

American Heart Association's nutrition committee.

A 1998 study, from the University of Maryland School of Medicine, of 350 patients with arteriographically defined coronary artery disease (CAD) concluded that triglycerides was an independent risk factor for heart disease.¹¹⁵ After adjusting for a variety of factors, "multiple logistic regression analysis revealed the following *independent predictors of CAD events*: . . . [triglycerides] > 100 mg/dl (RR 1.5, 95% CI 1.1% to 2.1%." [emphasis added] The researchers, led by Michael Miller, director of preventive cardiology, concluded that triglyceride levels previously considered "normal" are predictive of new coronary events.

In a separate paper, Miller stated:

Convincing evidence of a link between elevated triglyceride levels and CHD has been reported in a meta-analysis of patients whose plasma triglyceride levels were measured in the fasting state. Further evidence has come from several angiographic studies that have examined the relationship between plasma triglyceride levels and the progression of coronary artery disease....In an 18-year follow-up study, incidence and severity...correlated with plasma triglyceride level. At a triglyceride level of 100 mg. dl⁻¹, which current guidelines would consider to be low risk, patients had a reduced chance of survival from coronary events.¹¹⁶

While weight loss and exercise may be the most potent weapons against insulin resistance and high triglycerides, avoiding heavy consumption of added sugars also appears to be an effective weapon. Nutrition labeling should make it easier for people who are insulin-resistant or who for other reasons have high triglyceride levels to reduce their intake of added sugars. Although it is unclear whether naturally occurring sugars in fruit and milk products raise

¹¹⁵ Miller M, Seidler A, Moalemi A, *et al.* "Normal triglyceride levels and coronary artery disease events: the Baltimore coronary observational long-term study." *J Am Coll Cardiol.* 1998;31:1252-7.

¹¹⁶ Miller M. "Is hypertriglyceridaemia an independent risk factor for coronary heart disease? The epidemiologic evidence." *Eur Heart J.* 1998;19(Suppl H):18-22.

triglycerides in those people, it is clear that those people should limit their intake of added sugars before they cut back on fruit and low-fat milk products, which products may help lower the risk of cancer, heart disease, stroke, and osteoporosis.

(e) Added sugars contribute to obesity.

In June 1995, the Dietary Guidelines Advisory Committee told the Secretary of Health and Human Services and the Secretary of Agriculture that “Many Americans are overweight and gain weight as they grow older...the number of overweight people has increased.”¹¹⁷ Between NHANES II (1976-1980) and NHANES III (1988-1991), overweight increased from 8 percent to 11 percent in children, from 6 percent to 11 percent in adolescents, and from 25 percent to 33 percent in adults.¹¹⁸ By the updated NHANES III (1988-1994), those figures had risen to 14 percent of children, 12 percent of adolescents, and 35 percent of adults.¹¹⁹ Using the World Health Organization’s definition of overweight (BMI>25), a definition recently adopted by the U.S., the prevalence of overweight is 55 percent.¹²⁰ Obesity is more prevalent among the poor and minorities, especially women, than among their middle- or high-income counterparts.¹²¹

¹¹⁷ *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans* (1995) at 9, 13.

¹¹⁸“Update: Prevalence of overweight among children, adolescents, and adults--United States, 1988-1994.” *MMWR*. 1997;46:198-202.

¹¹⁹ *Ibid.*

¹²⁰ Flegal KM, *et al.* “Overweight and obesity in the United States: prevalence and trends, 1960-1994.” *International Journal of Obesity and Related Metabolic Disorders* 1998;22:39-47. See also http://www.nhlbi.nih.gov/nhlbi/cardio/obes/prof/guidelns/ob_home.htm, accessed July 31, 1999.

¹²¹ National Center for Health Statistics. *Healthy People 2000 Review 1998-99*. Hyattsville, MD. DHHS Publication No. (PHS) 99-1256, page 41; National Research Council.

Overweight is a serious public health problem, according to the Advisory Committee and others, because “Both overweight and adult weight gain are linked to high blood pressure, heart disease, stroke, diabetes, certain types of cancer, arthritis, breathing problems, and other illness.”¹²²

Foods that are high in added sugars appear to be contributing to the nation’s epidemic of obesity because they are often high in calorie density. A recent review of clinical studies suggests that diets rich in calorie-dense foods promote obesity.¹²³ The review states “...when the fat content was controlled but the energy density varied, subjects ate a constant weight of food; therefore, the greater the energy density, the greater was the energy intake.”¹²⁴ Calorie-dense foods are typically high in fat and/or sugar. For example, an Entenmann's Chocolate Fudge Cake has 34 grams of added sugars and a caloric density of 3.6 (310 calories per 3 oz.).¹²⁵ A Cinnabon contains 49 grams of added sugars and a caloric density of 3.2 (670 calories per 7.5 ounces). An order of Burger King Cini-minis with icing has 38 grams of added sugars and a caloric density of 4.0 (530 calories per 4.7 ounces).

Added sugars may contribute to obesity simply because they comprise a large fraction of

Diet and Health: Implications for Reducing Chronic Disease Risk. (Washington, D.C.: National Academy Press, 1989), 116.

¹²² *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans* (1995) at 9.

¹²³ Roberts SB, *et al.* “Physiology of fat replacement and fat reduction: effects of dietary fat and fat substitutes on energy regulation.” *Nutrition Reviews.* 1998;56:S29-41.

¹²⁴ *Ibid.* quoting: Bell EA, *et al.* “Energy density of foods affects energy intake in normal weight women.” *Am J Clin Nutr.* 1998;67:412-20.

¹²⁵ Based on the cake's calcium content, we estimate that two grams of the sugar in this product come from the whole milk it contains.

the excess caloric intake consumed by millions of Americans. “I think 18 percent sugar intake is very high in this country and it contributes very significantly to the caloric load that we're eating,” observed obesity expert Xavier Pi-Sunyer at a recent meeting of the Dietary Guidelines Advisory Committee.¹²⁶

Furthermore, sweetened foods are highly palatable. Studies suggest that a heightened preference for fatty sweets may contribute to obesity among some segments of the population.¹²⁷ This evidence is supported by a recent British study that found higher intakes of “high-fat sweet products” such as cake, cookies, and chocolate among women with a higher BMIs.¹²⁸ Interestingly, this positive association becomes inverse if individuals with low energy intakes--that is, individuals reporting presumably invalid data--are included. The apparent inverse association between BMI and fatty sweets is “due to the reduced reporting of these products by obese women,” conclude the authors.

The British results also suggest that studies reporting an inverse or null relationship between added sugars intake and BMI may be flawed by invalid data, especially from overweight individuals. Those studies may also have been unable to detect positive relationships between BMI and added sugars because they failed to examine specific categories of high-sugar foods -- such as fatty sweets or soft drinks -- or because they failed to examine relationships for particular

¹²⁶ Testimony by Xavier Pi-Sunyer, Dietary Guidelines Advisory Committee meeting, June 17, 1999, at 11.

¹²⁷ Drewnowski A, *et al.* “Taste responses and food preferences in obese women: effects of weight cycling.” *International Journal of Obesity and Related Metabolic Disorders*. 1992;16:639-48.

¹²⁸ Macdiarmid JI, Vail A, Cade JE, Blundell JE. “The sugar-fat relationship revisited: differences in consumption between men and women of varying BMI.” *International Journal of Obesity and Related Metabolic Disorders*. 1998; 22:1053-61.

segments of the population, such as women, men, children, the overweight, etc.

