ORIGINAL

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition for Advance Notice of Proposed Rulemaking on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods	)	Docket No. 2006P.0498

Submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

November 30, 2006

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Executive Summary

The prevalence of diet-related diseases is one of the most alarming – and preventable – health problems in the United States today. The typical American diet is based too heavily on foods high in calories, saturated fat, trans fat, salt, and added sugars and is too low in fiber- and micronutrient-rich fruits, vegetables, and whole grains, as well as low-fat, calcium-rich foods. While the Nutrition Facts Panel ("NFP") provides important information on the nutrient content of foods, a simplified labeling system using symbols on the Principal Display Panel ("PDP") could supplement the NFP and help more consumers choose a more healthful diet.

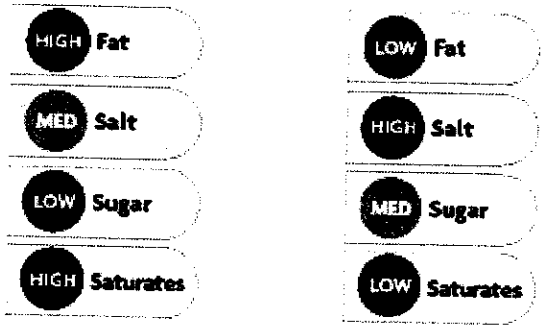
Several major food manufacturers have been adding "healthier" or "better for you"" symbols to the labels of some of their products. However, those programs have differing criteria and may be misleading or, taken together, may end up being more confusing than helpful to consumers. Development by the Food and Drug Administration ("FDA") of a simple, uniform science-based system would bring consistent and reliable information to the marketplace and help consumers choose more healthful diets.

FDA should announce an Advance Notice of Proposed Rulemaking ("ANPR") that would lead to the use on the PDP of a symbol(s), possibly with explanatory words, indicating a food's healthfulness. This symbolic approach to nutrition labeling would encourage consumers to choose more healthful foods and fewer less healthful foods. It would also encourage companies to improve the nutritional quality of their products.

In undertaking this project, the FDA should build on precedents in the U.S. and abroad. For instance, the United Kingdom's ("U.K.") Food Standards Agency ("FSA") has developed a simple labeling scheme that indicates the amounts of several nutrients that consumers should be consuming less of. Under the U.K.'s Multiple Nutrient Traffic Light System, foods are given

separate high, medium, or low ratings (and corresponding red, amber, and green color codes) for fat, saturated fat, salt, and sugar. Use of the system is voluntary.

Multiple Nutrient Traffic Light



Sweden allows companies to print a government-designed green "keyhole" symbol on

products meeting specified nutrition criteria that differ among food categories (cheese, pizza, margarine, etc.). The system does not identify less healthful foods. Use of the Swedish symbol is also voluntary. In addition, various U.S. manufacturers, retailers, and non-profit organizations have developed proprietary systems that utilize different nutrition criteria.

This FDA's ANPR should (a) announce the agency's intention to develop a symbol-based PDP nutrition labeling system, (b) announce its intent to conduct consumer research, and (c) solicit public comments on the desirability and nature of such a labeling system as recommended in Section V of this petition.

The ANPR should specifically discuss possible criteria that could be used to assign appropriate symbols to particular foods. One method could be based on the FDA's policy that 5 percent of the daily value ("DV") or less of a nutrient in a serving of food is considered low, and 20 percent of the DV or more is considered high. On that basis, foods with 5 percent DV or less of all problematical nutrients *and* 20 percent DV or more of one or more desirable nutrients would be categorized as "Most Healthful." Foods that contained 20 percent DV or more of any problematical nutrients would be categorized as a "Less Healthful Choice." Foods whose nutritional content did not meet either of those extremes would be categorized as "Intermediate: Eat in Moderation." Alternatively, like the Swedish approach, the nutrient criteria might vary by food category. Another option is to weight the amounts of problematical and desirable nutrients in a serving (or per 100 grams) and come up with a composite score or ranking, as at least two U.S. systems do.

Congress, in 1990, specifically instructed the FDA to consider using symbols to indicate amounts of desirable or undesirable levels of nutrients when it required the NFP to appear on almost all food products. The FDA should now take a fresh look at that mandate and develop a simple supplemental labeling system to indicate the nutritional quality of foods and beverages. When a uniform national program is implemented, the FDA should review whether existing PDP labeling schemes that are inconsistent with its program are misleading and should be ended.

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I. Action Requested

This petition is submitted pursuant to section 4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), and 21 C.F.R. §§ 10.25 and 10.30. The Center for Science in the Public Interest ("CSPI")[1] requests that the Food and Drug Administration ("FDA") announced an Advance Notice of Proposed Rulemaking ("ANPR") regarding the use of symbols on the principal display panel ("PDP") that would communicate to consumers the healthfulness of foods. The legislative history of the 1990 Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(q), specifically calls for the Secretary to consider such steps.[2] Such action is warranted to lower rates of often-preventable diet-related diseases, including heart disease, obesity, stroke, diabetes, cancer, and dental caries.

FDA should commence this effort by soliciting comments from scientists, health and communication experts, industry, and consumers on how best to rate and communicate to consumers through the use of symbols on food packages the nutritional quality of foods. It should also engage in consumer research to identify the program that would best help consumers choose a healthier diet. Work already completed by the Food Standards Agency ("FSA") of the

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[1] This petition is supported by the individuals listed in Appendix I. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by the 900,000 subscribers to its *Nutrition Action HealthLetter* in the United States and Canada. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971.

[2] H.R. Rep. 101-538, at 18 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3347.

United Kingdom ("U.K."), the Swedish government, supermarket chains, food manufacturers, and others could help inform this effort. Once FDA identifies the appropriate criteria and symbol(s) (with explanatory words if necessary), it should determine whether the system should be voluntary or mandatory.[3] FDA should also determine whether company and non-profit labeling programs that are inconsistent with its official labeling program are misleading and should be ended.

II. Introduction

The prevalence of diet-related diseases is one of the most alarming – and preventable – health problems in the United States today. The typical American diet is too high in foods rich in calories, saturated fat, trans fat, salt, and added sugars and too low in fiber- and micronutrient-rich fruits, vegetables, and whole grains, as well as low-fat calcium-rich foods. While the Nutrition Facts Panel ("NFP") provides important information on the nutrient content of foods, studies, as well as some companies' actual experiences, suggest that a simplified labeling system to supplement the NFP could help consumers choose more healthful foods.

Front-label symbols that alert consumers to the healthfulness of foods could help make "the healthy choice the easy choice," a slogan popularized by the World Health Organization.[4] By simply glancing at the front label of a food package, consumers would immediately know roughly how healthful a food was. The detailed NFP would provide more information for interested consumers. Several U.S. food manufacturers and grocery chains have been adding nutrition symbols to some of their products. While those programs may be useful, they may also

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[3] CSPI strongly believes that the new labeling, like the NFP, should be mandatory. If labeling is voluntary, companies would likely not use the labels on products that are low in valuable nutrients and high in undesirable nutrients.

[4] *See, e.g., Launch of the WHO/FAO joint consultation report on diet, nutrition and the prevention of chronic diseases*, April 22, 2003, http://www.who.int/dg/speeches/2003/rome/en/ (accessed November 21, 2006).

be deceptive, and, because they have differing criteria, taken together, they may end up being more confusing than helpful to consumers. Action by FDA would bring consistent and reliable information to the marketplace and help consumers choose more healthful diets.

