foods. Because few foods will be allowed to make absolute nutrient content claims on labels under the proposed regulations, relative claims would be the only mechanism available for many firms to feature nutrition information on the labels of most foods. Thus, under the proposed rules, relative claims would become the primary method for giving consumers nutrient information about products, fostering competition and encouraging innovation on nutrients across the broad range of food products that do not meet FDA's "low" or "high" definitions.

The proposed regulations for relative claims have two key elements. First, they would establish lengthy disclosures that would be required to appear in proximity to the claim. The proposed regulations would require that all relative claims identify the comparison food and provide several pieces of information on the characteristics of the two foods.[46] While this approach would provide added information if such claims are made, the required disclosures are so extensive that they may discourage many claims, especially those that compare products on several nutrient dimensions. Since the proposed disclosures, in part, duplicate information available in the mandatory nutrition panel, we question whether the added convenience for consumers is

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[46] See 56 Fed. Reg. at 60,446.

worth the loss of the truthful claims that are likely to be discouraged.

Second, in an apparent attempt to eliminate trivial or irrelevant comparisons, the proposals would limit what products may be compared and require that products achieve minimum absolute and percentage reductions before qualifying to make particular claims.[47] Because these regulations would eliminate many objective comparisons that could help consumers select more nutritious foods, however, we are concerned that the proposals may be counterproductive. For example, the proposed regulations would not allow brand-to-brand comparisons (e.g., "our soft drink has 25% less sugar than Coke"), which are among the most direct and easily used claims for consumers of the targeted product.

The regulations also would prohibit comparisons across food groups (e.g., "our fruit cocktail for dessert instead of cake saves you 8 grams of fat"). This class of claims could promote some of the most significant dietary changes that consumers could make. Similarly, the proposals would prohibit clear comparisons that are below the threshold amounts, e.g., "30 calories less than our regular brownie with 80 calories" (since the proposed regulations would require a minimum difference of 40 calories).

FDA requests comment on an alternative approach to treating relative claims that would retain the minimum absolute difference requirement, and most of the restrictions on the types of foods that can be compared, but would delete the requirement that the

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[47] See id.

difference between the compared products meet a minimum percentage.[48] For the reasons discussed below, we believe that eliminating the minimum percentage difference requirement would be an improvement, but we are concerned that the alternative proposal continues to prohibit brand-to-brand comparisons, comparisons across food groups, and clear comparisons for products when the nutrient difference between them does not meet or exceed the "low" threshold. These prohibitions may eliminate many useful comparisons that could help consumers improve their diets. Moreover, the proposals may discourage producers from making small but steady improvements in their products, the accumulation of which can have substantial effects. We believe that all relative terms that numerically disclose the difference between products in a nonmisleading way would meet the requirements of the NLEA, allow many more truthful claims than the current proposals, and still be effective in controlling deceptive and misleading claims.

A. Overview of the Proposed Regulations

The NLEA requires that all claims that characterize the level of a nutrient use terms defined by regulation by the Secretary.[49] The law specifically requires FDA to define a

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[48] Under this alternative proposal the terms "reduced" and "less" would be used interchangeably. Use of either term would require that the food be compared with an accepted reference food and that the difference in the amount of the nutrient between the reference food and the product with the claim meet or exceed the "low" threshold for that nutrient.

[49] 21 U.S.C. § 403(r)(2)(A)(i).

number of terms in its regulations, including the relative terms "reduced", "light" and "less."[50] FDA's proposed rules would implement these requirements by defining these relative terms as well as the term "more." The proposed regulations would also specify the information that must be contained in the claims, the foods that can be compared in each case, and the nutritional dimensions on which comparisons can be made. All other relative claims would be prohibited.[51]

Under the regulations, all relative claims would be required to disclose the reference food, the percentage (or fraction) by which the nutrient in the reference food has been modified, and the amount of the nutrient in the labeled food and in the reference food.[52] These disclosures would be required to be in type no less than one-half the size of the type of the claim.[53] As with all nutrient content claims, any relative claim would trigger the statement directing consumers to the label for nutrition information. Thus, the regulations would require claims analogous to the following for single nutrient comparisons:

> Reduced fat -- 50 percent less fat than our regular brownie. Fat content has been reduced from 8 grams to 4 grams per

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[50] See Section 3(b)(1)(A)(iii), 104 Stat. at 2361 (regulations for the implementation of 21 U.S.C. § 343(r)).

[51] A formal petition process is proposed, through which firms may request authorization of additional terms.

[52] See 56 Fed. Reg. 60,445-46.

[53] See id.

serving. See back panel for cholesterol and other nutrition information.

For multiple comparisons, the regulations would require claims analogous to the following:

> Reduced fat --- Reduced sodium -- Fewer calories than our regular popcorn. Fat and sodium reduced by 50 percent, from 8 grams to 4 grams per serving for fat and from 340 milligrams to 170 milligrams per serving for sodium. Thirty-three percent fewer calories, 80 calories per serving compared to 120 calories per serving for our regular product. See back panel for cholesterol and other nutrition information.

The proposed regulations also define the foods that may be used as the reference food for relative claims and the nutrients that may be compared.[54] In most cases, foods making "reduced" claims would be required to have at least a 50 percent reduction in the relevant nutrient, and those making a "less" claim, a 25 percent reduction. A food making any "less" or "reduced" claim would be required to also have an absolute change in the nutrient at least as large as the threshold for "low" claims, discussed in the previous section. For example, if one food product contains 5 grams of fat, a second product would have to contain at least 3 grams (the "low" threshold) of fat less than this product in order to use the terms "less" or "reduced." These regulations, and those for the terms "more" and "light," are summarized in Table 4.

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[54] See id.

TABLE 4

Basic Requirements for Major Relative Claims

Claim	"Reduced"	"Less/More"
	Minimum Change[1]	
Fat	50 percent 3 grams fat	25 percent 3 grams fat
Saturated Fat[2]	50 percent 1 gram sat. fat	25 percent 1 gram sat. fat
Sodium	50 percent 140 mg sodium	25 percent 140 mg sodium
Cholesterol[2] *(Only if 2 g sat. fat or less)*	50 percent 20 mg cholesterol	25 percent 20 mg cholesterol
Calories	33 1/3 percent 40 calories	25 percent 40 calories
Complex Carbohydrates	NA[3]	1 g complex carbohydrates
Unsaturated fat *(Only if trans fatty acids 1 percent or less of fat)*	NA	2 g unsaturated fat
Protein, fiber,[2] potassium, vitamins & minerals	NA	10 percent DRV/RDI
	Allowed Reference Foods	
	Market Share Weighted Industry Average	Market Share Weighted Industry Average
	Firm's Regular Product	Firm's Regular Product
		Similar Product in Valid Database (e.g., USDA data)
"Light" or "lite"	33 1/3 percent reduction in calories 40 calories less than industry average *If 50 percent calories from fat or more, also* 50 percent reduction in fat 3 g less fat *For Salt Substitute* 50 percent reduction in sodium	

NOTES. [1] Changes must be met per serving size and per reference amount. For meal-type products, change required on 100 grams of food.

[2] Triggered disclosure of fat in most cases and of cholesterol for saturated fat claims.

[3] NA = Not Applicable.

B. Triggered Disclosures May Be Unduly Cumbersome

Relative claims that simply state "less fat" or "reduced calories" raise concerns because consumers are left to infer, correctly or incorrectly, the comparison product and the magnitude of the nutrient difference between the two products. If these inferences are incorrect, the claims are likely to be misleading. A requirement that all relative terms identify the comparison food and the absolute difference in the relevant nutrient between the two foods should provide useful information without misleading consumers. For example, a statement like this would suffice: "Less fat -- 3 grams less than our regular popcorn."

FDA's proposed disclosure requirements would include this information, but in a more lengthy format. Specifically, the proposed regulations would require that the claim include the reference food, the percentage reduction of the nutrient, the absolute level of the nutrient in the labeled food and the absolute level of the nutrient in the reference food.[55] Thus, in the example above, FDA's proposal would require a statement of this form: "Less fat -- 38 percent less fat than our regular popcorn. This popcorn has 5 grams of fat compared to 8 grams in our regular popcorn." Both disclosures would require the consumer to fill in pieces of information with simple arithmetic;

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[55] See 56 Fed. Reg. at 60,445-47. The claim also triggers a bold-faced, half-size type disclosure in immediate proximity to the claim directing the consumer to the particular panel with the mandatory nutrition label. See id. at 60,446.

in our example above, FDA's disclosure would require the consumer to subtract 5 from 8 to get the fat difference between the products, and the shorter disclosure would require the consumer to add 3 grams to the 5 grams on the labeled product to get the fat content of the reference good.

