

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

Petition for Proposed Rulemaking and)
Regulatory Action to Prohibit)
Misleading Food Labeling)
_____)

Docket No. 95P-0246

Submitted by the
Center for Science in the Public Interest
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Food and Drug Administration
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CITIZEN'S PETITION

The Center for Science in the Public Interest (CSPI) submits this petition pursuant to § 4(d) of the Administrative Procedures Act, 5 U.S.C. § 553(e), and §§ 201(n), 403(a), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 321(n), 343(a), and 371(a), respectively, and 21 C.F.R. §§ 10.30, 101.18(b) and 102.5(b). We request that the Food and Drug Administration (FDA) take action to prohibit a variety of misleading labeling practices on food packages.

I. INTRODUCTION

The enactment of the Nutrition Labeling and Education Act of 1990 (NLEA) marked a watershed in the history of food labeling regulation. Consumers can now find not only mandatory nutrition information in the "Nutrition Facts" panel of nearly every food label, but can also rely on standardized definitions of terms such as "lite," "low fat," and "healthy."

While FDA has successfully implemented the NLEA, many misleading labeling practices not specifically covered by the Act still remain. In this petition, we outline some of the most

common problems. In some cases, misleading claims are made on the principal display panel of a product. In other instances, consumers may be misled by the brand name of the product, or by illustrations on the label. In either case, FDA should build on its successful effort to bring order to nutrition and health claims by undertaking a new effort to eliminate remaining instances of deceptive labeling.

II. REQUESTED ACTION

We request that the FDA take the following actions:

- Prohibit claims that misleadingly imply that fruits, vegetables and whole grains are present in foods in amounts greater than are actually the case;
- Prohibit the misleading use of claims concerning sugar content;
- Prohibit labels from bearing illustrations (or "vignettes") of ingredients not present in the product, or present in amounts smaller than what is depicted on the label.

Given the nature and prevalence of these problems, we urge FDA to issue a notice of proposed rulemaking that examines how the agency's existing regulations and compliance policy guides should be revised. In the interim, we urge FDA to take individual enforcement actions where appropriate.

III. MISLEADING CLAIMS CONCERNING INGREDIENTS REGARDED AS HEALTHFUL

The NLEA has helped ensure that nutrition claims such as "healthy" or "low fat" appear only on foods that meet criteria specified by the FDA. These requirements not only have

eliminated many misleading claims, but they have also led many companies to improve the nutritional value of their products in order to earn the privilege of making nutrition claims.¹

In some cases, however, manufacturers have chosen to continue to market foods on the basis of health by making misleading claims not covered by the NLEA. We are particularly concerned about food labels that misleadingly highlight the presence of specific ingredients (such as fruits, vegetables or whole grains) that are considered by consumers to be healthful, yet are present in the food in only minimal amounts.

While these claims may not be covered by the NLEA, they can most certainly be addressed under FDA's general authority to prohibit misbranding of foods, 21 U.S.C. §343(a). We urge FDA to remedy this problem by taking case-by-case enforcement actions and by issuing appropriate regulations. We urge FDA to give priority attention to the following areas:

A. Misleading Use of the Term "Fruit"

Health authorities urge Americans to increase their consumption of fruits and vegetables.² Some companies are properly capitalizing on this advice by using FDA-approved health and nutrition claims regarding the importance of consuming fruits

¹ For example, more "low fat" and "reduced fat" products were introduced in the marketplace in the last year than in any other previous period.

² See USDA/DHHS, *Dietary Guidelines for Americans 18-20* (3rd Ed. 1990); USDA Food Guide Pyramid (1992). The National Cancer Institute also urges consumers to eat at least five servings of fruits and vegetables a day.

and vegetables.³ Others, however, are merely touting the presence of "fruit" in product names or in claims on the principal display panel, thus misleading consumers by implying that these products contain much greater amounts of fruit than they actually do.