III. Statement of Factual Grounds

A. The American Diet Is Causing Devastating Health Problems

The *Dietary Guidelines for Americans 2005* (hereinafter "*Dietary Guidelines*") advises Americans to "consume a variety of nutrient-dense foods and beverages within and among the basic food groups while choosing foods that limit the intake of saturated and trans fats, cholesterol, added sugars, salt, and alcohol."[5] Americans are not eating that kind of diet. Indeed,

> Americans' poor dietary habits increase the risk of various chronic diseases and premature death. Life-threatening diseases and conditions linked to poor diet include hypertension, dyslipidemia, heart attacks, strokes, overweight and obesity, type 2 diabetes, osteoporosis, diverticular disease, malnutrition, and certain cancers.[6]

While the incidence per 100,000 people of diet- and activity-related deaths may have declined in the past several decades (due to improved diet and medical care and other factors), the total number per year of those deaths has been stable.

A growing body of evidence shows that following a diet that complies with the *Dietary Guidelines* would save lives. For example, one study estimated that adopting desirable dietary behaviors could eliminate approximately 16 percent and 9 percent of mortality from any cause in men and women, respectively, above age 45.[7] In addition, in 2004 the director of the National

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[5] U.S. Department of Health and Human Services and U.S. Department of Agriculture, *Dietary Guidelines for Americans 2005*, www.healthierus.gov/dietaryguidelines (accessed November 21, 2006) at 6.

[6] *See Dietary Guidelines* at 2. See, J.M. McGinnis and W.H. Foege, "The immediate vs the important," *JAMA* (2004) 291:1263–64 who estimated that in 2000, poor diets were responsible for 340,000 to 642,000 deaths per year, or 16 to 30 percent of all deaths.

[7] *Dietary Guidelines* at 3, *quoting* Kant AK, Graubard BI, Schatzkin A. Dietary patterns predict mortality in a national cohort: The national health interview surveys, 1987 and 1992. *J Nutr. 2004;* 134:1793-1799.

Heart, Lung, and Blood Institute and two colleagues estimated that reducing sodium levels in processed and restaurant foods by half would save 150,000 lives per year.[8] Furthermore, tens of thousands of fatal and non-fatal heart attacks could be prevented each year if trans fatty acids from partially hydrogenated vegetable oil were replaced by other fatty acids,[9] and thousands more lives could be saved if people ate fewer foods rich in saturated fat and more fruits and vegetables.[10]

Rising rates of overweight and obesity also suggest the need for clearer calorie information on foods, as well as greater encouragement to eat more foods high in dietary fiber and micronutrients. According to a study by the Centers for Disease Control ("CDC"), obesity caused about 100,000 deaths in 2000.[11] More than 30 percent of American adults were overweight or obese in 1999-2000, an increase from 23 percent in 1988-1994.[12] Obesity rates have doubled in children and tripled in adolescents over the last two decades.[13] Better food labeling could improve diets and help hold down obesity rates.

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[8] Havas S, Roccella EJ, Lenfant C. Reducing the Public Health Burden From Elevated Blood Pressure Levels in the United States by Lowering Intake of Dietary Sodium. *Am J Pub Health*. 2004; 94:19-22.

[9] D. Mozaffarian, M.B. Katan, A. Ascherio, et al., Trans Fatty Acids and Cardiovascular Disease, *N Engl J Med* (2006) 345:1601.

[10] H.C. Hung, K.J. Joshipura, R. Jiang, et al., "Fruit and vegetable intake and risk of major chronic disease," *J Natl Cancer Inst* (2004) 96:1577–84; S. Liu, I.M. Lee, U. Ajani, et al., "Intake of vegetables rich in carotenoids and risk of coronary heart disease in men: the Physicians' Health Study," *Int J Epidemiol* (2001) 30:130–35; and L.A. Bazzano, J. He, L.G. Ogden, et al., "Fruit and vegetable intake and risk of cardiovascular disease in US adults: the first National Health and Nutrition Examination Survey Epidemiologic Follow-up Study," *Am J Clin Nutr* (2002) 76:93–99.

[11] Flegal K, Graubard B, Williamson D, Gail M. Excess Deaths Associated with Underweight, Overweight, and Obesity. *JAMA* 2005; 293:1861-1867.

[12] Food and Drug Administration, *Counting Calories: Report of the Working Group on Obesity* [hereinafter "*FDA Obesity Report*"], Appendix G: Report from the Division of Market Studies Office of Scientific Analysis and Support, December 28, 2003, http://www.cfsan.fda.gov/~dms/owg-appg.html (accessed November 21, 2006).

[13] Ogden CL, Flegal KM, Carroll MD, and Johnson CL. Prevalence and Trends in Overweight Among US Children and Adolescents, 1999-2000. *JAMA*. 2002; 288:1728-1732.

B. The Nutrition Facts Panel Is Helpful, But Needs to be Improved

In 1994, FDA required the NFP on packaged foods pursuant to the Nutrition Labeling and Education Act ("NLEA"). The purpose of the NLEA was to "clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods."[14] Prior to enactment of the NLEA, there was insufficient nutrition information on food packages.[15] The aim of the NLEA, therefore, was to supply consumers with nutrition information they could use to craft a healthy diet,[16] as well as to encourage food manufacturers to compete, in part, on the basis of nutrition.[17]

While cause-and-effect relationships are difficult to establish, consumer research has shown that many consumers use the NFP and that the use of nutrition labeling is associated with healthier diets.[18] Despite the NFP, however, too few consumers choose healthy diets, according to FDA's report on obesity, *Counting Calories: Report of the Working Group on Obesity* ("*FDA*

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[14] H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337.

[15] H.R. Rep. No. 101-538, at 8-9 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3338-3339.

[16] H.R. Rep. No. 101-538, at 8-10 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3338-3339.

[17] CONG. REC. S16610 (daily ed. October 24, 1990) (statement of Sen. Howard Metzenbaum).

[18] *See* Nayga RM, *Do Nutrition Labels Affect Calorie Intakes and Diet Quality?* Prepared for the FDA Workshop: Exploring the Link Between Food Labeling and Weight Management, 2003 (finding that nutrition label users consume fewer calories from fat, less cholesterol and sodium, and more fiber, than non-label users); Kristal AR, Henderson MM, Patterson RE, Neuhauser ML. Predictors of Self-Initiated, Healthful Dietary Change. *J Am Diet Assoc.* 2001:762-765 (finding that the use of food labels is strongly associated with fat reduction); Mathios, Alan D. The Impact of Mandatory Disclosure Laws of Product Choices: An Analysis of the Salad Dressing Market. Abstract. *J Law Econ.* 2000:651-677 (finding that the addition of the NFP to food packages reduced the sale of high fat foods); The American Dietetic Association. *Nutrition Trends Survey 1997.* September 1997 (finding that approximately two-thirds of those reading the NFP reported that they stopped or started buying a food product because of something they read on the label, and 56 percent of consumers said the information on the nutrition label had caused them to switch brands). Some of those studies found associations between reading labels and healthier diets, but could not establish cause and effect.

Obesity Report").[19] The FDA found in focus group studies that consumers say they understand what makes up a healthy diet, but approximately 40 percent perceive the quality of their diets to be better than is actually the case. The inability of consumers to understand the true quality of their diets may be one reason why so many Americans do not eat healthfully.