The primary advantage of the proposed FDA disclosure would be that the nutrient level of the product would be placed with the claim on the package, so the consumer would need not turn to the nutrition label to find this information. The disadvantage compared to the shorter disclosure above is its added length. The length of the required disclosure is a concern primarily because it could reduce the information available to consumers by reducing producers' incentives to make valid relative claims, especially on the principal display panel of the package. Lengthy disclosures contribute to label clutter, which may discourage consumers from reading the information on the label. We are concerned that the length of the disclosures proposed for relative claims would discourage too many beneficial claims to justify the added convenience they provide.

Moreover, the greatest effect of lengthy disclosures could be to discourage relative claims for foods that are better on several nutritional dimensions. Lengthy disclosures could well encourage single dimension claims rather than multidimensional claims, and as FDA recognizes in many aspects of its proposed regulations, good nutrition is a multidimensional issue.

For example, consider the effect of the proposed rules on the label for microwave popcorn in the Appendix on page A-4. The label makes three relative claims, "63% less fat," "56% less sodium" and "47% fewer calories than our regular popcorn." The amount of space necessary for all of the required disclosures for the three claims would make it virtually impossible to feature all advantages on the front label. Yet, claims of superiority on several nutrients may be an important mechanism to help consumers get information on several nutrients that differ among products in a category. These claims could also be important for maintaining competitive pressure on producers to improve products in as many ways as feasible.

For these reasons, we suggest that FDA consider reducing the required disclosure, recognizing that much of the information now required in the claim must be included on the nutrition panel, or could be derived with simple arithmetic. For example, if firms using relative claims disclosed the difference in the level of the nutrient between their food and the reference food, the consumer could ascertain most of the information provided in the more extensive disclosures required in the current proposals.[56]

Under the proposed regulations, relative claims would be the primary means of highlighting nutrient claims to consumers on the vast majority of foods. These claims would also be the primary

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[56] Although consumers could not easily compute the exact percentage difference between the products under the recommended disclosure, they could place the change in approximate relative perspective.

label mechanism for generating nutrition competition among producers and facilitating innovation. Thus, we believe that restrictions on relative claims should be narrowly tailored to prevent only comparisons that are likely to mislead consumers about a food's nutritional advantages.

C. Additional Relative Claims For Foods That Would Help Consumers Improve Diets

As summarized in Table 4, the proposed regulations specify minimum percentage and absolute changes required for the use of FDA-approved terms "reduced," "less," "light" and "more." The proposed regulations also specify which foods may be used as the basis for comparisons.[57] This section first discusses restrictions on the types of foods that may be compared and then restrictions on the minimum differences necessary for such comparisons.

1. Restrictions on the Types of Foods That May be Compared

Under the proposed regulations, comparisons may be made only to a specified set of foods. In all cases, firms may use the market-share-weighted industry average for similar products as the reference food.[58] In all cases except "light," firms may also use their regular product as the reference food. For "less"

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[57] See 56 Fed. Reg. at 60,447-54.

[58] Computing the market-share-weighted industry average can become complicated. What constitutes a market is often difficult to ascertain and market share data is often confidential or costly to obtain.

and "more" claims, firms may also use a similar product[59] in a current valid food data base, such as the USDA's Handbook No. 8, Composition of Foods, Raw, Processed, Prepared.

FDA's apparent purpose in limiting the range of comparison foods is to preclude misleading claims about nutritional advantages based on irrelevant comparisons and to encourage truthful and useful comparisons. However, we are concerned that the proposed restrictions may be unlikely to achieve this goal.

a. Brand-to-Brand Comparisons

The regulations would prohibit firms from making direct brand-to-brand comparisons, such as "Our glazed chicken has 25 percent less fat than Brand X."[60] A prohibition on brand-to-brand comparisons would eliminate one of the most direct types of claims that consumers could use as a guide for making dietary improvements. We are aware of no substantial support for such a prohibition.[61] Such comparisons inform consumers of changes that they can consider that would improve their diets in some

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[59] The rules are not entirely clear in specifying how narrowly the FDA intends to define "similar product," but the discussion suggests a narrow definition. FDA says it will allow comparisons of foods within a product class, which is defined as foods that can be used interchangeably and have similar product characteristics." See 56 Fed. Reg. at 60,446. The examples given in the discussion compare potato puffs to potato chips or corn chips, waffles to pancakes or french toast, and imitation bacon bits to bacon bits. Id. at 60,446.

[60] USDA's Handbook No. 8 has a few food items listed by brand. In these cases a few firms might be able to make brand-to-brand comparisons.

[61] The FTC has long recognized the usefulness to consumers of comparative claims that clearly name the compared brand. See 16 C.F.R. § 14.15(b)(1991).

specified way. Further, the nutrition panel provides the full range of nutrient information needed to evaluate other nutrient properties of the product.

Brand-to-brand claims also may be important to innovators attempting to enter the market with a more nutritious brand. Without the ability to name the leading brands in the market, it may be harder for firms to get the attention of consumers of existing brands and convey the superiority of the new alternative.

Similarly, producers of the relatively "good" products within a category would be less able to alert consumers of the relatively "bad" products in the category of the gains they could achieve with simple brand switches within the category. If producers of the more nutritious brands are required to compare themselves only with the industry average, the less nutritious products in the category would be shielded from direct competition.

Because brand-to-brand claims are very concrete, and thus may be more effective in attracting the attention of those consumers who would find it easiest to make a desirable change, FDA might reconsider its proposal not to allow these claims.

b. Comparisons Across Food Groups

The proposed regulations on allowed referenee foods would also prohibit comparisons across food categories. This proposed restriction is apparently based on the premise that comparisons across food categories are likely to be misleading.

Certainly, misleading comparisons across food categories should not be allowed, and comparisons within food categories are likely to be the major focus of most of relative claims dealing with nutrition. However, there are many cases where consumers would benefit from substitutions across food groups and where producers would have incentives to suggest such substitutions.[62] A general prohibition of these claims, therefore, may unduly limit opportunities for manufacturers to provide consumers with this kind of truthful information.

For instance, under the proposed regulations producers could not make relative nutrient claims suggesting fish instead of steak, cereal as a snack food instead of peanuts, fruit as a dessert choice instead of pie, dried fruit for a snack instead of chocolates, or pasta for a main entree instead of meat. As long as the claim is truthful and nonmisleading, and the limitation is not required by the statute, we see little support for restricting comparisons to those only within specified food groups.

2. Minimum Requirements for Comparisons

Under the proposed rules for relative claims, summarized in Table 4, FDA proposes to include minimum percentage differences and minimum absolute differences in most definitions of approved terms. FDA's apparent goal is, in part, to set standards for

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[62] Many of the major dietary recommendations indicate that Americans would benefit from some changes in the mix of foods in their diets. See, e.g., The Surgeon General's Report on Nutrition and Health. Department of Health and Human Services, 1988.

different levels of relative terms. Thus, for instance, "reduced" claims could be used only for products with a greater percentage reduction than "less" claims. In addition to the required percentage reductions, the proposals also seek to eliminate misleading comparative claims for inconsequential reductions by requiring that in all cases the reduction be at least as large as the threshold for "low" claims.

Relative claims should not exaggerate nutritional differences. We question, however, whether it is appropriate to presume that all comparative claims are misleading if the difference between the foods is less than the required minimum percentage or absolute difference. In assessing the value of relative claims, we believe the proper focus should be whether the claims provide truthful information that consumers can use to choose healthier foods without being misled about the significance of the differences between the products. In making these assessments, we presume that a consumer's health is determined by the characteristics of his or her whole diet, not by the individual foods that make up their diet. The following examples illustrate why the proposed minimum difference requirements may not be appropriate.

First, with respect to the proposed minimum percentage difference requirement, consider two consumers, each of whom follows a diet that contains 80 grams of fat. Suppose one consumer realizes a 3 gram reduction of fat from a food that contains 4 grams of fat (a 75 percent reduction) and the other

consumer realizes a 3 gram reduction from a food that contains 15 grams of fat (a 20 percent reduction). Unless there are physiological differences in the effects of the two ways of reducing fat consumption, it appears that both consumers have gained equally, so that the information that led consumers to reduce their fat intake is equally useful. For this reason, the proposed minimum percentage reductions required for relative claims appear of little value in preventing claims likely to mislead consumers.

Similarly, in regard to the proposed minimum absolute difference requirement, if a consumer reduces total fat intake by 10 grams per day, it may not matter whether this reduction is achieved by eliminating 5 grams of fat in 2 foods per day, or by eliminating 2 grams of fat in 5 foods per day. While any small dietary change, on its own, may not have a significant health effect, the cumulative effect of small changes can be significant.[63] Because they require minimum absolute differences before truthful comparisons can be made, the proposed regulations would eliminate claims that could help consumers make relatively easy improvements in their diets.