1. Use of the term "fruit" on the labels of products that contain no fruit

The term "fruit" is sometimes used in association with products that contain no fruit at all. At best, such products contain only a trivial amount of fruit juice.⁴ For example:

- General Mills' "Berry Berry Kix" contains no berries, only a small amount of grape juice and a tinier amount of strawberry juice concentrate;
- Quaker Oats' Instant Oatmeal "Mighty Morphin Power Rangers Ultra-Fruit Power Bolts" contains no fruit or fruit juice;
- Betty Crocker's "Bugs Bunny And Friends Snacks Made with Fruit" states on the label "Assorted Fruit-Strawberry-Grape-Orange-Cherry." Yet the only fruit contained in the product is

³ For example, the labels of several Pillsbury brand Green Giant frozen vegetables utilize FDA approved health claims regarding the relationship between a diet rich in certain types of fruits and vegetables and a reduction in the risk of cancer. The Florida Department of Citrus has used similar claims in advertising to promote the consumption of orange juice.

⁴ We were able to determine that the quantity of fruit juice in these products was small by examining the order in which ingredients are listed on the label. In some cases, we were able to estimate the quantity of juice more precisely by examining its order on the ingredient label relative to ingredients like oil that supply nutrients that are declared on the Nutrition Facts label. For example, the only source of fat in Starburst Fruit Chews is soybean oil. These candies contain more oil than fruit juice and the Nutrition Facts label indicates that they contain three grams of fat per serving. Therefore, the product contains no more than three grams of fruit juice per serving.

grapes from concentrate;

- Hershey's "Amazin' Fruit Super Fruits" contains mostly corn syrup, sugar, and gelatin, and only a small amount of fruit juice concentrate;
- Brach's "Fruit Bunch Jellies" with "Real Fruit Juice" is made primarily from corn syrup, sugar, and modified corn starch, and contains only a small amount of fruit juice concentrate;
- Mars Inc.'s "Original Fruits Starburst Fruit Chews" contains only a small amount of fruit juice from concentrate, and is made primarily from corn syrup, sugar, and partially hydrogenated soybean oil;
- Aunt Jemima Blueberry Waffles do not contain any real blueberries, just artificially flavored blueberry bits consisting of sugar, dextrose, partially hydrogenated soybean oil, soy protein concentrate, artificial flavor, salt, citric acid, cellulose gum, blue dye, red dye, and malic acid.⁵

It is misleading for a product name to include the word "fruit" or "berry" when the product contains no fruit at all. The use of the word "fruit" in many candy products is particularly disturbing. The names of these products lead parents to believe that such products are a healthier alternative to "regular" candy for their children. Clearly, this is not the case for products such as the ones cited above. These products do not contain any fruit, and the small amount of fruit juice in them is typically of negligible value. To eliminate this deceptive practice, we urge the FDA to:⁶

⁵ See Appendix A for copies of product labels.

⁶ We urge FDA to require that all disclosures recommended in this petition be printed on a contrasting background, and in compliance with typeface requirements that prevent the disclosures from being obscured relative to other non-required information on the label.

- Require products that use the word "fruit" in product names or claims, but that contain only fruit juice, to state on the principal display panel "Contains No Fruit" in immediate proximity to such name or claim, and in type no less than the size of the name or claim.⁷
- Require products that use the term "fruit juice" in product names or claims to disclose the amount of fruit juice per serving (expressed in household measures) in immediate proximity to such name or claim, and in type size no less than one-half the size of the name or claim.

2. Use of the term "fruit" on the labels of products that contain minimal amounts of fruit

There are also a number of "fruit" products that contain only a small amount of fruit (and often more sugar) plus other ingredients that are artificially colored or flavored.⁸ For example:

- Betty Crocker's Strawberry "Fruit Roll Ups" contains strawberries, but also significant amounts of sweeteners, including sugar, pear puree concentrate, and corn syrup. It is described on the front label as "Chewy Snacks Made With Fruit" and as "Chewy Fruit Snacks."
- Colombo's "Fat-Free Peach Yogurt" with "Fruit on the bottom" claims to be "bursting with real fruit." However, a container of peach yogurt contains more sugar than fruit (a container typically yields only two

⁷ We recognize that FDA already requires these products to state that they contain natural and/or artificial flavors. We do not believe, however, that this disclosure alone is sufficient to prevent the misleading inferences about the fruit content of these products.