Several lines of evidence suggest that soft drinks, by far the largest source of added sugars in the average American's diet, may increase the risk of obesity. A review of the literature and a clinical study indicate that people do not compensate for the calories consumed in liquid foods as well as they do for the calories consumed in solid foods.¹²⁹ These results are particularly disturbing, considering that 46% of added sugars come from liquids (soft drinks, fruit drinks, and tea). In addition, a recent analysis of NHANES-III found that overweight boys and girls consume a greater percentage of their calories from soft drinks, but not other beverages, than do normal-weight children.¹³⁰ An analysis of 1994 CSFII data found that school-age children who consume non-diet soft drinks ingested more calories than did nonconsumers of soft drinks.¹³¹

While soft drinks are the largest source of added sugars, the growing consumption of fruit drinks may also be contributing to the rising incidence of overweight and obesity in the U.S. Among children aged 2 to 17, the consumption of fruit drinks rose by approximately 50 percent between the 1989-91 and the 1994-95 CSFII surveys.¹³² Those beverages, which typically contain 5 percent or 10 percent fruit juice mixed with water, additives, and added sugars, are now

¹²⁹ Mattes RD. "Dietary compensation by humans for supplemental energy provided as ethanol or carbohydrate in fluids." *Physiology and Behavior*. 1996;59:179-187; DiMeglio D, Mattes RD. "Liquid versus solid carbohydrate (CHO): effects on food intake and body weight." *FASEB Journal*. 1999;13:A870.

¹³⁰ Personal communication, Richard P. Troiano. *Am J Clin Nutr* (forthcoming).

¹³¹ Harnack *et al*.

¹³² Morton JF, Guthrie JF. "Changes in children's total fat intakes and their food group sources of fat, 1989-91 versus 1994-95: implications for diet quality." *Family Economics and Nutrition Review*. 1998;11(3):44-57.

the third-largest source of added sugars in the average American's diet.¹³³

Additional suggestive evidence that added sugars and other carbohydrates contribute to obesity comes from USDA's surveys. Carbohydrate intake (including added sugars) increased from 195.6 g per day in 1977-78 to 208.6 g in 1987-88 and to 255.4 g in 1994-96. Added sugars increased from 57 g in 1977-78¹³⁴ to 80.4 g in 1996,¹³⁵ according to two different USDA dietary surveys. In addition, USDA's sugars-disappearance data show that the availability of caloric sweeteners increased from 126 pounds per year in 1977-78 to 132 pounds in 1987-88 to 149 pounds per year in 1994-96. Thus, the increased intake of added sugars and other carbohydrates appears to have fueled the increasing rates of obesity. (In contrast, fat intakes have remained roughly constant over the past two decades, according to USDA's dietary surveys and disappearance data.)

Regardless of whether added sugars contribute to weight *gain*, nutritionists and weight-loss experts routinely advise individuals already overweight to consume fewer calories -- starting with cutting back on empty-calorie foods such as sugary soft drinks (as well as separated fats). For instance, the National Institutes of Health recommends that people who are trying to lose or control their weight should drink water instead of soft drinks with sugar.¹³⁶

Some parties argue that it is counterproductive to urge people to cut back on added sugars

¹³³ Personal communication, Shanthy Bowman, July 30, 1999.

¹³⁴ Woteki, at 18.

¹³⁵ Cleveland, at Table 6.

¹³⁶ National Heart, Lung and Blood Institute and Office of Research on Minority Health. "Embrace your Health! Lose Weight if You Are Overweight." NIH Publication No. 97-4061, Sept. 1997.

because high sugar intakes are not associated with obesity. Furthermore, they argue that the so-called “fat-sugar seesaw” will lead people who consume less sugar to consume more fat. In fact, correlations between sugar intakes and obesity are often confounded by age -- that is, people who consume more sugar are younger, so they have a lower incidence of obesity.¹³⁷ Many of those young people will become obese as they grow older. A recent study indicates that the few Americans who consume the recommended number of servings from the food groups in USDA’s *Food Guide Pyramid* appear to consume less added sugars than others.¹³⁸ Furthermore, the “seesaw” is partly due to the nature of percentages. As the percentage of one contributor goes up, others *must* go down. When researchers have attempted to examine fat and added-sugars intake without adjusting for calories, the two are positively correlated: that is, they rise in tandem (though that approach also has drawbacks).¹³⁹

(f) Added sugars contribute to tooth decay.

It is generally recognized that added sugars is one of several important factors that promote tooth decay (dental caries). Citing its own 1986 report on sugars, the FDA accepted that fact in 1993.¹⁴⁰ *The Surgeon General’s Report on Nutrition and Health* stated:

Frequent consumption of sugars, especially sucrose, promotes formation of dental plaque, the key predisposing cause of both caries and periodontal disease. . . . Evidence exists that sugars as they are consumed in the average American diet

¹³⁷ Drewnowski A, *et al.* “The fat-sucrose seesaw in relation to age and dietary variety of French adults.” *Obesity Research*. 1997;5:511-8.

¹³⁸ Krebs-Smith, *et al.*

¹³⁹ Emmett PM, *et al.* “Is extrinsic sugar a vehicle for dietary fat?” *Lancet*. 1995;345:1537-40.

¹⁴⁰ 58 Fed. Reg. at 2221.

contribute to the development of dental caries, suggesting that the general public should reduce its sugar consumption.¹⁴¹

The National Academy of Sciences–National Research Council, in its landmark report *Diet and Health*, concluded:

The committee does not recommend increasing the *intake of added sugars, because their consumption is strongly associated with dental caries*, and, although they are a source of calories for those who may need additional calories, they provide no nutrients.¹⁴² [emphasis added]

Caries rates have declined significantly in recent decades, thanks to such preventive factors as fluoride-containing toothpaste, fluoridated water, and tooth sealants. Nevertheless, new information published subsequent to the NLEA 1993 regulations demonstrates that caries remains a problem for some sub-groups. A large survey in California found that children (ages 6 to 8, 15) of less-educated parents have 20 percent higher rates of decayed and filled teeth.¹⁴³ A national study found that African-American and Mexican-American children (6 to 18 years old) are about twice as likely to have untreated caries in their permanent teeth as their white counterparts.¹⁴⁴ For people in such high-risk groups, prevention is particularly important.

The single largest source of added sugars, regular soft drinks, is not a sticky food, but it

¹⁴¹ U.S. Department of Health and Human Services, Public Health Service. *The Surgeon General's Report on Nutrition and Health* (Washington, D.C.: Government Printing Office, 1988), 368.

¹⁴² National Research Council, Committee on Diet and Health. *Diet and Health: implications for reducing chronic disease risk* (Washington, D.C.: National Academy Press, 1989), 15.

¹⁴³ The Dental Health Foundation. "A Neglected Epidemic: The Oral Health of California's Children." (San Rafael, Calif., 1997).