Several factors impede consumers' ability to use the NFP to choose more healthful diets. One FDA study found that most consumers are not able to use the NFP for tasks that require calculation skills.[20] When researchers asked consumers to perform four tasks of mounting difficulty evaluating information from the NFP, 78 percent of the subjects were able to accurately compare two products, and 58 percent accurately assessed nutrient-content claims. However, only 45 percent comprehensively balanced nutrients over a daily diet, and just 20 percent accurately calculated the contribution of a food to a daily diet.[21] The study concluded that

> [w]idespread effective consumer education will be facilitated if nutritionists develop ways for consumers to use food labels that rely primarily on easier, nonquantitative tasks.[22]

Similarly, another study found that some consumers may not interpret the NFP correctly because they may not be able to compute serving sizes and other data accurately.[23] In addition, some consumers do not use the NFP because of time constraints. Participants in FDA focus

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[19] *Counting Calories: Report of the Working Group on Obesity*, Food and Drug Administration (2004).

[20] Levy AS and Fein SB. Consumers' Ability to Perform Tasks Using Nutrition Labels. *J of Nutr Ed.* 1998; 30:210-217. In its review of 129 studies on consumer understanding of nutrition labeling, the European Heart Network, an alliance of heart foundations and non-governmental organizations throughout Europe, ranked this study as the highest quality experimental study on numerical-format nutrition labeling. *A systematic review of the research on consumer understanding of nutrition labelling*, European Heart Network, June 2003.

[21] *Id.*

[22] *Id.* at 216.

[23] Seiders K and Petty RD. Obesity and the Role of Food Marketing: A Policy Analysis of Issues and Remedies. *Journal of Public Policy and Marketing.* 2004:153-169, 157.

groups on obesity reported not wanting to spend a lot of time reading nutrition labels.[24] Consumers may be interested in the nutrient content of foods, but they are in a hurry at the supermarket and do not have the time to examine the NFP of every food they buy.[25]

Thus, while the NFP has been a valuable source of nutrition information for many consumers, its complexity has been an impediment to its effectiveness. A simpler, front-label, symbolic labeling system supplementing the detailed, number-oriented NFP on side or back labels would likely enable consumers to better assess the nutritional quality of foods and use that information to choose more healthful foods. A growing number of nations, companies, supermarkets, and others have recognized the value of such simple symbolic systems.

C. Private Sector Health Certification Symbols May be Deceptive and Confusing to Consumers

In the absence of a national FDA-mandated PDP labeling system, food companies and others have developed their own front-label symbols to indicate that a particular product is healthful or at least better than some other foods. These companies see consumers' confusion about how to structure a healthy diet as a marketing opportunity and use symbols to designate more-healthful items to encourage shoppers to buy those products.[26] These private systems allow manufacturers to effectively promote their healthier products to consumers, but on the basis of self-chosen nutritional criteria.

Kraft Foods, PepsiCo, the American Heart Association ("AHA"), and others award proprietary symbols to foods that meet a range of nutrition criteria (see Appendix II). In contrast, General Mills and the National Dairy Council use their symbols to highlight particular beneficial

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[24] *FDA Obesity Report*, p. 16

[25] Miller CK, Probart CK, Achterberg CL. Knowledge and Misconceptions About the Food Label Among Women With Non-Insulin-Dependent Diabetes Mellitus. *Diabetes Educ.* 1997 July-Aug; 23:425-432, 428.

[26] Pressler MW, "Says Who? Food Companies Know What's Best. Just Ask Them." *The Washington Post,* May 22, 2005: F1.

characteristics, even if the food as a whole might not be considered healthful by many nutrition experts.

Inconsistencies among such programs regarding the criteria used are evident in the comparison shown in Appendices II and III, and some programs allow the use of symbols on products that are not particularly healthy. Sodium cut-offs are one example of inconsistency: PepsiCo allows snacks to have up to 270 milligrams, Kraft up to 290, and the American Heart Association up to 480. Features of individual programs include:

- Kraft Foods' "Sensible Solution" program features a symbol (see Appendix III) – a green flag inscribed with the words "Sensible Solution" and a yellow sun – to indicate that a food has met "specific, 'better-for-you' nutrition criteria."[27] (Industry uses the term "better for you" for foods that may not be particularly nutritious, but that are healthier than some similar, traditional foods – for instance, reduced-fat versus regular cheese). Kraft has formulated specific "Sensible Solution" criteria for its beverages, cereals, dairy, convenient meal products, cookies and crackers, desserts, hummus, mayonnaise and Miracle Whip, meat and meat alternatives, salad dressings, and snacks. Nabisco Strawberry Newtons fits the Sensible Solution criteria, but the first four ingredients are all forms of refined sugars and flour (the product is 45 percent sugar). Oscar Mayer Light Hot Dogs gets the Sensible Solution label, but one hot dog contains 500 milligrams of sodium (21 percent of the DV), plus a dollop of saturated fat.[28] (The limits on sodium and other nutrients are ignored if a product has 25 percent less calories, saturated fat, or other undesirable nutrients.) Yes, the product is healthier than a higher-fat hot dog, but people should not be led by the "Sensible Solution" label to think it is healthy. Similarly, a one-ounce serving of Kraft Mild Cheddar Longhorn Style Cheese made with 2% milk provides 20 percent of the DV for saturated fat and 10 percent of the DV for sodium.

- PepsiCo's "Smart Spot" symbol (see Appendix III) features a white check-mark and the words "Smart Choices Made Easy" in a green circle to indicate which of its foods "contribut[e] to a healthier lifestyle."[29] PepsiCo has developed "Smart Spot" criteria for snacks.[30] Munchies Kid Mix, a snack mix containing Cap'n Crunch cereal, mini

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[27] *The Sensible Solution Program*, http://www.kraftfoods.com/kf/HealthyLiving/SensibleSolutions (accessed November 18, 2006).

[28] The web site indicates 6 grams of total fat and 6 grams of saturated fat, obviously an error. http://www.kraftfoods.com/main.aspx?s=product&m=product/Product_display&Site=1&Product=4470000241 (accessed Nov. 18, 2006).

[29] *The Smart Spot Program*, http://www.smartspot.com/1_smart_spot/1-0_home.php (accessed November 21, 2006).

[30] *Product Criteria*, http://www.smartspot.com/1_smart_spot/1-1_prod_criteria.php (accessed November 21, 2006).

pretzels, Cheetos cheese-flavored snacks, popcorn, and candy-coated chocolate pieces, proudly features a "Smart Spot" logo on its package. However, this snack would not qualify for a certification symbol under the criteria used by the American Heart Association or Kraft Foods because it is not low in fat. Also, the 250 milligrams of sodium (10 percent of the DV) in a 1-ounce serving is excessive. Quaker Quakes, which is basically refined carbohydrates flavored with salt, gets a Smart Spot, but is hardly the kind of snack that kids should be eating. And we question whether Tropicana Fruit Smoothie-Tropical Fruit, with 42 grams of sugar (mostly from apple and grape juices), should bear a symbol suggesting that the product is particularly healthful. There certainly are "worse-for-you" beverages and snacks, but consumers should not be led to think that products like Quakes and the smoothie are positively healthy.

- General Mills prints a "Goodness Corner" (see Appendix III) on the PDPs of its products featuring, as appropriate, one or several of 26 icons denoting specific nutritional benefits (e.g., "low saturated fat" or "good source of calcium"). In this way, the company highlights its products' more healthful attributes, without mentioning less healthful characteristics.[31] For example, the PDP for Chocolate Lucky Charms highlights the nutrient-fortified cereal's "12 vitamins and minerals," "good source of calcium," and "110 calories per serving." However, it fails to mention that the product is 50 percent sugar.