⁸ We were able to estimate the quantity of fruit in these products by actually measuring the fruit in the product, or by examining the order in which ingredients are listed on the label. In some cases, we were able to estimate the quantity of juice more precisely by examining its order on the ingredient label relative to ingredients like oil that supply nutrients that are declared on the Nutrition Facts label.

small pieces of peach and some peach preserves). Coloring is added to imply the presence of more fruit.

- Kellogg's "Nutri-Grain Cereal Bars" claim to be made with "fruit." The products are actually made with fruit preserves.
- Nabisco's SnackWell "Strawberry Cereal Bars" claim to be "Made With Real Fruit." This product, however, contains more sugar than strawberries. Furthermore, the strawberries in this product are mixed with dried apple bits that have been dyed red.
- Sunshine's "Oh! Berry Fat Free Strawberry Wafers" comes in a box that is completely covered on all sides with pictures of real strawberries. The wafers are largely sugar and flour and contain artificial red dye, presumably to illustrate the presence of strawberries. They contain only a small amount of strawberry puree.
- Ralston "Strawberry Muesli" depicts real strawberries on the front label and contains a lengthy essay about strawberries on the back label. The product, however, merely contains simulated strawberries apparently made from strawberry puree, strawberry juice concentrate, sweeteners, and other ingredients. Furthermore, the cereal contains more salt than strawberry puree or juice. A serving of the cereal contains less than a half gram -- or one-twentieth of a tablespoon -- of strawberry puree or strawberry juice concentrate.
- Kudos "Low Fat Blueberry Whole Grain Bars" contain no real blueberries, only "blueberry fruit bits" consisting of corn syrup, sugar, apple concentrate, blueberry concentrate, food starch-modified, malic acid, natural and artificial flavors and blue dye.⁹

Baby foods are of particular concern. The labels of some of these products make misleading claims about the nature of their ingredients.¹⁰ For example:

⁹ See Appendix B for copies of product labels.

¹⁰ In a letter dated April 20, 1995, CSPI urged the FDA to require that baby food labels bear percentage-ingredient labeling. See Letter to Dr. David Kessler, Commissioner, Food and Drug Administration, from Michael Jacobson, Ph.D., Executive Director, CSPI (Apr. 20, 1995); See Center for Science in the

- Heinz's Stage 2 "Bananas with Tapioca" contains added sugar, food starch-modified (from corn), modified tapioca starch and citric acid. This product contains less than one third as much bananas per unit weight as Heinz's Stage 1 "Bananas."¹¹

All of the above claims mislead parents into believing that these products contain more fruit than is actually the case. The FDA should prevent companies from implying that foods contain substantial amounts of fruit and are thus healthful, when in fact such foods contain only fruit juice or much smaller amounts of real fruit than consumers might reasonably expect.

To eliminate deceptive labeling practices concerning fruit content, we urge the FDA to take appropriate enforcement actions to halt the specific claims identified above.¹² In addition, we urge the FDA to:

- Require that claims about "fruit," or the name of a specific fruit,¹³ disclose in immediate proximity to such claim, and in type no less than one-half the size of the claim, the actual amount of fruit per serving, expressed in household measures (e.g., "Each bar contains about a teaspoon of strawberries").¹⁴

Public Interest, *Cheating Babies* (1995).

¹¹ See Appendix C for a copy of the product label.

¹² We recognize that FDA already requires these products to state that they contain natural and/or artificial flavors. We do not believe, however, that this disclosure alone is sufficient to prevent the misleading inferences about the fruit content of these products.

¹³ FDA should also require, where appropriate, that the amount of fruit juice per serving be disclosed in direct proximity to, and in no less than one-half the type size of, the term "fruit juice" in any product name or claim.

¹⁴ In some cases, it may be appropriate to require that the amount of fruit in a product be disclosed as a percentage of weight.

3. Products that imply that they contain only fruit but are made with both fruit and fruit juice

Some food labels imply that products consist entirely of fruit, when, in fact, they contain both fruit and fruit juice.