¹⁴⁴ Vargas CM, Crall JJ, Schneider DA. "Sociodemographic distribution of pediatric dental caries: NHANES III, 1988-1994." *J Am Dent Assoc.* 1998;129:1229-38.

can promote decay because it bathes the teeth of frequent consumers in sugar-water for long periods of time, not just at meal time. An analysis of data from 1971-74 found a strong correlation between the frequency of between-meal consumption of soft drinks and dental caries.¹⁴⁵ Those researchers took into account the consumption of other sugary foods and other variables. To prevent tooth decay, even the Canadian Soft Drink Association recommends limiting between-meal snacking of sugary and starchy foods, avoiding prolonged sugar levels in the mouth, and eating sugary foods and beverages with meals. Unfortunately, most consumers of soft drinks and other foods high in added sugars (and other carbohydrates) violate each of those precepts.

In summary, substantial scientific evidence indicates that diets high in added sugars contribute to a variety of health problems and health-related conditions. We grant that the proof that diets high in added sugars cause health problems does not attain the same level of certainty as, say, the evidence that saturated fat causes heart disease. Nevertheless, we do not believe that the NLEA compels the FDA to prove beyond a shadow of a doubt that diets high in added sugars have adverse health consequences before the agency requires better food labeling. The existing evidence and expert opinion is sufficient to impel FDA to help consumers -- including not just those who consume *average* amounts of added sugars, but also those who consume larger amounts -- maintain "healthy dietary practices," as stated in the NLEA, and protect the public health simply by ensuring that consumers have useful information on food labels (as opposed to sterner measures, such as limiting the sugars content of soft drinks).

¹⁴⁵ Ismail AI, Burt BA, Eklund SA. "The cariogenicity of soft drinks in the United States." *J Am Dent Assoc.* 1984;109:241-5.

(2) Contrary to the FDA's 1993 conclusion, there are ways to enforce regulations requiring disclosure of added sugars.

In January 1993 one of the reasons the FDA gave for not listing "added sugars" on the food label was:

There is currently no analytical methodology that would allow the agency to distinguish between sugars that are added to a food and those that are naturally occurring. Therefore, FDA would be unable to evaluate the accuracy of claims about the levels of added sugars in foods.¹⁴⁶

New analytical techniques, as well as older techniques, can often distinguish added sugars from natural sugars. Furthermore, the FDA's professed inability to measure added sugars has not prevented the FDA from promulgating and enforcing other regulations the enforcement of which depends upon an ability to assess the levels of added sugars, natural sugars, and other ingredients.

(a) Analytical methods can distinguish added sugars from naturally occurring sugars in many foods.

In the case of many manufactured foods, it is a simple matter to measure added sugars. For instance, many foods contain *only* added sugars; so the total measured sugars content is a direct measure of added sugars. Hard candies, soft drinks, ice pops, and many other foods contain sugars that are entirely, or almost entirely derived, from added sugars.

Also, many foods that contain added sugars contain natural sugars that are easily distinguished by normal analytical methods, such as liquid chromatography. Such foods include flavored milks (e.g., chocolate milk), pudding mixes, and many popular flavors of frozen desserts (e.g., vanilla ice cream) and yogurts (e.g., vanilla). The dairy ingredients provide significant

¹⁴⁶ 58 Fed. Reg. at 2222.

amounts of sugar, but that sugar is lactose (a disaccharide made up of galactose and glucose). The added sugars are usually sucrose, glucose, and fructose.

Some foods, such as sweetened breakfast cereals, contain mostly added sugars, along with small amounts of naturally occurring sugars. In many cases, one could determine how much naturally occurring sugars is present in equivalent unsweetened versions of those products (or in the ingredients of which those products are made) and determine the amount of added sugars by subtraction.

The most difficult foods to analyze are those that contain both fruit (or fruit juice) and added sugars, because fruit contains varying levels of sucrose, fructose, and glucose. Since the FDA's promulgation of nutrition-labeling rules in 1993, new analytical methods have been developed or refined that provide increasing ability to distinguish in many foods added refined sugars from naturally occurring sugars. Those methods are particularly adept at identifying the presence of added sugars in products that purport not to contain them.

One method uses high-pressure liquid chromatography (HPLC), gas chromatography, or capillary gas chromatography ("cap-GC") to measure a food's content of various sugars. That method can identify "marker" peaks of minor constituents (oligosaccharides, phytochemicals, etc.) in refined sugars (such as invert sugar and HFCS) and in fruit (or fruit juice). Quantifying the levels of those minor constituents may enable one to determine the amount of added sugars in foods that contain naturally occurring sugars. One study detected 5 percent added sugars (including high-fructose syrup and beet and cane invert syrup) in apple juice and orange juice.¹⁴⁷ In a study of pineapple juice, liquid or cap-GC detected 10 percent added HFCS, cane invert

¹⁴⁷ Low NH. "Determination of fruit juice authenticity by capillary gas chromatography with flame ionization detection." *JAOAC Int.* 1996;79:724-37.

syrup, and beet invert syrup.¹⁴⁸ Chromatographic methods are economical.

A second approach is based upon the different levels of carbon and hydrogen isotopes that occur in different foods or in the same foods grown in different geographic regions.¹⁴⁹ That method relies, in part, on the fact that most plants produce glucose by one of two enzymatic pathways that result in different levels in the glucose of two carbon isotopes, ^{12}C and ^{13}C (pineapple, which uses both pathways, is an exception). Corn (hence, corn sugar and HFCS) and sugar cane (hence cane sugar and cane invert sugar) utilize a metabolic pathway (C_4) that results in a $^{13}\text{C}/^{12}\text{C}$ ratio that is relatively high compared to most fruits (oranges, apples, cherries, and others) consumed in the United States and to sugar beets, which use a different pathway (C_3). Chemists can isolate and quantify the sugars from a food, then use combustion and mass spectrometry to measure isotope ratios. That method can ascertain added sugars to within an accuracy of about ± 5 -40 percent, depending on the food. It is ideal for foods that contain fruit and are sweetened by either corn sweeteners (HFCS, corn sugar, corn syrup) or cane sugar (cane sugar, invert sugar). It has been used to detect adulteration of orange and apple juices with cane sugar and HFCS.¹⁵⁰

¹⁴⁸ Low NH, Brause A, Wilhelmsen E. "Normative data for commercial pineapple juice from concentrate." *JAOAC Int.* 1994;77:965-75.

¹⁴⁹ Doner LW. "Stable carbon isotope ratios for detecting added sugars in orange and apple juices and added citric acid in lemon juices," in Linskens HF and Jackson JF. *Modern Methods of Plant Analysis* (Berlin Heidelberg: Springer-Verlag, 1988), New Series, Vol. 8, 120-33.

¹⁵⁰ Carbon-isotope analysis of individual sugars (sucrose, glucose, fructose) can be used to detect as low as 3 percent added C_4 sugar in orange juice. That sensitivity is made possible by the use of intermolecular isotope correlations between different components in the fruit (individual sugars and/or acids) to improve the sensitivity of the method. That approach is particularly useful for pineapple. Personal communication, Michele Lees, Eurofins Scientific S.A., Dec. 23, 1998.

Measuring $^{13}\text{C}/^{12}\text{C}$ ratios is of no use when beet sugar or invert beet sugar (C_3) is present (possibly mixed with cane sugar) in a food containing fruit (also C_3). To determine the amounts of added sugars in those situations, one can take advantage of a second isotopic difference: Deuterium/hydrogen (D/H) ratios vary in constituents of plants grown at different latitudes.¹⁵¹ That method often can detect beet sugar present in a food that contains C_3 fruit or fruit juice. According to the U.S. General Accounting Office, in the best situations, beet sugar can be detected if it comprises 10% to 20% of fruit juice.¹⁵² However, the sensitivity of using D/H ratios is greatly reduced when a sugar or fruit ingredient is not obtained from a limited geographic region, but is composed of a mixture of ingredients grown at different latitudes.