- In a similar fashion, Kellogg Co. prints one or several of 18 "Best to You" banners (see Appendix III) on the PDPs of its cereals, denoting specific nutritional benefits (e.g. "Sodium Free" and "Low Fat").[32] While these banners draw attention to a product's more healthful attributes, they do not disclose its less healthful characteristics. For example, Kellogg's Cran-Vanilla Crunch cereal displays banners that read "Energy," "10 Vitamins & Minerals," and "Excellent Source Iron." The 18 grams of sugar in a 55 gram serving are not mentioned.

- The Dairy processors may print a "3-A-Day" symbol (see Appendix III) on milk, cheese and yogurt, regardless of their fat and saturated-fat content, to promote the benefits of dairy foods.[33] Kraft Finely Shredded Sharp Cheddar Cheese carries the "3-A-Day" symbol even though a quarter-cup serving has six grams of saturated fat (30 percent of a person's recommended limit). Similarly, one ounce of Cracker Barrel Natural Extra Sharp Cheddar Cheese contains 6 grams of saturated fat, yet bears the "3-A-Day" symbol. Kraft American Singles, which also bears Kraft Food's own "Sensible Solution" symbol, has 4.5 grams of fat per slice, with 2.5 grams of that being saturated fat. None of those products can be labeled under FDA rules as low

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[31] *Goodness Corner*, http://www.generalmills.com/corporate/health_wellness/your_health_detail.aspx?CatID=7780&SelectCatID=7780&section=yourhealth (accessed November 21, 2006).

[32] *Best to You*, http://www.kelloggs.com/us/besttoyou/ (accessed November 29, 2006).

[33] *3-A-Day of Dairy*, http://www.3aday.org (accessed November 21, 2006).

fat or low in saturated fat. Those products also do not qualify for the AHA's heart-check logo.

- The nonprofit AHA has a "heart-check" food certification program "to provide consumers an easy, reliable way to identify heart-healthy foods."[34] Food manufacturers that have products that meet the AHA criteria and pay the designated fees may include the AHA "heart-check" symbol on the labels of those products (see Appendix III). AHA has separate criteria for packaged foods, whole grains, and seafood, meat, and poultry.[35] The AHA's criteria, however, do not consider trans fat or refined sugars. Similarly, the current AHA program, in use since 1995, has resulted in the "heart check" symbol being used on fewer than one thousand products.[36] Many more foods, including most fruits and vegetables, are eligible for the AHA symbol but do not use it.[37]

- Unilever has recently rolled out an "Eat Smart" labeling program (see Appendix III) that the company says is "based on the U.S. Dietary Guidelines."[38] However, the company's criteria for soup would allow 865 mg of sodium per eight ounces.[39] That is well over one-third of a person's maximum recommended limit and could not be labeled as "Healthy" under FDA regulations.

These programs also have differing requirements regarding whether foods can be fortified with vitamins and minerals in order to qualify for certain symbols, or whether those nutrients must occur naturally in qualifying food products. The AHA program does not permit fortification, the PepsiCo program does, and many of the other corporate programs are conspicuously silent about the matter.

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[34] *Food Certification Program*, http://www.americanheart.org/presenter.jhtml?identifier=2115 (accessed November 21, 2006).

[35] *What Certification Means*, http://www.americanheart.org/presenter.jhtml?identifier=4973 (accessed November 21, 2006).

[36] *Current Heart-Check Mark Products*, http://216.185.112.90/productlist.aspx (accessed November 18, 2006).

[37] In addition, private health organizations that focus on specific diseases may restrict their certification criteria to nutrients known to impact those specific ailments. Consumers who are concerned about other health conditions or diseases would be unable to rely on those symbols.

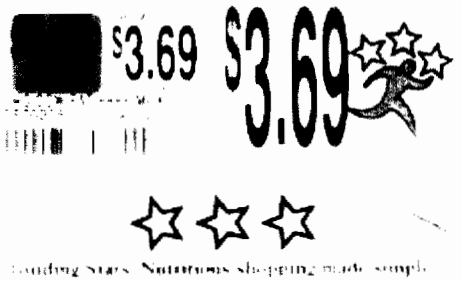
[38] *Unilever*, http://www.unilever.com/ourvalues/nutritionhygienepersonalcare/nutrition/choices/logo.asp (accessed November 18, 2006).

[39] *Unilever*, http://www.unileverusa.com/Images/US%20KOF%leaflet_tcm23-71936.pdf (accessed November 18, 2006).

In contrast, other entities have developed programs based on more sophisticated criteria:

- Hannaford Brothers has established a "star" system for processed foods in which some products receive no, one, two, or three stars on a shelf marker next to the item price or on a sign. One star indicates a good choice, two stars indicates a better choice, and three stars indicates the healthiest choice. One advantage of this approach is that it is not binary, but allows Hannaford to depict a gradation from less to more healthy. On the other hand, one may question the particular criteria and cut-offs used. Three–fourths of products sold receive no stars, because they are not especially healthful, as explained in a point-of-sale brochure.[40] Such products as General Mills' Count Chocula, Cookie Crisp, and Trix cereals do not qualify for any Hannaford "stars" because of their high (43 percent) sugar content. Yet, those cereals carry the American Heart Association's heart-check logo on their labels because they are low in fat and cholesterol.[41] Such inconsistent messages can only confuse consumers.

Hannaford Guiding Star Shelf Marker



- The Columbus (Ohio) Children's Hospital has developed a Snackwise Nutrition Rating System that rates the healthfulness of snack foods.[42] Like the Swedish Keyhole system, the Columbus system is focused on identifying more healthful choices in a particular food category. The Columbus system assigns a color-coded rating of red, yellow, or green to snacks using ten weighted factors: calories, fat, saturated fat, fiber, sugar, protein, calcium, iron, and vitamins A and C.[43] Green

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[40] Meeting with Lisa Sullivan, et al., Hannaford Foods, and Center for Science in the Public Interest, August 18, 2006, Washington D.C. *See* Zelman, K and Kennedy, E, Naturally Nutrient Rich . . . Putting More Power on Americans' Plates. *Nutrition Today*. 2005 Volume 40 Number 2 March/April:60-68.

[41] *American Heart Association*, http: 216.185.112.90 shoplistii.aspx (accessed Nov. 18, 2006).

[42] "NAMA to color-code snacks on health merits." *Nutraingredients USA*, January 1, 2005, http: www.nutraingredients-usa.com news ng.asp?id 57451 (accessed November 21, 2006).

[43] *Snackwise Frequently Asked Questions*, http: www.snackwise.org Patient_Family faq.pdf (accessed November 21, 2006).

signifies "Best Choice," yellow signifies "Choose Occasionally," and red signifies "Choose Rarely."[44] The system is of interest because the U.S. National Automatic Merchandising Association (NAMA) has encouraged its member companies to use it on their snack machines (although it is unknown if many have actually done so).[45]

Those and other private labeling programs may all have some merit in particular respects. Accordingly, the FDA should consult with the industry and non-profit organizations that have developed PDP–based nutrition symbols. At the same time, however, the FDA should bear in mind an important statement from the Institute of Medicine (IOM), in its report *Food Marketing to Children and Youth: Threat or Opportunity*:

> While representing an important step to draw attention to more nutritious products, the array of categories, icons, and other graphics, as well as the different standards employed by these companies may introduce some confusion, particularly for young consumers, thereby raising the need for developing and regulating standard and consistent approaches . . . The FDA has not yet fully explored its potential role for providing leadership and experience to food companies in order to develop and enforce an industry-wide rating system and graphic representation on food labels that is appealing to children and youth to convey the nutritional quality of foods and beverages.[46]

Because the FDA has failed to heed the IOM's call for leadership, consumers are faced with a growing variety of PDP labeling schemes. FDA must bring consistency to the marketplace and help consumers through the use of a single, objective PDP-based nutrition rating system.