For example:

- Polaner's "All Fruit Apricot Spreadable Fruit" contains more "grape juice concentrate" than apricots;
- Smucker's "Simply Fruit Strawberry Spreadable Fruit" has more "clarified white grape juice concentrate" than strawberries;
- Sorrell Ridge "100% Fruit Orange Marmalade Spreadable Fruit" states on the label "With 100% FRUIT It Has to be Better." The product, however, contains more grape and pear juice concentrate than orange or fruit pectin.¹⁵

Names like "All Fruit" and "Simply Fruit" mislead consumers into believing that these products consist entirely of fruit and that eating a "spreadable fruit" product is thus equivalent to eating a similar-sized serving of fruit.¹⁶

In addition, labels on a number of "spreadable fruit" products imply that the products are more healthful than foods meeting FDA's standards for "fruit butters, jellies, preserves

¹⁵ See Appendix D for copies of product labels.

¹⁶ Small print on each of these three labels states that the products are sweetened with fruit juice. These disclosures, however, are not sufficient to remedy the misleading impressions created by much more prominent claims such as "All Fruit" or "100% Fruit."

and related products."¹⁷ For example, the label of Polaner's "All Fruit Raspberry Spreadable Fruit" states "Sweetened only with fruit juice concentrates." Moreover, based on a comparison of ingredient labels (which list ingredients in order of predominance), Polaner's "All Fruit" may actually contain a smaller percentage of raspberries than Polaner's "Red Raspberry Preserves."¹⁸

In order to eliminate consumer deception regarding the nutritional quality of such products, we urge the FDA to take individual enforcement actions and issue a regulation to:

- Prohibit the use of claims such as "all fruit," "simply fruit" or words of similar intent on the labels of products that do not consist of 100% fruit.¹⁹

B. Misleading Use of the Term "Vegetable"

As noted above, leading health authorities urge Americans to increase their consumption of both fruits and vegetables. In light of these concerns, some companies highlight the vegetable

¹⁷ 21 C.F.R. Part 150. These food standards, among other things, require that each type of product contains a set amount of fruit or, in the case of jelly, fruit juice. Fruit butters must contain not less than five parts by weight of the fruit ingredient to each two parts by weight of the sweeteners. 21 C.F.R. § 150.110(d)(1). By contrast, fruit jellies must contain not less than 45 parts by weight of fruit juice ingredients. *Id.* at § 150.140(d)(1). "Fruit preserves and jams" must consist of either 47 parts by weight of "Group I" fruits, or 45 parts by weight of fruits listed in "Group II." *Id.* at § 150.160(d)(1).

¹⁸ Furthermore, consumers may believe that they are purchasing a superior product and thus may be willing to pay more for "spreadable fruit" than they would for ordinary preserves.

¹⁹ Products that contain both fruit and fruit juice should be required to comply with the disclosure requirements that we have previously recommended.

content of their products on the principal display panel in order to make the product seem more healthful than it really is. The products, however, oftentimes contain only a trivial amount of vegetables.²⁰ For example:²¹

- Health Valley's Fat-Free Crackers "Organic Wheat with Vegetables" does not contain a significant amount of vegetables. Rather, the ingredient label indicates that it contains only a small amount of carrot powder and a "natural vegetable and herb blend," which consists primarily of onion and garlic. The beta-carotene content of the crackers, which is highlighted on the front label, may also lead consumers to believe that the crackers contain significant amounts of vegetables.
- Lipton's Golden Saute "Chicken Broccoli Angel Hair Pasta" contains more salt than broccoli, and the only chicken in the product is chicken fat.
- Campbell's "Prego Spaghetti Sauce" claims to be "Made with Fresh Mushrooms." Yet, a typical serving contains only approximately 1/7th of a mushroom.
- Lipton's "Rice & Sauce - Cheddar Broccoli" claims to be made with broccoli. Yet, a typical serving contains only half of a tablespoon of what appears to be broccoli stalks.

²⁰ We determined the quantity of vegetables in these products by estimating the quantity of vegetables that would have provided the level of vitamin A declared on the label. In other cases, we actually measured the amount of vegetable per serving, or examined the order in which ingredients appeared on the label.