To maximize the utility of isotope analyses, it is sometimes appropriate to measure both D/H and $^{13}\text{C}/^{12}\text{C}$ ratios. By measuring both ratios, and by knowing the expected ratios in pure fruit(s), one can sometimes estimate accurately the amounts of cane and beet sugars present in a food.¹⁵³

Isotopic analyses (especially D/H ratios) can be expensive, but such analyses would only be used for a modest number of enforcement actions in cases in which the FDA or a state agency suspected that labeling was erroneous. Food manufacturers, because they know the recipes for the foods they make, know what fractions of the sugars in their products are added and naturally

¹⁵¹ Guillou C, Remaud G, Martin GJ. "Application of deuterium NMR and isotopic analysis to the characterization of foods and beverages." *Trends in Food Science & Technology*. (April 1991) at 85-9.

¹⁵² The General Accounting Office study was done because of Congressional concern about the costs and problems associated with the sale of adulterated fruit juice in school meal programs. General Accounting Office. *Fruit Juice Adulteration* (November 1995) GAO/RCED-96-18 at 17.

¹⁵³ Lees M, "Jus de fruit - pur," *Analysis Europa*. 1996(March-April 1996);20-6.

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occurring and could provide accurate labels without resorting to isotopic (or other) analyses.

(b) The enforcement of several existing FDA regulations requires distinguishing added sugars from naturally occurring sugars.

Though the FDA rejected in 1993 the listing of added sugars on nutrition labels because, among other reasons, the agency did not have techniques for measuring amounts of added sugars, the agency enforces four sets of regulations -- including two that were adopted in 1993 -- that can only be enforced by measuring levels of added sugars.

(i) Sugars in ingredient lists.

The FDA currently requires the accurate listing of ingredients in descending order by weight on the ingredient label.¹⁵⁴ Verifying the accuracy of ingredient listings requires determining the amounts of sucrose, glucose, fructose, corn syrup, HFS, honey, lactose, maltose, and other sweeteners that are added to foods as distinguished from the sucrose, glucose, fructose, lactose, and maltose that occur naturally in foods.

(ii) Claims such as "no added sugar."

The FDA now enforces regulations that allow the use of the terms "no added sugar," "without added sugar," or "no sugar added" only if no sugars or ingredients containing added sugars -- including jam, jelly, or concentrated fruit juice -- have been added to the food.¹⁵⁵ The enforcement of those regulations requires the ability to measure added sugars as distinct from naturally occurring sugars.

¹⁵⁴ 21 C.F.R. § 101.4(a).

¹⁵⁵ 21 C.F.R. § 101.60(c)(2).

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(iii) Percentage of fruit or vegetable juice.

The FDA now enforces regulations requiring the disclosure of the percentage of fruit or vegetable juice in a beverage, such as "contains 50 percent juice."¹⁵⁶ If the beverage contains 100 percent juice and also contains a non-juice sweetener, the regulations permit a label declaring that the beverage is "100% juice with added sweetener."¹⁵⁷ The enforcement of those regulations requires the ability to distinguish added sugars from naturally occurring sugars (for instance, the FDA must ensure that "with added sweetener" is disclosed on labels of the relevant products).

(iv) Standards of identity.

The FDA has established numerous "standards of identity" (recipes) that specify a minimum or maximum added-sugars content of certain foods. The FDA now enforces standards of identity for 22 different groups of foods,¹⁵⁸ including some that contain both added sugars and naturally occurring sugars. For example, for canned applesauce, the FDA's regulations distinguish between "sweetened" and "unsweetened" on the basis of whether a nutritive

¹⁵⁶ 21 C.F.R. §101.30.

¹⁵⁷ 21 C.F.R. §101.30(b)(3).

¹⁵⁸ Section 401 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 341, authorizes the Secretary to promulgate regulations fixing and establishing for any food a "standard of identity." The FDA has established food standards for milk and cream; cheeses and related cheese products; frozen desserts; bakery products; cereal flours and related products; macaroni and noodle products; canned fruits; canned fruit juices; fruit butters, jellies, preserves, and related products; fruit pies; canned vegetables; vegetable juices; frozen vegetables; eggs and egg products; fish and shellfish; cacao products; tree nut and peanut products; beverages; margarine; sweeteners and table syrups; and food dressings and flavorings.

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carbohydrate sweetener is added¹⁵⁹ even though apples contain sugar. To ensure that "unsweetened" applesauce has not been sweetened, FDA must be able to determine whether sugars have been added. Orange juice must be labeled either as "sweetener added" or "_____ added," with the name of the sweetener, if any amount of a sweetener -- defined as sugar, invert sugar, dextrose, dried corn syrup, or dried glucose syrup -- has been added even though orange juice itself contains sugar.¹⁶⁰ For fruit jelly, sweeteners may be added to fruit-juice ingredients provided that the fruit-juice ingredients are at least 45 percent by weight.¹⁶¹ For fruit preserves and jams, sweeteners may be added to fruit ingredients provided that the fruit ingredients are at least 45 percent or 46 percent by weight, depending upon the product.¹⁶² To enforce all of those standards the FDA must be able to distinguish between naturally occurring and added sugars.

In sum, even though it said in 1993 that it cannot distinguish by analytical methods added sugars from naturally occurring sugars, the FDA still apparently enforces numerous regulations requiring knowledge of added-sugars content, including regulations for net weight of ingredients, added sugars, fruit juices, and standards of identity. The FDA sometimes enforces those regulations by, in part, simply asking manufacturers to provide recipes,¹⁶³ invoices for ingredients

¹⁵⁹ If a sweetener is added and the soluble solids content of the finished food is not less than 16.5 percent, the applesauce may be called "sweetened" applesauce. 21 C.F.R. § 145.110(a)(3).

¹⁶⁰ 21 C.F.R. § 146.140(e)(2).

¹⁶¹ 21 C.F.R. § 150.140(d)(1).

¹⁶² 21 C.F.R. § 150.160.

¹⁶³ CSPI interview on November 18, 1998, with Felicia Satchell, Chief of Food Standards Branch, Office of Labeling, Center for Food Safety and Applied Nutrition, FDA.

Gross discrepancies between company labels and USDA's data base for about 6,000 foods might suggest products that the FDA should examine more closely.

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purchases, and other records. When reliable analytical methods are not available, the agency could enforce the regulations we request here in the same manner.

(3) Contrary to the FDA's 1993 conclusion, consumers would not be misled by information about added sugars.

In 1993 the FDA said that "in some fruits canned in heavy syrup, added sugars may represent only about 50 percent of total sugars. Disclosure of only the added sugars could be misleading to consumers who are concerned with total sugar intake."¹⁶⁴

Several points should be made about that argument.¹⁶⁵

First, CSPI is not urging that only added sugars be disclosed. It is reasonable to continue to show total sugars along with added sugars.

Second, another Federal agency, the USDA, obviously does not believe that consumers are now being misled by the *Pyramid's* quantitative daily dietary recommendations for added sugars. Indeed, the USDA believes that its recommendations will help consumers follow the guidance of the USDA-HHS *Dietary Guidelines for Americans*, which presents "choosing a diet moderate in sugars" as one of its seven guidelines. That guideline clearly refers to *added*, not naturally occurring, sugars. The FDA should help consumers comply with HHS's and USDA's

¹⁶⁴ 58 Fed. Reg. at 2098.