Moreover, because of the varying criteria in the various private labeling schemes, consumers cannot easily compare two products based simply on the presence or absence of the

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[44] *Id.* While this system is an improvement over the other programs because it provides consumers with information about all snacks, it still has several drawbacks. First, it may contribute to consumer confusion because its criteria differ from the other systems. Second, the Snackwise criteria do not consider trans fat or cholesterol content, though a revised version will include sodium. Third, the credit given to substantial amounts of certain positive nutrients may obscure the presence of unhealthful amounts of nutrients with negative effects.

[45] Despite a press conference and major publicity when the plan was announced, we are not aware that any company is actually using the system.

[46] *Food Marketing to Children and Youth, Threat or Opportunity*, Institute of Medicine, U.S. National Academies of Science, 2006. p. 325.

symbols.[47] The AHA, for example, allows its symbol on sugary breakfast cereals, such as General Mills' Trix, Cocoa Puffs, and Lucky Charms, because there is no criterion for added sugar.[48] In contrast, Kraft and Nabisco have limits for added sugars (though the limit is ignored in PepsiCo foods if a food contains over a certain amount of fiber and in both companies' foods if a product is reduced in fat, sodium, sugar, or calories). Unless uniform criteria are put in place, supermarket aisles will become ever-bigger quagmires of conflicting information, with some foods of low nutritional value bearing "better for you" symbols, and consumers having as hard a time as ever choosing truly healthier diets.

Because the private labeling systems are inconsistent and, in some cases, flawed, the FDA should implement a national labeling system that rates the healthfulness of foods (and should work with the U.S. Department of Agriculture to cover meat and poultry products). It should also consider whether other labeling systems are misleading, especially in light of the new national scheme, and hence should be restricted or prohibited.

D. FDA Should Design a Symbol(s) to Help Consumers Choose Healthy Foods

1. A Symbol on the PDP May Facilitate Consumer Choice

FDA's *Obesity Report* discussed the results of focus group studies indicating that a simple labeling scheme could help Americans make healthier food choices. The report stated:

> Half of the groups tested a "healthy" meat lasagna with a purple keyhole symbol on the PDP. There was generally a positive reaction to including a front-of-the package symbol indicating that a product was "healthy," as long as participants understood the definition of the symbol and could trust that it was true.[49]

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[47] The variation between private healthfulness symbols could have the additional consequence of lessening the credibility to consumers of *any* symbol or claim (even if legitimate) on food packages.

[48] *Current Heart-Check Mark Products*, http://216.185.112.90/productlist.aspx (accessed November 21, 2006).

[49] *FDA Obesity Report*, p. 16.

The *FDA Obesity Report* recommends behavioral research on consumer reaction to the current food label and possible changes to the food label, including using a "healthier" symbol to highlight lower-calorie, more-healthful foods.[50] FDA's Office of Scientific Analysis and Support states:

> Research is also needed to see how we can provide better signals on the front of the label, the principal display panel (PDP). Because consumers often do not look at the back of the label when there is a claim, and often take the claim to apply to the entire product, research is needed to see if FDA can provide an alternative signal that addresses the entire product.[51]

The National Heart, Lung, and Blood Institute ("NHLBI") has studied the impact of communicating simple information on the relative healthfulness of foods to help children make healthier choices. As part of its Dietary Intervention Study in Children ("DISC"), a randomized controlled trial to determine the efficacy and safety of dietary intervention to lower total fat, saturated fat, and cholesterol in children with elevated low-density lipoprotein cholesterol, NHLBI studied the impact of classifying foods as "Go" or "Whoa" foods based on the amount of saturated fat and cholesterol in the product. "Go" foods were listed in green, and "Whoa" foods were listed in red, in information distributed to children in the intervention group. Individual and group educational and behavioral sessions with a nutritionist were also conducted. Researchers found that such intervention was effective: The children in the intervention group increased their intake of recommended "Go" foods in all food groups except fruit, and decreased their intake of "Whoa" foods in all groups except pizza.[52]

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[50] *FDA Obesity Report,* Appendix G: Report from the Division of Market Studies Office of Scientific Analysis and Support.

[51] *Id.*

[52] Van Horn L, Obarzanek E, Friedman LA, Gernhofer N, Barton B, Children's Adaptations to a Fat-Reduced Diet: The Dietary Intervention Study in Children (DISC). *Pediatrics*. 2005:1723-1733. Similarly, the University of Texas's Coordinated Approach to Child Health ("CATCH") program educates children about healthful eating by categorizing foods into "Go," "Slow," and "Whoa" categories. CATCH Texas, Go-Slow-Whoa CATCH Food

An article in the *Journal of Public Policy and Marketing* that reviewed research on the disclosure of nutrition information reached conclusions similar to the FDA and the NHLBI. The authors of the article concluded that the absence of usable nutrition information related to obesity contributes to the obesity epidemic and that a simplified summary of nutrition information that highlighted calorie and fat information would likely motivate consumers to use labels more effectively.[53]

The article specifically reviewed three studies that showed that labels with simple reference information, designed to highlight calorie and fat information, would likely promote more information use and be more effective in addressing obesity risk than the current Nutrition Facts Panel.[54] Simplified information could also help increase the use of nutrition information on food labels by lower-income consumers.[55]

The FDA should undertake a complete literature review, review what is being done abroad and by domestic companies, conduct its own research, and solicit comments from the public to identify the most effective system to disclose on the principal display panel the nutritional value of foods.

Categories, http://www.sph.uth.tmc.edu/catch/PDF_Files/go_slow_whoa_description.pdf (accessed November 21, 2006).

[53] Seiders K and Petty RD, Obesity and the Role of Food Marketing: A Policy Analysis of Issues and Remedies. *Journal of Public Policy and Marketing.* 2004:153-169, 161.

[54] Burton, Scot, Abhijit Biswas, and Richard Netmeyer (1994), Effects of Alternative Nutrition Label Formats and Nutrition Reference Information on Consumer Perceptions, Comprehension, and Product Evaluations, *Journal of Public Policy and Marketing*, 13 (Spring), 36-47; Moorman, Christine, (1996), A Quasi Experiment to Assess the Consumer and Information Determinants of Nutrition Information Processing Activities: The Case of the Nutrition Labeling and Education Act, *Journal of Public Policy and Marketing*, 15 (Spring,) 28-44; Viswanathan, Madhubalan and Manojt Hastak (2002), The Role of Summary Information in Facilities Consumers' Comprehensive of Nutrition Information, *Journal of Public Policy and Marketing*, 21 (Fall), 305-318.

[55] Balasubramanian, Siva K. and Catherine Cole, (2002), "Consumers' Search and Use of Nutrition Information: The Challenge and Promise of the Nutrition Labeling and Education Act," *Journal of Marketing*, 66 (July) 112-27.