²¹ In addition, in a survey released in the March 1995 issue of *Nutrition Action Healthletter*, we found that the labels of numerous frozen dinners and entrees misleadingly implied that the products contained a serving of vegetables or fruit. Based on this analysis, we have asked both FDA and USDA to require that the principal display panel disclose in household measures the quantity of any ingredient that is mentioned or pictured on the product package. See Letters from Michael Jacobson, Ph.D., Executive Director, CSPI, to Commissioner David Kessler, U.S. Food and Drug Administration, and Michael Taylor, Undersecretary of Food Safety, U.S. Department of Agriculture (Mar. 2, 1995).

- De Cecco's "Spaghetti with Spinach" touts the presence of spinach yet contains only a tenth of a tablespoon of spinach per serving.
- Heinz's "Stage 2 Mixed Vegetables" baby food includes pictures of potatoes on its label. The product, however, contains no potatoes -- only potato flour.²²

These product labels are misleading because they imply that the products contain a larger amount of vegetables than is actually the case. In order to eliminate these deceptive practices, we urge FDA to take individual enforcement actions, as well as:

- Require that claims about "vegetables," or the name of a specific vegetable, disclose in immediate proximity to such claim, and in type no less than one-half the size of such claim, the actual amount of vegetables per serving, expressed in household measures (e.g., "Each serving contains 1/25 of a carrot").²³

C. Use of the Terms "Whole Wheat," "Whole Grain," "Graham," "Bran," or "Multi-grain"

The labels of many cracker products, as well as some breakfast cereals, breads, and frozen waffles, bear the words "whole wheat" or "graham." The use of such terms may mislead consumers into believing that some such products are made entirely, or primarily, from nutritious whole grains, when in

²² See Appendix E for a copy of the product label. See also "Cheating Babies," *supra*, page 6, n. 8.

²³ When appropriate, the FDA may wish to require that this disclosure be expressed as a percentage of weight. We recognize that this disclosure may not be necessary when there is no reasonable expectation by the consumer that the food would contain any nutritionally significant amounts of a vegetable. For example, a disclosure regarding the poppyseed content of a poppyseed bagel would not be required.

fact they contain primarily enriched white flour, which is lower in vitamins, minerals and dietary fiber than whole grains. In June 1993, CSPI petitioned FDA to stop these deceptive labeling practices.

On November 1, 1993, FDA provided an interim response to CSPI's petition.²⁴ The agency stated that, over the years, FDA has consistently advised manufacturers that a product that uses "whole wheat" as part of its common or usual name must be made from enough whole wheat to characterize the food. In addition, the agency cited the preamble to its final rule on nutrient content claims, where FDA addressed whether identity statements (e.g., "whole wheat bagels") can be considered implied nutrient content claims. Finally, the Commissioner noted that two warning letters had been sent regarding products cited in the CSPI petition.

Despite those actions by FDA, deceptive whole wheat claims continue to appear in the marketplace. For example:

- Nabisco's "Ritz Crackers with Whole Wheat" contains more white flour than whole wheat.
- Kellogg's "Nutri-Grain Cereal Bars" claims to be made with "whole grain oats." The cereal bars, however, contain more enriched white flour than whole oats.

In addition, other misleading "grain" and "bran" claims are also flourishing. For example:

- Roman Meal's "Round Top Bread" repeatedly boasts "natural grain goodness" but has more white flour (as

²⁴ See Letter from Dr. David Kessler, Commissioner, U.S. Food and Drug Administration, to Michael F. Jacobson, Ph.D., Executive Director, CSPI (Nov. 1, 1993).

well as more water and corn syrup) than whole wheat flour.

- Pepperidge Farm's "Hearty Slices" claims that it is a "Seven Grain" bread "baked with the wholesome goodness of 3 natural brans." This bread, however, contains more white flour than any whole grain or bran ingredient and even more salt than corn, rye meal, wheat kernels, rye flour, rice bran, barley, oatmeal, wheat germ, oat bran, rye, oat flour, amaranth bran flour, soya grits, malted barley, and oat fiber.²⁵

In addition to deceptive "whole wheat" claims, many products made primarily from white flour identify themselves as "graham," a term that is synonymous with "whole wheat."²⁶ For example:

- Nabisco's "Teddy Grahams Graham Snacks" is made primarily with white flour. Furthermore, the product contains more sugar, vegetable shortening, and honey than graham flour.²⁷

In light of this continuing problem,²⁸ we urge the FDA to reexamine CSPI's 1993 petition, conduct industry-wide enforcement actions on a case-by-case basis, and propose regulations that would prohibit companies from making deceptive "whole wheat," "whole grain," "graham," "bran," and "grain" claims.