Consider, further, a consumer who intends to eat a sandwich of whole wheat bread, lean ham, cheddar cheese and a mayonnaise-

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[63] Many dietary experts share the perspective that small dietary changes can be significant and it is the whole diet that counts. For example, see the recent advice for consumers issued by the American Dietetic Association, October 9, 1991, which advises consumers: "Make smaller changes, one at a time" and "Your total diet counts, not individual foods."

type salad dressing for lunch. This sandwich contains 19.6 grams of fat according to USDA nutrition data. Substituting a sandwich of reduced calorie whole wheat bread, skinless white meat turkey, swiss cheese and reduced calorie salad dressing would save the consumer 6 grams of fat, nearly one-third of the total in the sandwich and almost 8 percent of the DRV for fat. Yet none of the individual substitutions would meet the threshold of 3 grams of fat per serving proposed for relative claims. Thus, this information about the differences for the sandwich ingredients could not be provided under the proposed regulations.

For these reasons, we suggest that FDA reconsider its plan to require a minimum absolute change or minimum percentage change for relative claims. Claims that do not exaggerate small improvements are likely to be useful to consumers. Misleading claims could be prevented more directly with a requirement that claims include a simple statement of the absolute difference between the products (e.g., "2 grams of fat per serving less than our regular product.")[64]

3. Alternative Proposal

The intended distinctions between terms such as "reduced" and "less" may not be fully understood by consumers. In their normal usage, these terms are usually used interchangeably for

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[64] Recall that the NLEA requires such claims to trigger a prominent bold-faced statement referring the consumer to the nutrition panel with its more complete information, and FDA requires specific mention of any nutrients that exceed the disclosure levels.

comparisons, and the greater significance that FDA intends for "reduced" claims is unlikely to be perceived by many consumers.

In the alternative proposal for relative nutrient content claims, most relative terms are considered synonyms that can be used interchangeably. The alternative proposal would retain the minimum absolute difference requirement and most of the restrictions on the types of foods that can be compared, but would delete the requirement that the difference between the compared products meet a minimum percentage.[65] For the reasons discussed above, we believe that eliminating the minimum percentage difference would be an improvement, but we are concerned that the alternative proposal still would prohibit brand-to-brand comparisons, comparisons across food groups, and comparisons for products when the nutrient difference between them is below the threshold amounts. We believe that all relative terms that numerically disclose the difference between products in a nonmisleading way would: (1) meet the requirements of the NLEA; (2) allow many more truthful claims than the current proposal; and, (3) still be effective in controlling deceptive and misleading claims.

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[65] Under this alternative proposal the terms "reduced" and "less" would be used interchangeably. Use of either term would require that the food be compared with an accepted reference food and that the difference in the amount of the nutrient between the reference food and the product with the claim meet or exceed the "low" threshold for that nutrient.

IV. REGULATION OF HEALTH CLAIMS

FDA's efforts to develop regulations for health claims are among the most important challenges in FDA's efforts to redefine the regulations governing food labels. FDA's regulatory impact analysis describes the importance of the regulations governing health claims:

> As a component of labeling in general, health claims may be the primary motivating force behind consumer behavior changes (substituting toward more nutritious foods). As such, much of the benefits of the 1990 amendments will depend on how health claims are regulated.[66]

We agree with FDA that claims that truthfully relate the health reasons for better food choices are potentially very important to helping consumers appreciate the reasons for focusing more on the composition of their diets. To that end, we recommend that FDA consider a number of changes in the proposed regulations that would enhance the ultimate success of its policy.

This section provides detailed analysis of the aspects of the proposals that are likely to eliminate useful health claims and suggests changes, consistent with the NLEA, which would preserve these claims while protecting consumers against misleading claims.

A. Overview of the Proposed Regulations

FDA's proposed regulations would: (a) identify four diet-disease relationships that warrant health claims; (b) delineate nutrient content requirements that must be met before the health

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[66] 56 Fed. Reg. at 60,869.

claims are made; and (c) establish information required in the health claims and provide model statements that fulfill these requirements.

Under NLEA section 403(r)(3)(B)(i), in deciding whether to permit a health claim, the Secretary must first determine,

> based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.[67]

In addition, the NLEA requires the Secretary to determine whether health claims for ten diet-disease relationships are supported under this standard.[68] FDA has tentatively determined that four diet-disease relationships satisfy this standard and, accordingly, proposes that they may be the subject of health claims: calcium and osteoporosis, lipids (fat) and cancer, lipids and heart disease, and sodium and hypertension. At present, FDA has concluded that there is not significant scientific agreement

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[67] 21 U.S.C. § 343(r)(3)(B)(i).

[68] The ten areas include calcium and osteoporosis, lipids and cancer, lipids and heart disease, fiber and cancer, fiber and heart disease, sodium and hypertension, folic acid and neural tube defects, antioxidant vitamins and cancer, zinc and immune function, and omega-3 fatty acids and heart disease. Sections 3(b)(1)(A)(vi) and (x), 104 Stat. at 2361.

on other diet-disease relationships, including fiber and cancer, fiber and heart disease, and antioxidant vitamins and cancer.[69]

Additionally, NLEA section 403(r)(3)(A)(ii) allows health claims to be placed on a food label only if the food for which the claim is made

> does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices . . .[70]

To implement this statutory provision, FDA has proposed establishing "disqualifying nutrient levels" for total fat, saturated fat, cholesterol and sodium. Thus, if a food product exceeds the disqualifying level for any of these nutrients, it could not bear a health claim relating to any diet-disease issue.[71]

The proposed regulations also would require that foods making health claims satisfy the definition of "low" or "high"

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[69] The NLEA requires the FDA to allow firms to petition the agency for permission to use health messages about diet-disease relationships not yet approved and sets standards for review. See Sections (3)(a)(4)(A)-(C).

[70] 21 U.S.C. § 343(r)(3)(A)(ii).

[71] See 56 Fed. Reg. at 60,543-45. For example, a product that contains more than 45 milligrams of cholesterol per reference amount, per serving or per 100 grams of food may not have a health claim on its label. The proposed disqualifying levels are set forth in Table 5.

for the nutrient involved in the health claim.[72] All of the disqualifying nutrient levels and all of the "low" requirements for the relevant nutrient must be met for the reference amount,[73] for the serving size and for 100 grams of the food. These requirements are described in Table 5. The "high" requirements for calcium would not need to be met on a 100 grams of food basis, as shown in Table 5.

Finally, FDA has proposed model label statements for each of the four permitted health claims. Firms would not be required to use the precise language drafted by FDA, as long as they convey the information required in the regulations for specific health claims, which are reflected in the relevant model statement.[74]

B. Health Claims Can Provide Useful Information and Enhance Understanding of Nutrient Content Claims

As FDA recognizes in its evaluation of the likely benefits of its proposed regulations, the use of health claims on labels may be important to consumer understanding of the reasons for changing eating behavior. The regulations for health claims are especially important in light of the current lack of consumer understanding of even the most basic diet-disease relationships. As discussed below, even many educated consumers lack knowledge

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[72] See id. at 60,553. For example, a product bearing a health claim on the relationship between fat and cancer may not contain more than 3 grams of fat per reference amount, per serving or per 100 grams of food. Table 5 also summarizes these requirements for each of the four approved diet-disease relationships.

[73] See Table 1 for definition of reference amount.

[74] See id. at 60,550-51.

TABLE 5

Requirements for Food to Make Health Claim on Label

Must Not Exceed Disqualifier Levels		
All Health Claims	11.5 g fat or less 4 g saturated fat or less 45 mg cholesterol or less 360 mg sodium or less	per reference amount and per serving size and per 100 g food
Additional Requirements for Particular Health Claims		
Lipids/ Cancer	3 g fat or less	per reference amount and per serving size and per 100 g food
Lipids/ Heart Disease	3 g fat or less 20 mg cholesterol or less 1 g saturated fat or less 15 percent or less of calories from saturated fat	per reference amount and per serving size and per 100 g food
Sodium/ Hypertension	140 mg sodium or less	per reference amount and per serving size and per 100 g food
Calcium/ Osteoporosis	180 mg calcium Less phosphorous than calcium on a weight for weight basis	per reference amount and per serving size

SOURCE. FDA Proposed Labeling Rules, *Federal Register*, Vol. 56, No. 229, November 27, 1991.

of diet-disease relationships, and consumers who do not know why a particular nutrient is important appear less likely to react to nutrient-content claims than those who understand the disease implications of the particular nutrient. Thus, when consumers are given the health implications of increasing or decreasing consumption of particular types of foods, they are more likely to react to nutrient content claims and improve their diets. For these reasons, it is important that the implementing regulations regarding health claims not inadvertently bar truthful claims that otherwise meet the NLEA's requirement.

Review of FDA Diet and Health Surveys provides insight into the importance of health claims across different segments of the population.[75] As a general matter, these surveys suggest that consumer knowledge has grown significantly since 1984, when health claims were first allowed on labels (and in advertising). Nonetheless, the surveys indicate that many consumers, especially those with less education, are still unaware of three of the diet-disease relationships that are proposed for health claims, as well as the disallowed issue of fiber and cancer.