¹⁶⁵ The FDA presented *no* evidence to support its conclusion. The FDA's failure to present any evidence in support of this conclusion renders it "arbitrary and capricious" within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). *Cf. Menorah Medical Center v. Heckler*, 768 F.2d 292 (CA 8 1985)(regulation for reimbursing Medicare health providers for the portion of their malpractice-insurance premiums attributable to Medicare patients is invalid because there was no evidence in the record to support the Secretary's conclusion that lower malpractice awards for Medicare patients leads to lower malpractice-insurance premiums).

recommendations by requiring disclosure of added sugars.

Third, more and more academic experts are recognizing the importance of distinguishing natural from added sugars. That is reflected in the broad support for the goals of this petition (see Exhibit 1). Also, at the March 9, 1999, meeting of the Dietary Guidelines Advisory Committee, Alice Lichtenstein of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University said, "I think that there needs to be a mechanism for distinguishing sugar that comes from fruit and milk from other kinds of sugar. . ." ¹⁶⁶

Fourth, survey research indicates strong consumer support for labeling of added sugars. In July 1999, CSPI commissioned a nationally representative telephone survey of 776 randomly selected primary or joint grocery shoppers. ¹⁶⁷ The survey found that 54 percent of respondents preferred to have the label indicate "both the total amount of sugar and the amount of sugar used to make processed food," as compared to 30 percent who preferred to have labels indicate "only the total amount of sugar in a serving." The remaining respondents did not know or preferred something else. Considering the complete absence of public discussion of sugars labeling, it appears quite remarkable that more than half the respondents favor specific labeling of added sugars. (When asked what term should be used on labels to indicate the sugars used to manufacture foods, 44 percent preferred "added sugar," 27 percent preferred "refined sugar," 21 percent did not know, and 8 percent preferred some other term .)

Far from misleading consumers, disclosing the amount of added sugars would enable consumers to evaluate foods that contain naturally occurring sugars (many of which foods, such

¹⁶⁶ Dietary Guidelines Advisory Committee meeting, March 9, 1999, at 372.

¹⁶⁷ The survey was conducted by Bruskin/Goldring Research on July 9-11, 1999.

as fruit, are usually accompanied by various nutrients and whose consumption is associated with a lower risk of cancer, osteoporosis, stroke, and other diseases) versus foods higher in added sugars (which are often high in empty calories and calorie density and may contribute to tooth decay, obesity, and heart disease). For example, such a disclosure would tell consumers how much sugars has been added to yogurt, ice cream, puddings, frozen fruit bars, sorbet, canned or frozen fruit, fruit snacks, juice drinks (beverages, cocktails, etc.), jams, jellies, breakfast cereals, cereal bars, blueberry (or other fruit) muffin, and raisin (or other fruit) cookies, and would apprise consumers of the percentage of the recommended daily limit (%DV) of added sugars that servings of those foods provide. Many of those foods carry label claims such as “made with fruit” or “real fruit juice,” which appeal to consumers who want to follow advice to eat more fruit to reduce the risk of cancer and other health problems. In fact, many of those products contain far more added sugars than fruit. Yet, in most cases, consumers have no way of determining how much added sugars the foods contain and how those amounts compare to the recommended intake.¹⁶⁸

(4) The FDA’s conclusion in 1993 that naturally occurring sugars and added sugars have the same physiological impact ignores the adverse health impact of diets high in added sugars.

In 1993 the FDA gave as one of its reasons for rejecting mandatory disclosure of added sugars that “There is no scientific evidence that the body makes any physiological distinction

¹⁶⁸ Juice drinks, beverages, cocktails, etc. disclose juice content, enabling nutritionists to estimate the amount of added sugars. Other foods, including those made with juice, do not provide information about added and naturally occurring sugars.

between added sugars and those naturally occurring in a food.”¹⁶⁹ The FDA’s observation, while correct, ignores the large body of scientific evidence, discussed above in sections III.C.(1)(b) and (c), that foods high in added sugars squeeze healthier foods out of the diet, thereby having different nutritional consequences from foods that contain naturally occurring sugars.

Elsewhere in its 1993 decision not to require added-sugars labeling, FDA recognized that foods rich in naturally occurring sugars have a more important role in a healthy diet than foods rich in added sugars. However, the FDA erroneously assumed that it could make that critical distinction clear to consumers without requiring added sugar labeling. The agency stated that:

While FDA is not distinguishing, on the nutrition label, between added and naturally present sugars, the agency does intend to include information about this distinction in the consumer education program that it is preparing. This information will help consumers: (1) Use the information on the nutrition label to differentiate between sugar-containing foods with high versus low levels of other important nutrients, (2) use the ingredient statement to distinguish foods with naturally occurring versus added sugars, and (3) appreciate the important role in the total daily diet of foods, such as fruits and dairy products, with naturally occurring sugars.¹⁷⁰

While the FDA may have had good intentions, it is clear that any consumer- education efforts have failed. The annual *per capita* consumption of added sugars continued to climb by eleven pounds -- from 144.4 pounds in 1993 to 155.6 pounds in 1998 -- in the short time since it issued its labeling regulations. The continued climb in soft-drink consumption and the concomitant decline in milk consumption indicates that the FDA has failed in getting the public to appreciate the important role that foods such as low-fat dairy products play in the diet. Furthermore, no matter how vigorous a consumer-education program FDA mounted, the public would still be unable to figure out how much added versus naturally occurring sugars are in

¹⁶⁹ 58 Fed. Reg. at 2098.

¹⁷⁰ *Ibid.*

foods that contain both (see Exhibit 5).

(5) The FDA's conclusion in 1993 that there is no consensus on a daily reference value for added sugars ignored important information, which has been buttressed by new information.

In 1993 the FDA gave as one reason for not establishing a DRV for added sugars that there was no consensus on whether there should be one and, if so, what it should be.¹⁷¹ However, it did acknowledge that there was some support for a DRV, namely the WHO's recommendation of 10 percent added sugars. The FDA also notes that setting a DRV for total sugars would be inconsistent with dietary guidelines that recommend consuming more fruits and dairy products, which contain naturally occurring sugars. That reason is irrelevant to this petition, which specifically asks the FDA to establish a DRV for *added*, not total, sugars.

Importantly, the FDA failed to acknowledge that *USDA's Food Guide Pyramid* -- which was first issued in April 1992 and revised in 1996 -- (by interpolation) recommends limiting daily consumption of added sugars to 40 grams a day for a diet of 2,000 calories, with larger or smaller amounts and percentages of calories from added sugars considered appropriate for people who consume more or fewer calories.

The FDA also did not acknowledge an earlier influential report, *Dietary Goals for the United States*, which was published in 1977 by the Senate Select Committee on Nutrition and Human Needs.¹⁷² That report's third goal stated:

Reduce the consumption of refined and other processed sugars by about 45 percent to account for about 10 percent of total energy intake.

¹⁷¹ 58 Fed. Reg. at 2221-2.

¹⁷² *Dietary Goals for the United States*, at 27-34.

While the Senate committee was not itself an expert scientific body, it received testimony from a large number of expert witnesses. Further, it prepared its recommendation with the close assistance of several key consultants, including D. Mark Hegsted, a professor of nutrition at the Harvard School of Public Health who subsequently became the chief of human nutrition at the U.S. Department of Agriculture, and Philip Lee, the director of the Health Policy Program at the University of California at San Francisco who later became Assistant Secretary for Health at HHS.