2. *Other U.S. Government Agencies Use Symbols to Communicate Information in a Clear, Simple Way to Consumers*

Several government agencies require the use of symbols to help consumers compare products. The U.S. Department of Transportation National Highway Traffic Safety Administration ("NHTSA") runs a New Car Assessment Program ("NCAP") to provide consumers with information about the safety of new cars, primarily front and side crash results and rollover ratings. NCAP uses a star-based rating system, with one star signifying a 46 percent or greater chance of serious injury in certain types of crashes and five stars signifying a 10 percent or less chance of serious injury.[56] According to a National Academy of Sciences study, the NCAP rating system has led to safer cars. The study found that "NCAP scores have improved steadily since the inception of the program, with the greatest improvements in the early years . . . Improvements in test performance have been matched by real-world reductions in fatality likelihood for drivers in head-on crashes similar to those simulated by the NCAP test."[57]

NHTSA also uses a rating system known as the Uniform Tire Quality Grading System ("UTQGS") to help consumers compare different tires for passenger cars.[58] Tire manufacturers are required to grade tires based on their treadware rate, traction performance, and temperature resistance. Treadware rates are given numerical grades, while traction is graded (from highest to lowest) AA, A, B, or C, and temperature is graded (from highest to lowest) A, B, or C. This information is cast into tire sidewalls, printed on labels affixed to the tire tread surface, and

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[56] *Frequently Asked Questions*, http://www.nhtsa.dot.gov/cars/testing/ncap/Info.htm#iq1 (accessed November 21, 2006).

[57] *Shopping for Safety: Providing Consumer Automotive Safety Information*, Transportation Research Board, National Research Council, Special Report 248, National Academy Press, Washington, DC, 1996 at 67-68. The study adds, "The NCAP is not the sole stimulus for this improvement in safety; the 1984 regulations leading to automotive passenger restraint systems and air bags were another important factor. But the program can claim part of the credit." *Id.*

[58] *Tire Safety: Everything Rides On It*, http://www.nhtsa.dot.gov/cars/rules/TireSafety/ridesonit/brochure.html (accessed November 21, 2006).

included in consumer brochures. According to a 1992 study assessing the effectiveness of the tire-quality grading system, more than 50 percent of potential consumers rated UTQGS information as important in their tire-purchase decisions.[59]

The Department of Energy and the Environmental Protection Agency operate the EnergyStar Program, which awards an EnergyStar symbol to major appliances, office equipment, lighting, home electronics, new homes, and commercial and industrial buildings that meet certain energy efficiency guidelines. Americans have purchased more than 1 billion EnergyStar qualified products, and more than 1,100 buildings have earned the EnergyStar label for energy efficiency.[60] More than 40 percent of Americans recognize the EnergyStar symbol.[61] In 2004, partly due to EnergyStar, Americans saved $10 billion in energy costs.[62]

The Los Angeles Environmental Health Food Inspection Program gives letter grades to restaurants based on their food-safety inspection scores.[63] According to a survey conducted in 2001, Los Angeles residents like the rating system, and their behavior is influenced by the restaurants' scores.[64] Of those Los Angeles residents who eat at restaurants, 88 percent would

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[59] Sandra Weiss, *An Evaluation of the Uniform Tire Quality Grading Standards and Other Tire Labeling Requirements*, NHTSA Report Number DOT HS 807 805, January 1992, http://www.nhtsa.dot.gov/cars/rules/regrev/evaluate/807805.html (accessed November 21, 2006).

[60] *Energy Star – The Power to Protect the Environment through Energy Efficiency*, http://www.energystar.gov/ia/partners/downloads/energy_star_report_aug_2003.pdf (accessed November 21, 2006).

[61] *Id.*

[62] *About Energy Star*, http://www.energystar.gov/index.cfm?c=about.ab_index (accessed November 21, 2006).

[63] *Retail Food Inspection Guide Online*, http://lapublichealth.org/eh/rfig/index2.html (accessed November 21, 2006).

[64] *Retail Food Facility Inspection System Survey Results*, http://www2.co.la.ca.us/supdocs/sops2002/sd02-2987a.pdf (accessed November 21, 2006).

eat at an "A" restaurant all or most of the time, only 25 percent would eat at a "B" restaurant, and a mere 3 percent would eat at a "C" restaurant.[65]

We urge the FDA to follow the lead of those government agencies and supplement the NFP with a simple, easy to understand symbol(s) on the PDP that would readily communicate information to consumers about the healthfulness of foods.

3. Food Regulatory Authorities in Other Countries have Developed Symbols to Indicate the Healthfulness of Foods

Symbols indicating the healthfulness of foods are already administered by governments in the U.K., Sweden, and other countries. The FDA should examine the work recently completed by the U.K.'s FSA, which has designed a PDP labeling scheme that rates the amounts of several key undesirable nutrients in foods. An important aim of the government plan is to reduce potential confusion among consumers caused by various private labeling schemes used by U.K. manufacturers and retailers.[66] The FSA, after an intensive research effort, instituted a "signposting" system. Foods are given separate high, medium, or low ratings (and corresponding red, amber, and green color codes) for fat, saturated fat, salt, and sugar. Companies are encouraged to use color-coded traffic-light symbols on the fronts of food packages indicating the amounts of those nutrients. The FDA could consider adding calorie content to such a list of nutrients.

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[65] *Id.*

[66] *Further consumer research on signposting labelling*, March 18, 2005, http://www.food.gov.uk/consultations/ukwideconsults/2005/signpostconsultmar05 (accessed November 21, 2006).

U.K. Multiple Nutrient Traffic Light—Two Examples

The voluntary system was instituted in March 2006. Some companies, including the Waitrose, New Covent Garden Food, and Sainsbury's, are utilizing the system (the latter uses color-coded pie graphs instead of colored dots). Sainsbury's has reported that use of the scheme has significantly influenced sales patterns in a positive manner.[67] Other retailers, including ASDA Walmart and COOP, are expected to follow.[68] At least one manufacturer, McCain's, has announced it will use the FSA traffic light system on all of its products sold in the U.K. (but not the U.S.).[69]

The retailer Tesco, however, said it will instead print an abbreviated nutrition label on the fronts of house-brand packages, instead of using FSA's system.[70] In addition, many major manufacturers, including Kraft, Danone (Dannon), Kellogg, Nestle, and PepsiCo, will only provide fat, sugar, salt, and carbohydrate content information on the backs of food packages, along with information on recommended daily amounts. That action will result in labels

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[67] *Industry Divides Over Nutrition Labeling*, Food Magazine, Issue 74, July/August 2006, p. 18.

[68] *Simpler labelling for healthier choices*, The European Consumer's Organization, July 12, 2006, page 16.

[69] *UK chip make puts traffic lights on products,* Food Chemical News, September 18, 2006, p. 21.

[70] *Food Labelling Explained,* http://www.tesco.com/health/eating/?page=label (accessed November 18, 2006).

somewhat akin to the current U.S. FDA Nutrition Facts Panel, albeit with information about fewer nutrients.

Since 1989 the Swedish National Food Administration has allowed more-nutritious foods within particular food categories to be labeled with a green keyhole symbol; use of the keyhole is voluntary.[71] One major Swedish retailer, ICA, has used the keyhole symbol and reports that "in 2003 and 2004 sales of keyhole products rose by over 15%."[72] The same retailer told CSPI that when it introduced the keyhole labeling into its Norwegian stores, sales of products bearing the symbol increased by 20 percent.[73]

Swedish Keyhole Symbol

The Swedish keyhole only identifies more-healthful food choices within particular food categories like pizza, cheese, margarine, and 23 others.[74] This approach differs significantly from the U.K. FSA traffic light system which calls for the use of color-coded symbols (green, yellow, and red) on all foods, not just those that are relatively healthful within a specific food category. The Swedish system, while useful, does not identify which foods are less healthy.