²⁵ See Appendix F for copies of product labels.

²⁶ Whole wheat flour, for instance, is sometimes identified on labels as "graham flour."

²⁷ See Appendix G for a copy of the product label.

²⁸ While food labels now disclose fiber content, this disclosure does not address all health concerns caused by the misleading labeling claims described above. The fiber content of some products is boosted by ingredients such as cellulose or gums, ingredients that are not nutritionally equivalent to whole grains, which contain valuable constituents other than fiber. Thus, the fiber content disclosure on the Nutrition Facts panel does not, by itself, remedy this problem. Furthermore, bold statements on the front label are much more visible to consumers than disclosures of fiber content on the Nutrition Facts panel.

Specifically, we urge the agency to:

- Prohibit use of the terms "whole wheat" or "graham" in the common or usual name or brand name of a product, unless whole wheat or graham flour is the predominant ingredient, and the product contains no white flour.
- Require products that make whole wheat claims, such as "made with whole wheat," to disclose on the principal display panel, in immediate proximity to the whole wheat claim, and in type no less than one-half the size of that claim, the amount of whole wheat flour, expressed as a percentage of the total flour ingredient of the product.
- For products like pizzas that have a distinct wheat component, permit a "whole wheat" claim only if it is expressly limited to the flour-based component and the label discloses the amount of whole wheat the flour component contains, expressed as a percentage of the total flour ingredient.
- Require products that make "bran" or "grain" claims (such as "Natural Grain Goodness" or "Made with Multigrains") to disclose in immediate proximity to the claim, and in type no less than one-half the size of that claim, the amount of bran and grains (other than white flour) expressed as either a percentage or in household measures.
- For products like pizzas that have a distinct wheat component, permit a "bran" or "grain" claim only if it is expressly limited to the flour-based component and the label discloses the amount of bran or grains (other than white flour) in the flour component, expressed as either a percentage or in household measures.²⁹

IV. MISLEADING CLAIMS REGARDING SUGAR CONTENT

Per capita consumption of caloric sweeteners -- comprised mainly of sucrose (table sugar from cane and beets) and corn sweeteners (mostly high fructose corn syrup) -- continues to

²⁹ We urge that the FDA require that these disclosures appear in type no less than one-half the size of the claim, and meet requirements for prominence that we have previously described, *supra*, p.5, n.6.

increase. In 1993, each American consumed, on average, a record 147 pounds of caloric sweeteners.³⁰ Because sugars supply calories but no other nutrients, and because sugars promote dental caries, the *Dietary Guidelines for Americans* advises that sugars should be consumed in moderation.³¹ Such advice is especially important considering that the extra calories from sugar are likely to contribute to rising rates of obesity.³²

Some food manufacturers are attempting to exploit consumer concerns regarding sugar consumption by portraying highly sweetened foods as containing only small amounts of sugar. Breakfast cereal labels, in particular, often state that the cereal is "lightly sweetened," when in fact the product contains large amounts of sugar. For example:³³

- Kellogg's "Frosted Mini-Wheats," described on the label as "lightly sweetened shredded whole grain wheat," contains 12 grams of sugar per 55 gram serving (22% sugar by weight).
- General Mills' "Crispy Wheats 'n Raisins," described on the label as "lightly sweetened, honey-touched whole wheat flakes and raisins," contains 11 grams of added sugars per 55 gram serving (20% sugar by weight);

³⁰ Judith Jones Putnam and Jane E. Allshouse. Food and Consumer Economics Division, Economic Research Service, U.S. Department of Agriculture, Statistical Bulletin No. 915, *Food Consumption, Prices, and Expenditures, 1970-93* p. 19 (December 1994). While this figure reflects disappearance data, as opposed to actual consumption, it clearly indicates an increase over previous years.

³¹ *U.S. Dietary Guidelines for Americans* at 21-22.