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[75] Consumer knowledge data are taken from the Health and Diet Surveys, national telephone surveys directed by the FDA in collaboration with the National Heart, Lung, and Blood Institute (NHLBI). These surveys, which were conducted in 1978, 1982, 1984, 1986, 1988 and 1990, deal with a variety of health and diet issues, including hypertension and sodium, fiber and cancer, fat and cancer, and fat and heart disease. For the purposes of this comment, the 1984 and 1988 surveys are specifically relied upon. For a detailed description of the survey techniques see Levy and Stephenson (1990) at note 14.

These observations are illustrated by the specific survey results for 1984 and 1988, set forth in Table 6, showing the proportion of consumers reporting knowledge of certain diet-disease relationships by education level.[76]

The results in Table 6 demonstrate two important points. First, between 1984, when health claims were not allowed, and 1988, after they had been allowed for several years, knowledge increased substantially in virtually all education groups for each diet-disease relationship except sodium/hypertension.

Second, notwithstanding the substantial increase in knowledge in 1988, a large percentage of consumers still did not

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[76] Knowledge levels reflect responses to questions phrased as follows: "Have you heard about [the particular disease] being related to things people eat or drink?" Respondents who gave affirmative answers were then asked to name the items. For the fat/heart disease relationship, respondents who mentioned fats, cholesterol, fried foods, dairy products, or red meat in up to four responses were coded as aware of the diet-disease relationship. Similarly, respondents were identified as aware of the fat/cancer relationship if responses were fats or meats; aware of the fiber/cancer relationship if responses were fiber, roughage, whole grains, cereals, or bran; and aware of the sodium/hypertension relationship if responses were salt or sodium.

For the relationship between fiber and cancer, the inquiry varied as follows: "Have you heard about things people eat or drink that might prevent cancer?" Because FDA recognizes there is some association between diets rich in fiber and lower cancer risks, see infra, consumer knowledge of a possible fiber/cancer relationship is relevant to understanding how health claims affect dietary selections.

The 1984 Diet and Health Survey did not contain questions regarding calcium and osteoporosis. In the 1988 survey, knowledge of the link between calcium and osteoporosis was determined by the question "Have you heard about health problems related to calcium consumption?" Respondents who answered in the affirmative and mentioned either osteoporosis or problems with bones were recorded as knowing the relationship between calcium and osteoporosis.

TABLE 6

Reported Knowledge of Diet-Disease Relationships, By Education (Percent)

Education	Fat/ Heart Disease		Fat/ Cancer		Fiber/ Cancer		Sodium/ Hypertension		Calcium/ Osteoporosis	
	1984	1988	1984	1988	1984	1988	1984	1988	1984	1988
Less Than High School	10.1	58.3	7.1	19.2	1.1	15.0	47.8	35.8	NA	14.6
High School Grad	12.8	66.6	9.7	20.9	5.2	27.2	50.6	47.1	NA	39.6
Some College	35.7	73.7	17.7	19.1	12.8	29.4	55.0	50.5	NA	43.5
College Grad	40.2	86.9	15.2	29.3	16.4	43.4	54.4	62.6	NA	56.9

DATA. *Diet and Health Surveys*, U. S. Food and Drug Administration, 1984 and 1988. Reported knowledge based on responses to the question "Have you heard anything about (the particular disease) being related to things people eat or drink?" See text for particular responses included in each case. NA indicates not available.

report knowledge of key diet-health relationships in 1988, other than the fat/heart-disease relationship. This was true even in the highest education group but, generally, the lack of knowledge was higher at lower education levels.

In sum, these results suggest that although knowledge of many established diet-disease relationships has increased, it is still not widespread for many diet-disease relationships even among the most educated consumers. Furthermore, such knowledge is quite limited among less educated consumers.

In addition, FDA surveys, in combination with a recent FTC staff study on the ready-to-eat cereal market,[77] suggest that those consumers who do not know the disease implications of a particular nutrient are less likely to respond to nutrient claims than those who do. Specifically, the FTC study indicated that consumption of fiber cereals increased significantly only after some cereal companies focused their advertising and labeling on the association between foods high in fiber and reduction in the risk of certain forms of cancer.[78]

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[77] Ippolito and Mathios supra note 5.

[78] Id. See also, Ippolito and Mathios "Health Claims in Food Marketing: Evidence on Knowledge and Behavior in the Cereal Market," 10(1) Journal of Public Policy and Marketing 15-32 (1991).

During the period when health claims were prohibited, firms were free to disclose the fiber content of their cereals and many did. However, these nutrient claims alone did not significantly increase consumption of fiber from cereals. Thus, in the cereals market, increases in fiber consumption occurred only after consumers were provided information on the diet-disease relationship.

Similarly, the 1986 FDA survey data suggest the importance of knowledge about diet-disease relationships. These data indicate that knowledge of the relationship between fiber and cancer varied with education levels. In contrast, FDA data further indicate, knowledge of cereals as a good source of fiber was quite high (greater than 78 percent) and approximately equal across education groups. Thus, fiber consumption from cereal, which also varies with education levels,[79] better matches knowledge of the fiber-cancer relationship than knowledge of the fiber content of cereals. This suggests that knowledge of the disease implications of nutrients is important for consumers to make dietary changes.

C. Foods That are Important to Improving Diets Should Be Allowed to Make Health Claims

This section examines several aspects of the proposed FDA regulations that appear to restrict unnecessarily the foods that can mention truthful health reasons for desirable dietary changes.

1. Disqualifying Levels Eliminate Many Beneficial Claims

The NLEA requires that products bearing a health claim not "raise the risk of a disease," taking into account the food's significance in the diet.[80] FDA has implemented this requirement, in part, by proposing "disqualifying levels" for four nutrients. Analysis of 1986 USDA food consumption data

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[79] See Ippolito and Mathios (1989) supra note 5.

[80] 21 U.S.C. § 343(r)(3)(A)(ii).

indicates that the proposed disqualifying levels for fat, saturated fat, cholesterol and sodium would prevent manufacturers from making potentially beneficial health claims for healthful foods, including many foods that dietary authorities recommend to consumers. This analysis raises the concern that the proposed regulations would prevent many foods that could assist consumers in making dietary improvements from discussing on their labels truthful health reasons for making desirable changes.

Table 7 summarizes some of the key findings of an analysis of the USDA consumption data using FDA's proposed disqualifying levels. In this analysis, all food items in the USDA food database eaten by at least one person in the USDA consumption survey were examined to determine (based on the USDA nutrition data for each food item) whether the food was disqualified from making any health claim by the proposed disqualifying levels, shown in the top part of Table 5.[81]

The first column of Table 7 indicates the percentage of food items within each food category that would be prohibited from including any health message on the label because of the disqualifying levels proposed by FDA. The data reveal that a majority of foods across many food groups are prohibited from making any health claim, notwithstanding the fact that many of

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[81] Since package label data are not available, the test could not be conducted on a serving size basis. As a result, Table 7 overstates the proportion of products that could make claims in each category.

TABLE 7

Percent of Foods Categorized As Raising the Risk of Disease Using FDA Proposed Disqualifying Levels[1]

Food Category (N)[2]	Using FDA Criterion	Without 100g Criterion	By Cholesterol Criterion Alone
Poultry (170)	100	100	41[3]
Fish (94)	99	93	36[3]
Meat (206)	100	100	17[3]
Franks/Lunch Meat (74)	100	99	3
Mixed Foods (Grain) (102)	89	89	7
Bread (107)	80	17[4]	1
R-T-E Cereal (84)	91	31[4]	0
Pasta/Rice/Cooked Cereal (54)	50	50	0
Soups (61)	97	97	2
Milk (47)	53	45	0
Cream & Substitutes (14)	79	0[4]	0
Cheese (46)	98	65[4]	0
Yogurt (11)	27	27	0
Eggs (23)	96	96	41
Fats/Gravies/Dressings (65)	94	60[4]	0
Muffins/Sweet Breads (39)	90	44[4]	11
Cakes (58)	85	62[4]	31[3]
Pies (27)	100	100	11
Cobblers, etc. (18)	61	61	0
Frozen Desserts, Pudding (45)	55	55	5
Cookies (49)	92	6[4]	8
Crackers/Salty Snacks (44)	82	2[4]	5
Nuts, Nut Butters (27)	100	96	0
Candy (59)	81	46[4]	0
Jams, Jellies, Sweet Sauces (31)	7	0	0
Vegetables/Fruit/Legumes (420)	17	11	1
Coffee, Tea, Soft Drinks, Alcoholic Beverages (131)	1	1	0

DATA. All food items reported in the 1986 Continuing Survey of Food Intakes by Individuals, Women 19-50 Years and Their Children 1-5 Years, 1 Day, U. S. Department of Agriculture, Human Nutrition Information Service.