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[71] *The key-hole symbol*, http://www.slv.se/engdefault.asp (accessed September 7, 2006).

[72] "We want to make it easier for our customers to eat healthy: *Facts and questions from ICA on the health debate.*" ICA AB, Solna, Sweden (owner of Giant Foods and Stop and Shop in the U.S.)

[73] Personal Communication, Erin Boyd. ICA (Royal Ahold USA), Nov. 2, 2006.

[74] *Supra*, n. 69.

E. FDA Should Solicit Comments on Nutritional Criteria for its System of PDP Symbol(s)

In its ANPR, the FDA should suggest and solicit comments on sample criteria that could be used to assign appropriate symbol(s) to particular foods.[75] For example, criteria could be based on the FDA's existing framework of DVs. The FDA advises that 5 percent of the DV or less of a nutrient in a serving of food is considered low, and 20 percent DV or more is considered high, for various nutrients.[76] Based on that guidance, foods with 5 percent DV or less of fat, saturated fat, cholesterol, and sodium *and* 20 percent DV or more of dietary fiber, calcium, iron, vitamin A, or vitamin C could be categorized as "Most Healthful." Foods that contained 20 percent DV or more of fat, saturated fat, cholesterol, or sodium could be categorized as a "Less Healthful Choice." Foods whose nutrient content did not meet either of those extremes would be categorized as "Intermediate: Eat in Moderation." FDA could also build on this model by adjusting for serving size, adding criteria for calories, trans fat, and added sugars, and varying the criteria for different food groups (grains, dairy, etc.).

The FDA should also explain and solicit comments on the criteria and symbols used by the U.K.'s FSA, the Swedish government, and those developed by Hannaford Brothers, the American Heart Association, PepsiCo, Kraft, and others.

FDA's experience regulating the use of the word "healthy" on food labels underscores the pitfalls involved in developing criteria for a PDP-based symbol(s) to communicate nutritional content. The "Healthy" term is an absolute one—foods either meet or fail the criteria.[77] While FDA took an important step by specifying criteria for the use of the word "healthy" on the food

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[75] The FDA should consider whether to develop different criteria for various food categories, similar to the Swedish keyhole system, or set uniform criteria applicable to all foods.

[76] *How to Understand and Use the Nutrition Facts Label*, http://www.cfsan.fda.gov/~dms/foodlab.html (accessed November 21, 2006).

[77] *See* 21 C.F.R. § 101.65(d)(2)-(4).

label, the system has not resulted in a large number of products bearing the "healthy" claim. According to an FDA marketplace data analysis, only 69 brands carried a "healthy" claim five years after the rule took effect (while 50 brands carried such a claim immediately before the rule took effect).[78] Based on this limited experience, the use of an absolute, compared to a relative approach, may not be appropriate for a PDP based labeling program using symbols.[79]

IV. Statement of Legal Grounds

FDA has legal authority to undertake the actions requested in this petition. The NLEA was designed to allow for changes to the food label based on new information and research. This flexibility was built into the statute to give the Secretary "the discretion to take new information into account and the ability to require that the nutrition label of foods be consistent with new research and other information."[80]

The House Report to the NLEA specifically states that the Secretary has discretion to require the use of universal symbols (such as traffic-light color codes or stars). The House Report states:

> In order to present nutrition information in a manner that facilitates the public's understanding, the Secretary may choose among a variety of options. For example, one way that this could be accomplished would be to include information about the recommended daily intake on the label. This could include the use of descriptive terms such as "high," medium," and "low" or *use of universal symbols* to indicate desirable or undesirable levels of particular nutrients. While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand

[78] 68 Fed. Reg. 8163, 8165 (February 20, 2003).

[79] Furthermore, FDA's definition of "healthy" completely omits consideration of added-sugars content. Theses omissions render the Agency's definition obsolete given the current obesity epidemic and studies showing that sweetened beverages contribute to that problem. Similar observations can be made about the FDA's failure to consider trans fat content in its definition of "healthy." The "healthy" criteria also are invariant regardless of serving size or calorie content. Thus an 8-oz. serving of soup and a 1-oz. serving of baked potato chips both are limited to 480 milligrams of sodium. That amount of sodium in a one-ounce serving would be extraordinarily high. Finally, it is possible that the absence of an officially designated symbol detracted from the use of the "healthy" claim.

[80] H.R. Rep. 101-538, at 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3344.

the nutrition information pertaining to a particular food in relation to recommended dietary information.[81] (emphasis added)

FDA therefore has the authority, and the responsibility, to institute a new, simpler labeling system to supplement the NFP that would help consumers make healthier food choices. Doing so would ensure that nutrition information is "conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."[82]

The symbol(s) should appear on the PDP. At the current time, 21 C.F.R. § 101.2(b) provides that nutrition information may appear either on the PDP or on the information panel. Since consumers often look only at the PDP when considering a product, placement of the symbol(s) on the front label is necessary to ensure that the information is accessible and used as much as possible.

After establishing a national labeling program, FDA may find that inconsistent labeling schemes operated by companies or non-profit organizations are misleading for a variety of reasons. First, the criteria for awarding such symbols may not accurately convey the nutritional value of the food. Second, such symbols may imply that a food is healthful overall when the food is only healthful in one particular respect. Third, even programs that are not objectionable in isolation may in the aggregate mislead consumers; various symbols may be confused with one another and with the national program that FDA itself establishes.

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[81] H.R. Rep. 101-538, at 18 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3347.

[82] NLEA, P.L. 101-535§2(b)(1)(A).

Misleading labeling constitutes misbranding and is not protected by the First Amendment.[83] Hence, when the national program is in place, the FDA should announce whether private labeling schemes should be allowed to continue.

V. Recommended Questions for FDA's ANPR

FDA should announce an Advance Notice of Proposed Rulemaking to develop a PDP-based labeling system for nutrition information that utilizes a symbol(s) to communicate the healthfulness of foods to consumers.

The Agency should solicit public comment on such issues as the following:

- What proprietary front-label (or supermarket shelf marker) symbols are currently in use?
- What impact has the voluntary use of certification symbols indicating nutritional quality had on consumer preferences and product formulation?
- Does existing consumer research indicate that a PDP-based symbol(s) effectively communicates the healthfulness of foods to the typical consumer?
- Is additional research needed, and, if so, what kinds of studies?
- Should PDP-based symbol(s) be applied to all foods or just the most healthful foods?
- Should the FDA develop a PDP-based labeling system and symbol(s) that would indicate relatively healthier and less healthier foods?
- Should criteria vary according to food group (for example, fiber and sodium are particularly important for grain foods, while saturated fat is important for dairy foods)?

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[83] *Central Hudson Gas and Electric v. Public Service Commission,* 447 U.S. 557 (1980).

- Should the program be voluntary or mandatory?[84]
- What should the nutrition criteria for the use of such symbol(s) be?
- What should the symbol(s) look like? Should symbol(s) be accompanied by explanatory terminology or should the symbol(s) be self-explanatory?
- Do any special requirements of specific population groups (low income, children, non-English speakers, elderly) need to be addressed?
- If the FDA devises a PDP-based symbolic system, should the Agency consider private nutrition symbols that are based on criteria inconsistent with the Agency's system to be misleading and prohibit their further use?
- What other scientific, public health, marketing, legal, and consumer behavior issues should the Agency consider in the context of this ANPR?

VI. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. § 25.30 and therefore does not require the preparation of an environmental assessment.