The FDA also did not acknowledge that numerous nations, especially technologically advanced nations rather similar to the U.S., have adopted nutrition guidelines. According to one survey, 82 out of 100 sets of dietary guidelines from 30 countries (including governmental and private health organizations) analyzed through 1991 said “eat less [added] sugar”; 74 made the recommendation for everybody, and eight for people at high risk (meaning obese or diabetic).¹⁷³ Twenty-three of the reports set targets for added sugars, the average being 10 percent or less of calories.

1991 United Kingdom, Department of Health, COMA	10%
1981, 1987 Sweden, National Food Administration	10%
1982 Norway, Ministry of Health	10% or less
1986 Netherlands, Ministry of Health	0-10%
1987 Australia, Department of Health	12%
1987 Finland, Nutrition Board	10% or less
1980, 1989 Scandinavia, Nordic Council of Ministers	10% or less
1989 Poland, National Institute	less than 10%
1989 Singapore, National Advisory Committee	less than 10%

Furthermore, in 1992, *Consumer Reports* surveyed 94 nutrition professionals -- scientists, clinicians, registered dietitians, and educators -- who had served on federal advisory boards

¹⁷³ Cannon G. *Food and Health: The Experts Agree*. (London: Consumers Association, 1992).

relating to nutrition, or on nutrition committees of professional organizations.¹⁷⁴ Sixty-eight of them completed a comprehensive 18-page questionnaire. “Half of them recommended reducing the average intake of sugars to 5 percent [of calories] from the current average of 11 percent.”

Finally, this petition is supported by a letter from more than two dozen nutrition, public-health, dental, medical, obesity, osteoporosis, and nutrition-education experts and more than three dozen health and citizen organizations who endorse the recommendation for setting a DRV of 40 grams. While those people do not constitute an expert committee, they reflect broad new support among health experts for establishing a DRV for added sugars and listing added sugars on food labels.

Thus, two expert agencies (USDA, WHO), a Senate committee advised by scientists, numerous foreign nations, and numerous academic experts have all endorsed a recommendation that the average person limit intake of added sugars to about eight to ten percent of calories. The most sophisticated and well-substantiated of those recommendations is USDA’s, because it is based on Americans’ dietary patterns and recognizes that the sugar allowance may increase with increased caloric intake/expenditure. The time has now come for the FDA to enable consumers to follow that recommendation.

D. Consumers need a disclosure of both the amount of added sugars and the “%DV” to help them gauge their added-sugars intake against recommended levels.

(1) Consumers need a disclosure of the amount of added sugars.

Consumers need a disclosure of the amount of added sugars in foods so they can monitor -- and in many cases -- reduce their intake. Furthermore, as noted above, a nationally

¹⁷⁴ “Are you eating right.” *Consumer Reports*. October, 1992; 644-55.

representative survey indicates that consumers want that information. Without added-sugars labeling, consumers cannot figure out how much added versus naturally occurring sugars are in foods -- including fruit muffins, fruit drinks, fruit snacks, frozen fruit bars, cereal bars, ice cream, yogurt, frozen yogurt, and puddings -- that contain both (see Exhibit 5).

FDA suggests, in its 1993 decision to require only total sugars on the label, that its education program will help consumers “use the information on the nutrition label to differentiate between sugar-containing foods with high versus low levels of other important nutrients” and “use the ingredient statement to distinguish foods with naturally occurring versus added sugars.”¹⁷⁵ Using the nutrition label, consumers would only be able to distinguish between foods that contain low or high amounts of vitamins A and C, calcium, and iron. That information would not help them determine how much added versus naturally occurring sugars a food contains. Using the ingredient label, consumers would only be able to estimate very roughly how much added sugar a food contains. A nutritionist armed with a calculator might be able to estimate the added-sugars content based on the ingredient list, but it is naive to expect the average consumer to make those estimates, especially when several different added sugars (for example, sucrose, invert sugar, corn syrup) are scattered among a long list of ingredients. Clearly, a line in the Nutrition Facts label listing the amount of added sugars and %DV would be a far stronger tool than the current ingredient list for helping consumers ascertain the added-sugars content of foods. Even if an occasional consumer were able to figure out the amount of added sugars, the absence of a %DV would prevent the consumer from knowing how that amount of added sugars fit into an overall diet.

¹⁷⁵ 58 Fed. Reg. at 2098.

(2) Consumers need a disclosure of the “%DV”.

Nutrition Facts labels disclose not only the absolute quantities of key nutrients, but a “%DV” to help consumers determine how much of a day’s worth of several nutrients a serving of the food supplies. Without a %DV for added sugars, it is difficult, if not impossible, for the public to compare the added-sugars content of a food to the recommended daily limit. It is likely that the absence of that information has contributed to the rising intakes of added sugars in the U.S.

If the FDA were only to require added-sugars disclosures in grams, but not %DV, it would fail to give consumers the information they need. Few Americans outside of USDA’s Beltsville Human Nutrition Research Center know how much added sugars is appropriate in a healthful diet. While consumers could use declarations of added-sugars contents to compare two foods, without a %DV they could not determine how a quantity like 20 or 30 or 40 grams of added sugars fits into a total daily diet.

CSPI requests that the FDA establish a Daily Reference Value (“DRV”) for “added sugars” of 40 grams and to require a mandatory disclosure of added sugars in both grams per serving and % Daily Value, i.e., the percentage of that DRV. As discussed in section III.B. above, the figure of 40 grams is based on USDA’s advice to consumers -- who ingest 2,000 calories per day *and* consume recommended levels of a variety of healthful foods *and* consume 30 percent of their calories from fat -- that they “try to limit” their consumption of added sugars to 10 teaspoons per day. In the chart at the bottom of some nutrition labels that provide recommendations for several nutrients in the context of a 2,500-calorie diet, the DRV should be, interpolating USDA’s recommendations, 60 grams (15 teaspoons).

We recognize that, as with fat, sodium, and other nutrients, there is no absolute level of

added sugars below which there is assurance of health and safety and above which there is harm or risk. The DRV of 20 grams for saturated fat, for instance, was not dictated by studies showing that 20 grams was the highest safe level. In fact, there is a gradient: the less saturated fat one consumes, the greater the benefit, with no known lower limit. Rather, the 20-grams figure reflects a compromise between saturated-fat's atherogenicity, current levels of consumption, and the practicality of reducing consumption. In the case of added sugars, the USDA based its recommendation largely on broad nutritional concerns, not the causation of a specific disease. The USDA recognized that the more added sugars one consumes, the greater the likelihood that a diet would not contain adequate levels of healthful foods and the nutrients contained therein. Of course, increasing consumption of added sugars might also contribute to obesity (and its sequelae), dental caries, and heart disease (due to increased blood triglycerides).

The USDA recommendations are particularly credible, because they were based solely on nutritional concerns and arrived at outside of the politicized regulatory process. They should be adopted by the FDA for setting the DRV at 40 grams for a 2,000-calorie diet. Any DRV proposed by the FDA that was higher than 40 grams would be highly suspect as being influenced by commercial pressures.

E. Nutrient-content and health claims about added sugars should be held to the same standards as claims about fat, saturated fat, cholesterol, and sodium.