NOTES. [1] Percentages are underestimates, because data limitations preclude analysis on a labeled serving size basis.

[2] N is the number of items in the category consumed by at least one person.

[3] Categories where percentages would change if cholesterol level was made to be consistent with USDA consumption data.

[4] Categories with low weight servings for which 100 gram criterion is significant. For instance, 100 grams is approximately 4 slices of bread, 3.5 cups of cereal, nearly 7 tablespoons of cream, 3.5 slices of cheese, 10 cookies, 33 crackers, 7 cups of popcorn, 1/5 of a cake without icing, and two 2oz. candy bars.

these foods are generally recognized as helpful to consumers' efforts to improve the healthfulness of their diets.

For example, over 99 percent of the food items in the categories Chicken, Meat and Fish are disqualified from mentioning the health reasons for changes in consumption, despite recommendations from dietary authorities to substitute lean chicken and fish for meats, and to move to leaner cuts of meat.[82] Significant variation in nutrient characteristics exists within these food categories and consumers could dramatically reduce their fat intake by shifting consumption within them. Similarly, nearly 90 percent of the items in Mixed Foods, Ready-to-Eat Cereals, Cheese, and over 80 percent of the items in Bread and Crackers/Salty Snacks are prohibited from mentioning any health issues on their labels because of these disqualifying levels, even though many of the excluded foods would help consumers better meet dietary guidelines.[83]

Table 8 demonstrates that if a food also is required to meet the "low" or "high" threshold for the nutrient involved in the claim, only a minority of foods could have labels explaining the reasons consumers should care about fat, saturated fat,

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[82] See, e.g., National Academy of Sciences, Diet and Health: Implications for Reducing Chronic Disease Risk at 13 (1989); The Surgeon General's Report at 9, supra note 62 .

[83] The second column of Table 7, which we discuss infra, indicates the percentage of each food category that would be disqualified from making health claims if the FDA eliminated the requirement that foods meet the disqualifying level on a 100 grams basis.

TABLE 8

Percent of Foods Eligible to Make Health Claim

Using FDA Proposed Criteria

Food Category (N)[1]	Fat/ Heart	Fat/ Cancer	Sodium/ Hypertension	Calcium/ Osteoporosis
Poultry (170)	0	0	0	0
Fish (94)	0	0	0	0
Meat (206)	0	0	1	0
Franks/Lunch Meat (74)	0	0	0	0
Mixed Foods (Grain) (102)	2	2	3	0
Bread (107)	8	11	9	0
R-T-E Cereal (84)	8	8	8	0
Pasta/Rice/Cooked Cereal (54)	33	41	48	0
Soups (61)	3	3	3	0
Milk (47)	17	26	21	23
Cream & Substitutes (14)	0	0	21	0
Cheese (46)	2	2	2	0
Yogurt (11)	9	45	55	73
Eggs (23)	4	4	4	0
Fats/Gravies/Dressings (65)	2	5	3	0
Muffins/Sweet Breads (39)	0	0	0	0
Cakes (58)	3	3	3	0
Pies (27)	0	0	11	0
Cobblers, etc. (18)	0	0	0	0
Frozen Desserts, Pudding (45)	13	36	38	2
Cookies (49)	2	2	4	0
Crackers/Salty Snacks (44)	5	5	14	0
Nuts, Nut Butters (27)	0	0	0	0
Candy (59)	19	19	17	0
Jams, Jellies, Sweet Sauces (31)	65	77	84	0
Vegetables/Fruit/Legumes (420)	66	67	57	0
Coffee, Tea, Soft Drinks, Alcoholic Beverages (131)	86	97	98	2

DATA. All food items reported in the 1986 Continuing Survey of Food Intakes by Individuals, Women 19-50 Years and Their Children 1-5 Years, 1 Day, U. S. Department of Agriculture, Human Nutrition Information Service.

NOTES. [1] N is the number of items in the category consumed by at least one person.

cholesterol, sodium, or calcium. While labels for a narrow category of foods can contain health claims under the proposed policy, consumers may not be willing to give up their favorite foods for the health benefits of switching to this limited selection of foods. If so, for many consumers, dietary improvements will be achieved primarily by making a variety of smaller changes in the foods they are currently consuming. However, the restrictions in the proposed health claims regulations would preclude many foods that could contribute to better diets from having labels mentioning truthfully health reasons for making desirable substitutions even where there is general scientific agreement on the desirability of these changes.

We now turn to some particular details of the disqualifying levels that are responsible for eliminating many health messages that otherwise meet the NLEA's requirements.

a. Assumptions Underlying the Determination of the Cholesterol Disqualifying Level May Be Inconsistent with Consumer Behavior

The third column of Table 7 indicates the percentage of food items in each category that are disqualified solely because of their cholesterol content (which may not exceed 45 milligrams per reference amount, per serving, and per 100 grams of food). Nearly 40 percent of the items in the poultry and fish categories are eliminated by the cholesterol disqualifying level alone. Similarly, 17 percent of meat entries are disqualified by cholesterol, but not by fat or saturated fat. In all three

categories, cholesterol is the nutrient that eliminates the leaner foods within the category.

In order to set the disqualifying level for cholesterol, FDA assumes that a consumer typically consumes 20 items a day, and that approximately 10 of these items contain more than a measurable amount of cholesterol (6 milligrams). FDA arrives at 45 milligrams of cholesterol as a disqualifying level by dividing 450 milligrams (the amount considered not to cause disease) by the number of items individuals consume that contain more than 6 milligrams of cholesterol per day (450/10 = 45).[84]

We do not address the scientific basis for the determination of the level of cholesterol that raises the risk of disease. This level is based on FDA's review of the science. However, we have analyzed FDA's assumptions about consumer behavior, specifically the number of foods that consumers eat that contain cholesterol.[85] Examination of USDA's 1986 consumption data indicates that cholesterol consumption is significantly more concentrated in the diet than FDA assumes and that under the

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[84] See 56 Fed. Reg. at 60,543-45.

[85] Cholesterol was the focus of this evaluation because the cholesterol threshold eliminates many low fat fish, chicken and meat items usually recommended as better dietary choices in most dietary guidelines. Because the time available for comment was limited, we examined only one of these thresholds. However, the same analysis could be applied to establish whether the assumptions used for the other thresholds are reasonably consistent with consumption data.

methodology employed by FDA, the cholesterol disqualifying level would change if it were to be consistent with the USDA data.[86]

For women aged 19-50 included in the 1986 USDA data, the average number of items containing more than six milligrams of cholesterol per day was only four, rather than the ten estimated by FDA. Moreover, in the USDA data, individuals consumed 99 percent of their cholesterol from these four items per day, on average. Consequently, if FDA were to apply its methodology with an assumption for cholesterol concentration in the diet that better matched consumption, the disqualifying level for cholesterol would change.[87] Footnote 3 in Table 7 indicates which food categories would be affected if FDA changed the cholesterol disqualifying level so that it is consistent with the USDA data. For example, fewer meat, poultry, and fish items would be disqualified from making health claims while the egg category would be unaffected.

This analysis is also consistent with the scientific evidence indicating that in the amounts commonly consumed, saturated fat plays a more important role in raising blood

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[86] The FDA makes reference to the USDA data in discussing the assumptions behind its approach. See id. at 60,543.

[87] To test the sensitivity of this result, we also conducted an analysis of the cholesterol characteristics of the diets of individuals in the USDA sample who consumed more than 450 milligrams of cholesterol per day. This evaluation also confirms the conclusion that the cholesterol level should be changed. For these individuals, the average cholesterol intake was over 674 milligrams per day, yet the average number of food items that contain more than six milligrams of cholesterol per day was six, again well below the ten estimated by FDA.

cholesterol than does dietary cholesterol. In its review of the science, FDA concludes that "[e]xcessive saturated fat consumption is the major contributor to total blood cholesterol levels. Dietary cholesterol raises blood cholesterol levels, but the effect is less pronounced than that of saturated fat."[88] Given this conclusion, FDA should ensure that the cholesterol disqualifying level is appropriately set to avoid unnecessarily limiting claims for foods that could play a significant role in reducing saturated fat intakes.

b. Disqualifying Levels Per 100 Grams Eliminates Beneficial Foods

The proposed regulations require that a food bearing a health claim on the label not exceed the disqualifying level per reference amount commonly consumed, per labeled serving size, and per 100 grams of food.[89] The latter condition is included so that foods with small serving sizes on a weight basis (e.g., potato chips) that contain relatively high concentrations of the targeted nutrients cannot make health claims. The proposal states that the 100 gram requirement was added because the other serving size criteria did not eliminate these types of foods, and because such foods often do not conform to national dietary recommendations.[90] The proposal states that this requirement

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[88] 56 Fed. Reg. at 60,482.