VII. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.[85]

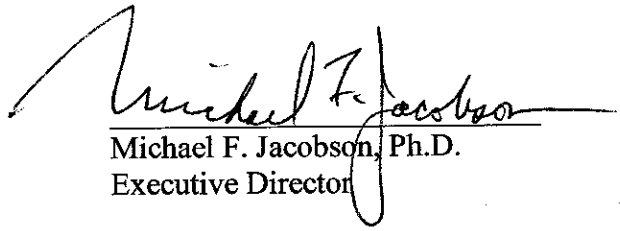
[84] As noted above, at supra 3, CSPI strongly urges that PDP nutrition labeling be mandatory.

[85] 21 C.F.R. § 10.30(b).

VIII. Certification

The undersigned parties certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Respectfully submitted,



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Appendix I

The following individuals have asked that they be listed as supporters of this petition:

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Appendix II

Comparison of Nutritional Criteria for Several Food Labeling Systems

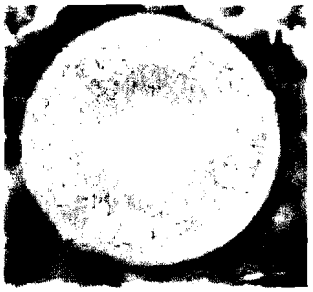
Nutrients	FDA's Definition of "Healthy" (per serving)	American Heart Association Certification System (per serving) (for products other than whole grains, meat, poultry, and seafood)	PepsiCo's Smart Spot (per serving)		Kraft Foods' Sensible Solution (Salted Snacks, Cookies and Crackers) (per serving)	General Mills Goodness Corner (selected icons) (per serving)
			Foods (except snacks)	Snacks		
Calories	No limit.	No limit.	No limit.	No limit.	≤100 calories (some exceptions apply).	Icon indicating number of calories may be posted on the package.
Fat	≤ 3 g.	≤ 3 g (5 g for meat, poultry, and seafood).	≤ 30% of calories.	≤ 35% of calories.	≤ 30% of calories (some exceptions apply).	≤ 3 g per serving or per 50 g if serving size is 30 g or less.
Saturated Fat	≤ 1 g.	≤ 1 g (2 g for meat, poultry, and seafood).	≤ 1 g.	≤ 1 g.	≤ 10% of calories from saturated fat plus trans fat.	≤ 1 g and ≤ 15% of calories.
Trans Fat	No limit.	No limit (except 0.5 g for whole grains).	< 0.5 g.	< 0.5 g.	≤ 10% of calories from saturated fat plus trans fat.	No icon.
Cholesterol	≤ 60 mg.	≤ 20 mg. (95 mg for meat, poultry, and seafood).	≤ 60 mg.	≤ 60 mg.	No limit.	≤ 20 mg per serving or per 50 g if serving size is 30 g or less. Must also contain ≤ 2g of saturated fat.
Added Sugars	No limit.	No limit.	≤ 25% of calories from added sugar unless the product contains ≥ 10% DV of fiber.	≤ 25% of calories from added sugar unless the product contains ≥ 10% DV of fiber.	≤ 25% of calories.	Icon indicating number of grams of sugars may be posted on the package.
Sodium	≤ 360 mg/ 480 mg, depending on food.	≤ 480 mg.	≤ 480 mg.	≤ 270 mg.	≤ 290 mg.	No icon.

Must contain:	At least 10% of the Daily Value of: protein, vitamins A and C, calcium, iron, or fiber. Except raw vegetables; frozen or canned single ingredient fruits or vegetables; enriched cereal-grain products that conform to standard of identity. (Fortified foods do not qualify).	At least 10% of the Daily Value of naturally occurring: protein, vitamins A and C, calcium, iron, or dietary fiber. (Fortified foods do not qualify).	At least 10% of the Daily Value of: protein, vitamins A and C, calcium, iron, or dietary fiber. (Requirement may be achieved through fortification.)	No requirement.	At least 10% of the Daily Value of: protein, vitamins A, C, and E, calcium, magnesium, potassium, iron, or fiber **or** contains at least a half-serving of fruit, vegetable or a nutritionally significant amount of whole grain **or** has a functional nutrition benefit. (It is unclear whether requirement can be achieved through fortification).	No requirement.
Alternative Criteria	AND food must comply with established definition and declaration requirements for any specified nutrient content claim.	None.	OR delivers a functional benefit via natural or fortified ingredients proven to be effective; OR is reduced in calories, fat, sugar, or sodium by at least 25% compared to base product or other appropriate reference product.	OR delivers a functional benefit via natural or fortified ingredients proven to be effective; OR is reduced in calories, fat, sugar, or sodium by at least 25% compared to base product or other appropriate reference product.	OR must be free of or low in calories, fat, saturated fat, sugar or sodium; OR must have 25% less of one of these in comparison to the base product or an appropriate reference product; AND must be reviewed by Nutrition Department.	Good source of fiber: contains ≤ 2.5 g or ≥ 10% of the Daily Value. Excellent source of fiber: contains ≥ 5 g or ≥ 20% of the Daily Value. Good source of calcium or iron: contains ≥ 10% of the Daily Value. Excellent source of calcium, or iron: contains ≥ 20% of the Daily Value. Vitamins and minerals: contains ≥ 10% of the Daily Value of the number of vitamins and minerals

						indicated on the icon. Good source of whole grain: contains ≥ 8 g. Excellent source of whole grain: contains ≥ 16 g.

Appendix III

PDP Symbols Used by Private Label Programs



PepsiCo: "Smart Spot"

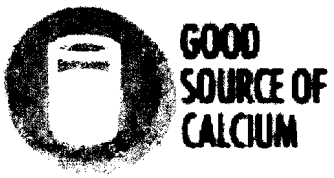
Unilever: "Eat Smart"

American Dairy Assn.: "3-A-Day of Dairy"

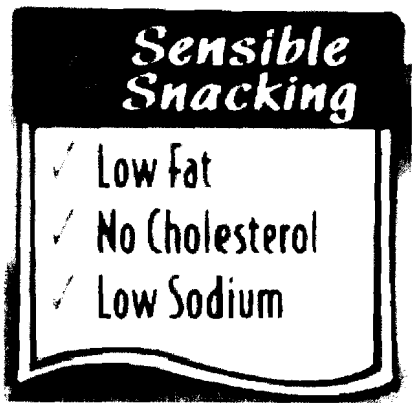
American Heart Association

Products displaying the heart-check mark meet American Heart Association food criteria for saturated fat and cholesterol for healthy people over age 2

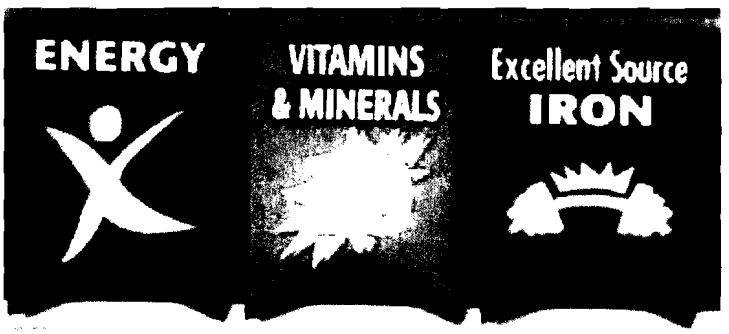
American Heart Association's Food Certification Program: "Heart-Check"



General Mills: "Goodness Corner"



Kraft: "Sensible Solution"



Kellogg's: "Best to You"