In addition to adding "added sugars" to the nutrition label and establishing a DRV for added sugars, the FDA should make corresponding changes to its nutrient-content and health-claim regulations so that added sugars are treated in the same fashion as fat, saturated fat, cholesterol, sodium, and calories.

The FDA's regulations now require that foods (other than "meal products" and "main dish products") containing more than 20 percent of the DRV for fat, saturated fat, cholesterol, or sodium must comply with two particular labeling requirements. First, *no* health claim may be made for such foods (unless the FDA has permitted the claim based on a finding that such a claim will assist consumers in maintaining health dietary practices).¹⁷⁶ That ban should also be applied to foods containing added sugars in excess of 20 percent of the DRV.

Second, the FDA now regulates when a food can claim to be "low" in fat, saturated fat, cholesterol, and sodium.¹⁷⁷ In January 1993, the FDA explained that applying "low" to various nutrients "should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients."¹⁷⁸ At that time the FDA decided that: (a) "low" fat means less than 5 percent of the DRV for fat, (b) "low" saturated fat means less than 5 percent of the DRV for saturated fat, (c) "low" cholesterol means less than 6.8 percent of the DRV for cholesterol, and (d) "low" sodium means less than 5.8 percent of the DRV for sodium.¹⁷⁹ Applying the same rationale to added sugars would mean that a food could say it is "low" in added sugars only if it contains less than 5 percent of the DRV -- 2 grams -- of added sugars per serving.

¹⁷⁶ 21 C.F.R. § 101.14(e).

¹⁷⁷ 21 C.F.R. §§ 101.62(b)(2), 101.62(c)(2), 101.62(d)(2), and 101.61(b)(4). In early 1993 the FDA refused to define "low" in connection with sugar because there was no "consensus" on a quantitative recommendation for the daily intake of sugars. Thus, the FDA did not issue a DRV for sugar and therefore, did not define "low" for sugar. 58 Fed Reg. at 2335.

¹⁷⁸ 58 Fed. Reg. at 2334.

¹⁷⁹ 21 C.F.R. §§ 101.62(b)(2)(i)(A), 101.62(c)(2)(i), 101.62(d)(2)(i)(A), and 101.61(b)(4)(i).

Third, the FDA now regulates when a food can claim to be reduced in sugar or have less sugar than another food.¹⁸⁰ As discussed above in section III.C.(1), public health concerns focus on added sugars, not naturally-occurring sugars, and so the provision dealing with reduced sugar or less sugar should be amended to allow such claims for added sugars provided that such foods that are not “reduced” or “lower” in total sugar bear a disclosure indicating that they are not reduced or lower in total sugar.

Fourth, if there is a claim characterizing the level of any nutrient for a food that contains fat, saturated fat, cholesterol, or sodium exceeding 20 percent of the DRV, then there must be a label stating “see nutrition information for ____ content,” with the blank filled in with the identity of the nutrient(s) exceeding the specified level.¹⁸¹ The FDA explained, in January 1993, that a slightly different version of that requirement¹⁸² will ensure that “if a nutrient content claim is made, the label must provide the consumer with the facts that bear on the advantages asserted by the claim and with sufficient information to understand how the product fits into a total

¹⁸⁰ 21 C.F.R. § 101.60(c)(5). Another portion of this regulation already indicates when the terms “no added sugar,” “without added sugar,” or “no sugar added” may be used. 21 C.F.R. § 101.60(c)(2).

¹⁸¹ 21 C.F.R. § 101.13(h)(1). 21 C.F.R. § 101.13(h)(2) deals with disclosure for a “meal product,” and 21 C.F.R. § 101.13(h)(3) deals with disclosure for a “main dish product.” The former uses 40 percent of the DRV of fat, saturated fat, cholesterol, or sodium to trigger the disclosure statement, and the latter uses 30 percent of the DRV to trigger disclosure. We request the same trigger for added sugars in these two provisions, i.e., 16 grams and 12 grams.

¹⁸² The current version comes from section 305 of the Food and Drug Administration Modernization Act of 1997, P.L. 105-115, which amended section 403(r)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(2)(B). The earlier version said that the disclosure should state “See [appropriate panel] for information about [nutrient requiring disclosure] and other nutrients.” The FDA explained in 1998 that the 1997 statutory change simply referred to how the disclosure is to be made and not the conditions triggering it. 63 Fed. Reg. 26978 (May 15, 1998).

dietary regime.”¹⁸³ As discussed above in section III.C.(1) there is now scientific evidence about the public health impact of added sugars analogous to that for fat, saturated fat, cholesterol, and sodium, and so this provision should be expanded to include foods that provide more than 20 percent of the DRV for added sugars, i.e., 8 grams per reference serving.

Finally, FDA’s current regulations provide that a food may be labeled as “healthy” only if it is low in fat and saturated fat, is not high in sodium or cholesterol, and is a good source of vitamin A, vitamin C, calcium, iron, protein, or fiber.¹⁸⁴ That provision should be expanded to require that a healthy food not be high in added sugars, i.e., that it not exceed 8 grams of added sugars per serving (16 grams of added sugars in a “meal product” and 12 grams of added sugars in a “main dish product”). Clearly, it would be inappropriate for a low-fat -- but high-sugar -- ice cream, cake, or cookie to carry a “healthy” label, even if it supplies 10% of the DV for vitamin A or C, calcium, iron, protein, or fiber.¹⁸⁵

IV. STATEMENT OF LEGAL GROUNDS

A. In 1990 Congress decided that to assist consumers in maintaining healthy diets, the FDA should ensure that its nutrition-labeling regulations are consistent with new research and other information.

Section 2(a) of the NLEA¹⁸⁶ provides that the Secretary may require food-labeling

¹⁸³ 58 Fed. Reg. at 2307.

¹⁸⁴ 101 C.F.R. §101.65(d).

¹⁸⁵ The FDA should determine whether additional conforming changes to related labeling regulations need to be made to regulate claims regarding sugar and added sugar in a manner consistent with the agency’s regulations for fat, saturated fat, cholesterol, and sodium claims.

¹⁸⁶ 21 U.S.C. § 343(q)(2).

information both for nine specific nutrients (including sugars) and for any additional specific nutrients if the Secretary determines that providing such information “will assist consumers in maintaining healthy dietary practices.” The NLEA does not require the FDA to prove a direct effect of a nutrient on the prevalence of a particular disease or health problem. By not including such a requirement in the NLEA, Congress showed particular wisdom, given the complexity of nutrition science and the difficulty in identifying the exact causes of conditions, such as obesity, that are affected by a multitude of factors. The House of Representatives Committee on Energy and Commerce’s report on the NLEA explains that that statutory provision gives 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.”¹⁸⁷ As discussed above in section III, a considerable body of new (since the FDA’s 1993 decision) research and other information on added sugars makes it essential that the agency fulfill its mandate to “assist consumers in maintaining healthy dietary practices” by taking the actions requested in this petition.

It is well established that an agency, faced with new developments or in light of reconsideration of the relevant facts and its mandate, may alter its past interpretation and overturn past administrative rulings and practice. The Supreme Court has said that agencies must be given ample latitude to "adapt their rules and policies to the demands of changing circumstances."¹⁸⁸ "[T]his kind of flexibility and adaptability to changing needs...is an essential part of the office of a regulatory agency. Regulatory agencies do not establish rules of conduct to

¹⁸⁷ H.R. Rep. 101-538, 101st Cong. 2d Sess. (1990) at 14.