[89] 56 Fed. Reg. at 60,543.

[90] Id. at 60,544.

might disqualify "some dessert toppings, gravies, crackers, cookies and chocolate candies."[91]

Analysis of the USDA data suggests that the addition of the 100 gram criterion would also disqualify claims for many foods that would assist consumers in developing healthful diets. For instance, as seen by comparing the first and second columns of Table 7, the USDA data indicate that 60 percent of ready-to-eat cereals will be excluded by the 100 gram requirement, because the sodium content of 100 grams of cereal (approximately 3.5 cups) exceeds the disqualifying level for sodium.[92] These cereals would not be disqualified on a reference or serving size basis, because the typical serving size for cereals is approximately 1 ounce (28 grams). Similarly, 60 percent of breads in the USDA data would be excluded by the sodium in 100 grams of bread (approximately 4 slices), but allowed on a reference or serving size basis, since FDA's reference amount is 55 grams, or approximately 2 slices of bread. The 100 gram criterion also excludes "diet" margarine, lower fat salad dressings, lighter cheeses, quick breads, and snacks, such as popcorn, etc., as well as the items described by FDA.

The addition of the 100 gram criterion excludes many foods that would not appear to "raise the risk of a disease" (as FDA

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[91] Id.

[92] Cereals such as frosted flakes, frosted mini wheats, and other high sugar cereals are not prohibited because there is no disqualifier for the level of sugar. Sugar tends to replace sodium in such products so that more of the 100 grams of the food is sugar.

has defined it) given the amounts in which they are customarily consumed. Of particular concern is the fact that this criterion eliminates many of the complex carbohydrate foods that most dietary guidelines recommend for increased consumption by consumers.[93] We suggest that FDA reconsider its proposed addition of the 100 gram requirement, because it does not effectively identify foods that raise the risk of disease and does not reflect the role of such foods in the diet, as required by the NLEA. Moreover, the requirement precludes truthful health claims on foods that can be an important component of consumers' efforts to bring their diets into conformity with major dietary recommendations.

It is important to recognize that many of the foods that led FDA to propose adding the 100 gram requirement would appear to be restricted from having health claims on their label under the general requirements that the claim be truthful and nonmisleading.[94] For instance, for the potato chips currently on the market, we cannot envision a noncomparative health claim that would not be misleading under these general requirements.

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[93] See, e.g., Surgeon General's Report supra note 62 at 12 (advising increased consumption of complex carbohydrates and fiber); Diet and Health: Implications for Reducing Chronic Disease Risk, supra note 82 at 672 (recommending increased consumption of whole grain breads and cereals).

[94] 56 Fed. Reg. at 60,564.

2. Requiring Health Messages to Meet "Low" Definition Eliminates Many Truthful Health Claims

The NLEA dictates that approved health claims cannot be made on a food that contains a nutrient in an amount that increases the risk of a disease.[95] FDA-defined disqualifying levels implement this condition. FDA has also added requirements beyond those required by the NLEA on foods that otherwise would be allowed under the NLEA to bear health claims on their labels. The proposed regulations would require that a product meet the definition of "low" or "high" for the nutrient on which the health claim is based. For instance, as summarized in the bottom half of Table 5, a product would have to contain no more than 3 grams of fat per reference amount, per serving and per 100 grams of food to make a health claim regarding fat and cancer. This additional requirement eliminates health claims for a broad range of foods that could have a beneficial impact on consumers' diets.

FDA solicits comments on whether health claims should be permitted on foods that do not meet the "low" or "high" definitions. In particular, the agency

> requests comment on whether use of claims on foods that meet the definitions of 'reduced,' 'more,' or even other comparative claims will be useful to consumers in achieving the efforts that are highlighted by the claim, or whether allowing the claims on such foods will be misleading because the nutrient levels are not low enough, or not high enough, to really contribute to the claimed effect.[96]

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[95] See 21 U.S.C. § 343(r)(3)(A)(ii).

[96] 56 Fed. Reg. at 60,553.

Consumers can benefit from competition on fat content and other health dimensions within many food categories that do not meet the proposed standards. For instance, the 1986 USDA food consumption data indicate that approximately 69 percent of fat in the diet of U.S. women comes from meat, chicken, fish, dairy products, desserts, and snacks. Consequently, these are the foods where changes must be made to reduce fat in the diet. It is unrealistic to assume that consumers will be willing to give up these food categories entirely. Instead, consumers are more likely to seek to substitute healthier versions of the foods they are currently consuming.

However, FDA thresholds for "low fat", "low saturated fat" and "low cholesterol" are set at such low levels that, with the exception of the very low fat dairy products, virtually no products in these categories could have labels that explain why switching from a high fat version of the product to a lower fat version is important to consumers' health. As discussed in Section II supra, relying on nutrient content claims alone presumes that consumers already understand the diet-disease links, an assumption that appears to be invalid for many consumers.

For instance, Table 9 gives nutritional data for a selection of meat, poultry and fish products. This selection of items was chosen to illustrate the range of fat and cholesterol amounts characterizing common products in these categories. In particular, the table illustrates that there is considerable

Table 9

Nutritional Features of Selected Meat, Poultry & Fish Products

(Per 100 grams = 3.5 ounces, Separable Lean Only, Trimmed to 1/4" fat)

	Total Calories (kcal)	Fat (g)	Saturated Fat (g)	Cholesterol (mg)
BEEF (Good/Select)				
Rib, broiled	206	10.4	4.2	77
Bottom Round, braised	196	6.8	2.3	96
Eye of Round, roasted	160	4.0	1.5	69
Top Round, broiled	169	3.7	1.3	84
Ground Beef, medium, pan-fried				
Regular	306	22.6	8.9	89
Lean	275	19.1	7.5	84
Extra Lean	255	16.4	6.5	81
Frankfurter	322	29.4	12.0	48
PORK				
Ham, roasted				
Cured (11% fat)	178	9.0	3.1	59
Extra lean (5% fat)	145	5.5	1.8	53
Loin, center, broiled	258	14.9	5.2	94
Loin, tenderloin, roasted	166	4.8	1.7	93
Bacon, fried (3 strips)	109	9.4	3.3	16
CHICKEN				
Light Meat				
Roasted, wo/skin	173	4.5	1.3	85
Roasted, w/skin	197	7.8	2.2	84
Fried, flour-coated w/skin	222	8.9	2.5	89
Dark Meat				
Roasted, wo/skin	205	9.7	2.7	93
Fried, flour-coated w/skin	254	14.4	3.9	94
Frankfurter	257	19.5	5.5	101
FISH				
Haddock, broiled	112	0.9	0.2	74
Haddock, breaded, fried	205	10.4	2.6	80
Shrimp, steamed	99	1.1	0.3	195

DATA. Nutrition data from Agricultural Handbook, Number 8, 1990.

variation in the fat, saturated fat and cholesterol characteristics of meat, poultry and fish products and that consumers could substantially reduce these nutrients in their diets by switching among such products. This table also illustrates that the thresholds used in FDA's fat and cholesterol descriptors would not allow any of these products to promote their features by highlighting the health reasons for switching to leaner versions within a category or to other substitutions that would reduce fat (e.g., switching from meat to fish).

Similarly, FDA regulations require that food products making a calcium/osteoporosis claim meet or exceed the "high" threshold for calcium. Table 8, which indicates the percentage of items within each food category that may make a particular health claim, demonstrates that only four categories have any items that may include a calcium/osteoporosis claim on a label. The 23 percent of milk products, 73 percent of yogurt items, and 2 percent of frozen desserts and drinks account for a significant portion of calcium, but certainly not all of the calcium in the diet. Consequently, consumers who are unfamiliar with the link between calcium and osteoporosis would likely be less attracted to the other significant sources of calcium in the diet, such as lower-fat cheeses, lower-fat ice cream, and dark green vegetables.

Truthful comparative health claims that indicate to consumers that switching between two products might have an effect on a disease provide useful information for consumers even

if the product switched to does not meet the "low" or "high" threshold. For example, a claim such as "concerned about reducing fat because of its association with heart disease and cancer; switching from regular cheese to our lower fat cheese saves you 6 grams of fat per slice" can provide important information to consumers. We believe the consumers' interest would be served better by allowing truthful health claims that meet the NLEA standards for products that do not meet the "low" or "high" standard as long as the health claim is made in a clear and nonmisleading manner. The NLEA does not require FDA to limit health claims to foods that meet the "low" or "high" thresholds. At a minimum, FDA should reconsider allowing accurate comparative health claims for foods that are below the disqualifying levels in one or more nutrients. Such comparative health claims are likely to assist consumers in identifying and appreciating the importance of the various ways to reduce fat, saturated fat, cholesterol and sodium in their diets.