³² Wayne Miller, Ph.D., et al, Dietary Fat, Sugar and Fiber Predict Body Fat Content, Vol. 94 *Journal of the American Dietetic Association*, Pg. 612 (June 1994).

³³ See Appendix H for copies of product labels.

These claims mislead consumers who are trying to reduce their sugar consumption. This problem is exacerbated by the FDA's failure to define the term "low sugar."³⁴ In the absence of a standardized definition of this term, consumers are especially vulnerable to principal display panel claims devised by manufacturers. To remedy these problems, we urge the agency to:

- Define terms such as "lightly sweetened"³⁵
- Require that a claim about sugars content disclose, in immediate proximity to such claim, and in type no less than one-half the size of the claim, the actual amount of sugars per serving, expressed in household measures or the percentage of sugars by weight.

V. MISLEADING USE OF PICTURES OF HEALTHFUL INGREDIENTS ON LABELS

Some products, in addition or as an alternative to making express claims about ingredients, use pictures (or "vignettes") on the principal display panel to imply that a product contains a significant amount of a desirable ingredient.

For example:

- General Mills' "Berry Berry Kix" includes on its front label pictures of raspberries and a cherry, but contains neither of those fruits nor juice from those fruits.

³⁴ FDA rules do define the terms "sugar free," "no added sugar," and "reduced sugar." See 21 C.F.R. §101.60(c).

³⁵ FDA has a compliance policy guide that addresses the use of the term "honey," but only in the name of non-standardized bakery products. In this guide, the agency states that "FDA believes that at least 8% honey (based on weight of flour) should be used in a bread labeled as honey bread." *Food and Drug Administration Compliance Policy Guides*, Chapter 2, §7102.03 (reissued: March 8, 1988).

- Jell-O "Strawberry-Banana Gelatin Dessert" includes pictures of strawberries and bananas on its principal display panel but contains neither fruit nor fruit juice.³⁶
- Yoplait's "Triple Dipped Frozen Yogurt Bars" pictures strawberries on its principal display panel but does not contain any strawberries or strawberry juice.
- General Mills' "Trix" cereal depicts oranges, grapes and lemon on its front label next to the statement "Natural Fruit Flavors with Real Fruit Juice." However, the product contains no orange or lemon juice, only grape juice concentrate.³⁷
- Farley's "The Roll Strawberry Fruit Roll" pictures a strawberry on the label, but is made primarily from less expensive pears, not strawberries.

FDA's most recent discussion of "vignettes," in the preamble to the agency's revised fruit juice labeling rules, reiterated its position that "[a] vignette that pictures a fruit or vegetable that is not present in the product results in a label that is false and misleading and therefore in violation of section 403(a) of the act."³⁸ The same logic should apply to cereal, gelatin deserts, ice cream, and all other products.

In order to eliminate the misleading use of pictures on labels, we urge the FDA to take individual enforcement actions as well as to:

- Issue a regulation prohibiting a vignette of an

³⁶ The term "artificial flavor," which appears on the principal display panel, does not adequately dispel the misleading impression caused by the illustrations of fruit on the label.

³⁷ See Appendix I for copies of the product labels.

³⁸ 58 Fed. Reg. 2891, 2922 (1994).

ingredient (such as a fruit or vegetable) not present in a product, or present in a smaller quantity than the amount pictured on the label, if the vignette would lead consumers to believe erroneously that the product contains such ingredients, or greater amounts of such ingredients than is actually the case.³⁹

- Issue a regulation requiring the disclosure of the amount of any ingredient pictured on a food label. This disclosure should appear in immediate proximity to the illustration of the ingredient, on a contrasting background, and in compliance with typeface requirements that prevent the disclosure from being obscured relative to other non-mandatory information that is presented on the label.