3. The Secretary Should Exercise Discretion to Allow Some Types of Additional Health Claims

Our comments above discussed FDA's implementation of its requirements under the NLEA. NLEA section 403(r)(3)(A)(ii) also grants broad powers to the Secretary of Health and Human Services to make exceptions to the requirements of the NLEA, if the exceptions would assist consumers in maintaining healthy dietary practices.[97]

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[97] 21 U.S.C. § 343(r)(3)(A)(ii).

Although the range of food products for which manufacturers could make valid claims would be expanded by the changes suggested in previous sections, the proposed regulations would continue to prohibit manufacturers from making useful label claims. There are important reasons for the Secretary to use the discretion afforded under the NLEA to allow nonmisleading health claims that encourage desirable food substitutions even if the food exceeds the currently proposed disqualifying levels.

For instance, the proposed regulations would prohibit manufacturers of all cooking oils from making label claims that mention the health reasons for choosing oils that are lower in saturated fat, because all oils have 14 grams of fat per reference amount and thus exceed the fat disqualifying level of 11.5 grams of fat. Similar issues arise in the margarine market. While we share FDA's concern about not allowing misleading claims that would encourage increased fat consumption, we believe it is equally important to allow truthful health claims to convey to consumers the importance of also focusing on the type of fat in the fat products they continue to consume. As FDA recognizes in its discussion of the scientific literature on lipids and coronary disease,[98] most experts agree that the strongest relationship between lipids and coronary disease has been established for saturated fat. Yet, under the proposed policy health claims based on the products saturated fat content could not be placed on labels of products that have high overall fat

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[98] 56 Fed. Reg. at 60727.

content, but which offer less saturated fat than competing products. Instead of banning the health claim, FDA could address its concern about total fat by requiring a clear message on such products that consumers should consume less fat.

D. A Broader View of Potential Diet-Disease Claims Would Likely Be Beneficial

In applying the standard set forth at section 403(r)(3)(B)(i) of the NLEA,[99] FDA has determined that health claims are appropriate for four diet-disease relationships: lipids/cancer, lipids/heart disease, calcium/osteoporosis and sodium/hypertension. No other health claims are presently proposed. The FDA appears to have interpreted the NLEA to limit allowable health claims to those for which there is significant scientific agreement for the relationship between the nutrient and disease mentioned on food labels.[100] However, there are other types of claims about the relationships between diet and disease that could be considered and that would be valuable to consumers. For example, claims with the NLEA required level of scientific support that discuss the relationships between diets high in particular foods and disease do not fall into this narrow class of claims considered by FDA.[101]

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[99] 21 U.S.C. § 343(r)(3)(B)(i).

[100] See 56 Fed. Reg. at 60,552, 60,576-77.

[101] In its evaluation of the scientific literature as to a relationship between fiber consumption and heart disease and cancer risks, FDA concludes that although there is strong scientific support that diets containing fiber-rich foods are associated with lower cancer risks and heart disease, the (continued...)

The NLEA does not appear to preclude FDA from considering other diet-disease claims for which there is the NLEA required level of scientific agreement. We believe that such claims should be permitted because they provide useful information for consumers. For instance, many consumers would probably want to increase consumption of fruits, vegetables, and whole grain products, which are rich in fiber, if they understood that, in FDA's determination, there is significant scientific agreement that such diets may reduce certain cancer risks. The fact that scientists are not certain that it is fiber per se, as opposed to something that tends to occur with fiber in such foods, does not alter the practical implications of the information -- increasing consumption of such foods is likely to reduce cancer risks. The rigorous standard for scientific support that remains applicable should allay any concern that carefully crafted claims would be misleading or undermine the credibility of the label.

FDA might also consider diet-disease claims where there are strong reasons to believe that there is an important diet-disease relationship and where there is significant scientific agreement that the claim, as qualified, is true. FDA appears to have

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[101](...continued)
evidence about foods cannot be extrapolated to fiber itself with the required level of scientific certainty. Id. at 60,576-77. Thus, FDA proposes not to permit any health claim relating to fiber per se.

However, FDA also recognizes that virtually all public health groups recommend that consumers increase their consumption of fiber-rich foods, in part because of the evidence indicating their likely role in reducing cancer and heart disease risks. See id. at 60,576-77 and 60,593.

considered this type of claim in its consideration of the fat-cancer relationship. For example, in the proposed regulations governing the use of the fat-cancer health claim FDA states that,

> to reflect the strength of the scientific evidence regarding the relationship of dietary lipids to cancer risk, FDA is proposing that any health claim make clear that ingestion of diets low in fats 'may' reduce the risk of some types of cancer. This requirement is based on the relationship and is supported by evidence documented and summarized in Federal government reports, in other authoritative documents, and in the science review incorporated previously in this document. However, given the fact that the etiology of cancer is multifactorial the claim cannot state that a low fat diet will definitely reduce the risk of this disease.[102]

We believe that this interpretation of the NLEA is clearly within the mandate and spirit of the Act, and that it provides useful nutrition information to consumers to assist them in maintaining healthy dietary habits while preserving the integrity of health messages.

In summary, we believe that FDA should consider allowing claims that have the NLEA required level of scientific support for claims linking foods and disease. Moreover, we believe properly qualified claims should also be permitted where there is the NLEA required level of scientific agreement.

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[102] 56 Fed. Reg. 60,774.

E. Dietary Recommendations Should Be Allowed

FDA also specifically requests comment on whether to approach statements that provide dietary recommendations or guidance as health claims under the NLEA, or as claims subject to its general regulatory requirements that a label be truthful and nonmisleading.[103] FDA identifies the National Cancer Institute's "Five-A-Day" program to illustrate the issue presented.

We believe that such dietary guidance should be allowed provided it is not deceptive. Public health organizations can be more effective in reaching consumers if firms with products that fit into their dietary recommendations are free to convey this information on their labels. Additionally, consumers are more likely to notice and appreciate the significance of dietary recommendations if they come from a respected public health organization, such as the Surgeon General or the National Institutes of Health.

Thus, so long as it is truthful and nonmisleading, a dietary recommendation that does not identify a particular disease ought not be treated as a health claim under the NLEA.[104] Rather, we recommend that the dietary recommendations be evaluated under FDA's general regulatory requirements.

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[103] 56 Fed. Reg. at 60,542.

[104] An exception might also be made when a disease constitutes part of the name of the sponsoring organization, but the claim does not otherwise mention the disease.

This approach, which is consistent with the NLEA, will facilitate the dissemination of recommendations on how to improve the diet. Major dietary recommendations are developed under procedures that provide many safeguards to ensure that the advice is sound. Thus, the primary issue in such cases is that the advice not be used deceptively, and that issue is appropriately handled under the FDA's general truthful and nonmisleading requirements.

F. Model Health Claims Appear Burdensome

While FDA is not proposing to dictate, word for word, the health claims that firms must use when their products meet the conditions described above, the agency does provide model label statements that provide a safe harbor for firms.[105] The agency also requires that all health claims convey basic items of information that are reflected in the model claim.[106]

The model health claims for most diet-disease relationships are quite long and require firms to provide relatively extensive information to the public concerning diet and health. For example, the model health message for calcium and osteoporosis provides:

> Osteoporosis affects older persons, especially middle-aged, white women and those whose families tend to have fragile bones in later years. A lifetime of regular exercise and eating a healthful diet that includes enough calcium, especially during teen and early adult years, builds and maintains good bone health; and may

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[105] See id. at 60,552-53.

[106] See id.

> reduce the risk of osteoporosis later in life. Adequate calcium intake is important, but intakes above 1,800 mg are not likely to provide any additional benefit.[107]

The length of such a statement will limit its effectiveness, and therefore limit firms' incentives to make claims that relate diet to health. While containing useful information, the model claim goes beyond what is necessary for a truthful nonmisleading claim. Given the likely effects such extensive requirements will have on discouraging truthful diet-disease claims, FDA should consider reducing the burden of the model claims and using public education efforts to spread other useful information to consumers.

In conclusion, we appreciate the opportunity to provide these comments, and we welcome questions and further discussion.

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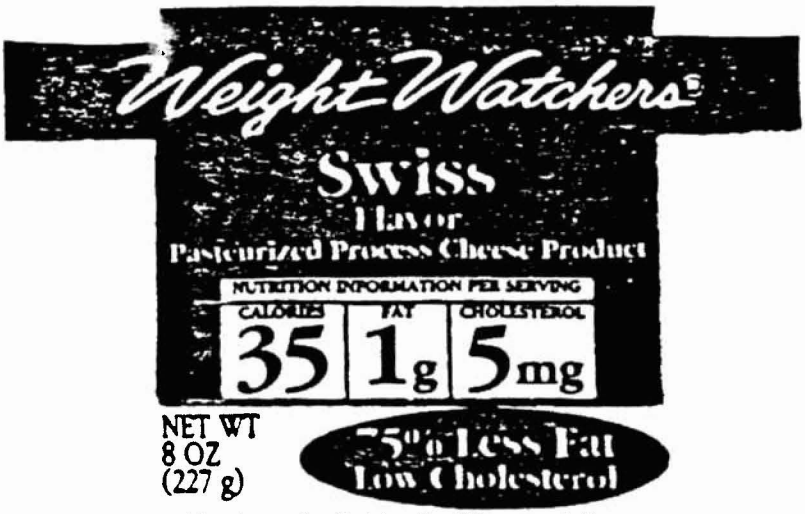
[107] Id. at 60,706.

APPENDIX A

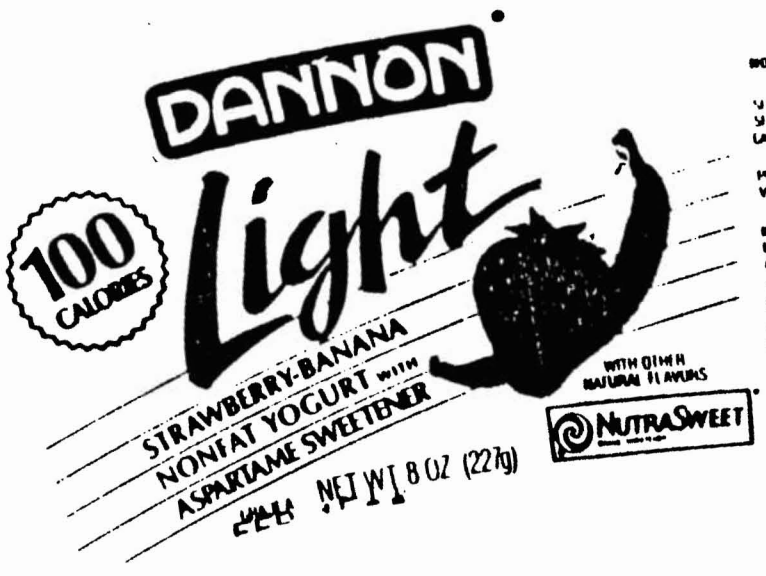
ILLUSTRATIONS OF EXISTING LABELS THAT WOULD BE PROHIBITED UNDER PROPOSED REGULATIONS

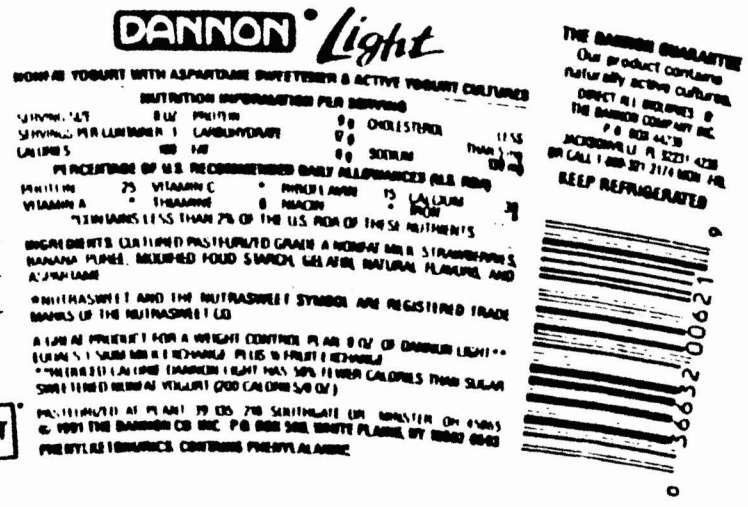


12 2/3 oz Individually Wrapped Slices

Illustrations of Prohibited Quantitative Claims and Highlighting

Illustrations of Prohibited Quantitative Claim and Highlighting





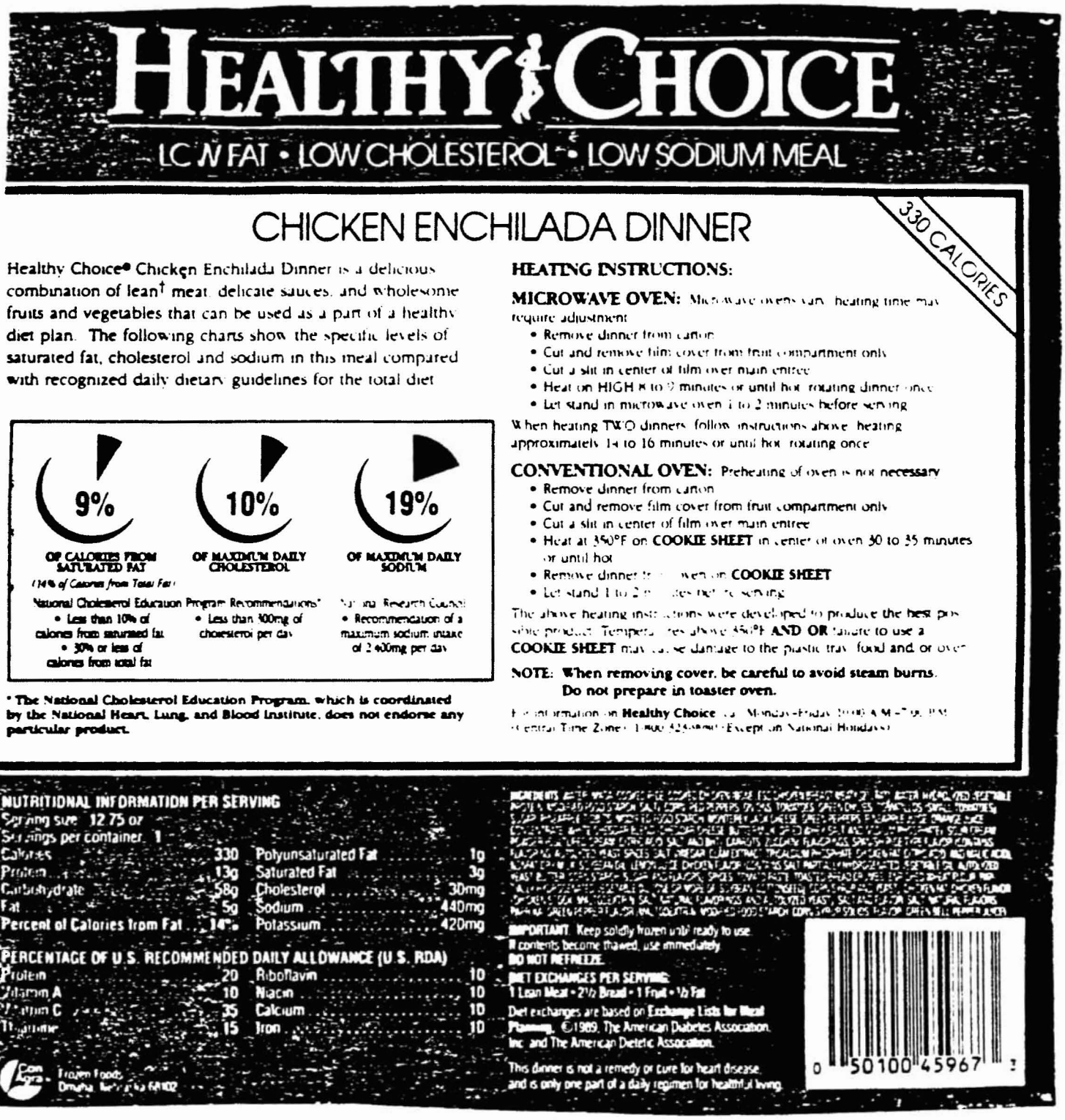


Illustration of Prohibited Dietary Advice and Graphics

● 63% LESS FAT
● 56% LESS SODIUM
● 47% FEWER CALORIES than our Regular Microwave Popping Corn
GIANT
Pops In Minutes
Needs No Refrigeration
Light
CHOLESTEROL FREE
BUTTER FLAVOR
ARTIFICIALLY FLAVORED
MICROWAVE
POPPING CORN
3 BAGS
GIANT
POPPINGCORN
LIGHT REGULAR
CALORIES 80 150
FAT 3 g 8 g
SODIUM 70 mg 160 mg
INGREDIENTS YELLOW POPPING CORN PARTIALLY HYDROGENATED SOYBEAN OIL SALT NATURAL AND ARTIFICIAL FLAVORS BETA CAROTENE FD&C YELLOW NO 6
NUTRITION INFORMATION PER SERVING
SERVING SIZE 3 CUPS POPPED
SERVINGS PER CONTAINER 4
CALORIES 80
PROTEIN 2 g
CARBOHYDRATE 12 g
FAT 3 g
CHOLESTEROL 0 mg
SODIUM 70 mg
PERCENTAGE OF U S RECOMMENDED DAILY ALLOWANCES (U S RDA)
PROTEIN 2
VITAMIN A *
VITAMIN C *
THIAMINE *
RIBOFLAVIN *
NIACIN *
CALCIUM *
IRON 2
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