VI. STATEMENT OF LEGAL AUTHORITY

FDA has the authority to take the actions requested in this petition under sections 201(n), 403(a), 403(f), 403(I), 403(k), and 701(a) of the FFDCA.⁴⁰ Section 701(a) authorizes the agency to adopt regulations for the "efficient enforcement of this Act."⁴¹ Section 403(a) prohibits labeling that is "false or misleading in any particular."⁴²

³⁹ FDA proposed a regulation requiring that food labels that depict a food not actually contained in the food package bear a statement to that effect. See 39 Fed. Reg. 20,888 (1974). While this proposal was withdrawn because FDA said it could not determine when the use of such illustrations were misleading, the agency stated that "[t]he withdrawal of this proposal does not preclude similar rulemaking from being proposed in the future should the Commissioner determine it is needed, nor does it preclude other regulatory actions against individual products whose label vignettes are false or misleading." See 42 Fed. Reg. 62,159 (1977).

⁴⁰ 21 U.S.C. §321(n), §343(a), §343(f), §343(I) §343(k), and §371(a).

⁴¹ 21 U.S.C. §371(a).

⁴² 21 U.S.C. § 343(a) (emphasis added). See *American Frozen Food Institute v. Mathews*, 413 F.Supp. 548 (D.C. Cir. 1976), affirmed, 555 F.2d 1059 (1977); *United States v. Vitasafe*

In determining whether the labeling is misleading, section 201(n) states that "representations made or suggested by statement, word, design, device, or any combination thereof" shall be taken into account, as well as the extent to which the labeling fails to reveal facts material to any such representations.⁴³ Therefore, a claim may be misleading unless it is accompanied by certain material facts that are necessary for consumers to understand the nature of the claim.

FDA has relied on this authority to prescribe requirements for affirmative disclosures, most recently as part of its nutrient content claim regulations. These regulations require that such claims be accompanied by statements that disclose the amount of the particular nutrient in the product and in the relevant reference food.

Formula, 226 F.Supp. 266 (D.C.N.J. 1963), remanded on other grounds, 345 F.2d 846, cert. denied, 382 U.S. 918 (any single misleading, ambiguous or overemphasized statement or representation in labeling of a food renders it misbranded); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 42 (C.A. Mass. 1957) cert. denied, 354 U.S. 923 (1958) (the intent of the act is to prevent deception whether by "palpably false claims" or by "clever indirection and ambiguity in the creation of misleading impressions.")

⁴³ 21 U.S.C. § 321(n). The recommended "disclosure" approach for remedying many of the misleading labeling practices discussed in this petition is based on this section of the FDCA, which provides that a material omission can render a label misbranded. This approach is consistent with the approach followed by FDA in its nutrient content claim regulations, which require that certain claims be accompanied by disclosure statements in order to prevent deception. For example, a "reduced," "lower," "less," or "light" claim must be accompanied by a statement that discloses the amount of the particular nutrient in the product and in the relevant reference food. See, e.g., 56 Fed. Reg. 60421, 60446 (1991); 21 C.F.R. §101.62(b)(4).

In addition, section 403(k) of the Act states that a food product, not subject to a standard of identity, will be considered misbranded unless its label includes the common or usual name of the food.⁴⁴ FDA's "common or usual name" regulations require that a food label accurately identify or describe the basic nature of the food or its characterizing properties or ingredients.⁴⁵ Without an appropriate common or usual name, a label does not adequately inform consumers of the true nature of the product.

FDA regulations also specify that the common or usual name of a product should include the percentage of any characterizing ingredient when this percentage has a material bearing on price, on consumer acceptance, or when the labeling creates an erroneous impression that such ingredient is present in an amount greater than is actually the case.⁴⁶

Therefore, the FDA has ample authority to issue the regulations requested in this petition which we believe are necessary to eliminate misleading labeling practices and protect consumers' health.

⁴⁴ 21 U.S.C. § 343(k).

⁴⁵ 21 C.F.R. § 102.5(a).

⁴⁶ 21 C.F.R. § 102.5(b).

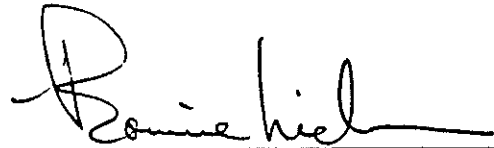
VII. CONCLUSION

In conclusion, we applaud the agency for making great strides in reducing the prevalence of misleading food labels through its implementation of the NLEA. However, we urge FDA to take the actions outlined in this petition to eliminate the deceptive labeling practices that still remain.

Respectfully submitted,



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