¹⁸⁸ *Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968).

last forever; they are supposed, within the limits of the law and fair and prudent administration, to adapt their rules and practices of the Nation's needs in a volatile, changing economy. They are neither required nor supposed to regulate the present and the future within the inflexible limits of yesterday."¹⁸⁹

B. In 1993 the FDA decided that using a “%DV” disclosure best complied with the Congressional mandate to provide nutrition information in a way that facilitates the public’s understanding.

Section (2)(b)(1)(A) of the NLEA¹⁹⁰ directs that the FDA’s “regulations shall require the required information to be 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.” The House Committee report states “one way that this could be accomplished would be to include information about the recommended daily intake on the label.”¹⁹¹

In 1993 the FDA, relying in part on focus-group discussions that it conducted, decided that “DRVs provide an appropriate approach to accomplishing the statutory mandate.”¹⁹² As discussed above in section III.D.(2), a DRV for added sugars would help consumers choose a more healthful diet by ensuring that the information is “conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand

¹⁸⁹ *American Trucking Assns., Inc. v. Atchison, T. & S.F.R.. Co.*, 387 U.S. 397, 416 (1967).

¹⁹⁰ 21 U.S.C. § 343 note.

¹⁹¹ H. R. Rep. 101-538, 101st Cong. 2d Sess. (1990) at 18.

¹⁹² 58 Fed. Reg. at 2207.

its relative significance in the context of a total daily diet,” as the NLEA states.

C. Congress directed the FDA to prohibit nutrient-content and health claims on food labels unless they are made in accordance with regulations issued by the Secretary.

Section 3(a) of the NLEA¹⁹³ provides that a food that makes a claim regarding either the level of a nutrient or the relationship of a nutrient to a disease or health-related condition shall be deemed to be misbranded unless the claim complies with a regulation issued by the Secretary.

Two sections of the Federal Food, Drug, and Cosmetic Act ("FFDCA") provide the general legal basis for FDA's regulation of nutrient-content and health claims.¹⁹⁴ Section 403(r)(1)(A)¹⁹⁵ of the FFDCA prohibits any claim that characterizes the level of any nutrient that is of the type listed on the Nutrition Facts label unless such claim uses terms defined in regulations issued by the Secretary. That statutory provision gives the FDA ample power to amend its nutrient-content-claim regulations.¹⁹⁶ Section 403(r)(1)(B) of the FFDCA¹⁹⁷ deals with health claims¹⁹⁸ and bars a claim about the "relationship of any nutrient...to a disease or a health-

¹⁹³ 21 U.S.C. §§ 343(r)(1).

¹⁹⁴ Section 403(r)(2)(B) of the FFDCA, 21 U.S.C. § 343(r)(2)(B), also deals with nutrient-content claims and provides that if "the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet-related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for _____ content.'"

¹⁹⁵ 21 U.S.C. § 343(r)(1)(A).

¹⁹⁶ 21 C.F.R. §§ 101.13 and 101.60.

¹⁹⁷ 21 U.S.C. § 343(r)(1)(B).

¹⁹⁸ The health claim regulations are contained in 21 C.F.R. § 101.14.

related condition” if, as stated in section 403(r)(3)(A)(ii) of the FFDCFA,¹⁹⁹ the food contains “any nutrient in an amount which increases to persons in the general population the risk of a disease *or health-related condition* which is diet related, taking into account the significance of the food in the total daily diet. . .”²⁰⁰ [emphasis added]

Finally, the FDA has general authority to promulgate regulations to prevent the misbranding of food under sections 201(n), 403(a), and 701(a) of the FFDCFA,²⁰¹ and the agency in May 1994 relied in part on such authority to issue regulations governing when the term “healthy” may be used on a food label.²⁰²

In sum, those statutory provisions give the FDA ample power to amend its nutrient-content and health-claim regulations²⁰³ to include added sugars.

V. CONCLUSION

For the reasons stated above, the FDA should initiate a rulemaking to establish a daily reference value for added sugars, to require nutrition labeling of added sugars, and to make corresponding changes to its regulations governing nutrient-content and health claims.

¹⁹⁹ 21 U.S.C. § 343(r)(3)(A)(ii).

²⁰⁰ The House Committee report explains that “By requiring the Secretary to decide this issue in the context of the total daily diet, the bill permits the Secretary to differentiate between different foods which have the same level of a nutrient. For example, a particular level of fat in a frozen dinner might not trigger the provision, whereas the same amount of fat in a snack food product might trigger it.” H.R. Rep. 101-538, 101st Cong. 2d Sess. (1990) at 21.

²⁰¹ 21 U.S.C. §§ 321(n), 343(a), and 371(a).

²⁰² 59 Fed. Reg. 24249 (May 10, 1994). The “healthy” regulations are now in 21 C.F.R. § 101.65(d).

²⁰³ 21 C.F.R. §§ 101.13, 101.14, 101.60, and 101.65(d).

VI. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion under 21 C.F.R. §§ 25.30(k) and 25.32(p) and therefore does not require the preparation of an environmental assessment.

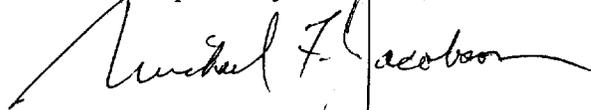
VII. ECONOMIC IMPACT

No statement of the economic impact of a revision of this rule is presented because none has been requested by the Commissioner.²⁰⁴

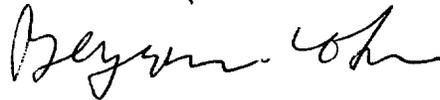
VIII. CERTIFICATION

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

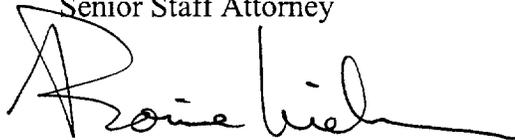
Respectfully submitted,



Michael F. Jacobson, Ph.D.
Executive Director



Benjamin Cohen
Senior Staff Attorney



Bonnie Liebman, M.S.
Director of Nutrition

²⁰⁴ 21 C.F.R. §10.30(b).

August 3, 1999

The Honorable Jane Henney, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

The undersigned support the petition filed by the Center for Science in the Public Interest (CSPI) asking the Food and Drug Administration to require "Nutrition Facts" labels to disclose the quantity of *added* sugars present in packaged foods and to set a Daily Reference Value (called a Daily Value on labels) for refined sugars added to foods.¹

When the FDA in 1993 issued the current nutrition-labeling regulations, it failed to require disclosure of added sugars and did not establish a Daily Value for added sugars, in part because no health authorities had issued quantitative recommendations on added-sugars intake. However, in 1996, the U.S. Department of Agriculture's "Food Guide Pyramid" recommended that Americans should limit their daily intake of added sugars to about ten teaspoons (40g) for a 2,000-calorie healthful diet (the less healthful the diet, the less room there is for added sugars). We urge the FDA to adopt USDA's recommendation as the Daily Value for added sugars. Without a %DV for added sugars, consumers could not compare the added-sugars content of a food to recommended daily intakes.

The FDA also said it could not determine by chemical analysis the added-sugars content of foods. However, chemists can determine the amount of added sugars in many foods; for other foods, the FDA could obtain information from the producers.

The FDA's 1993 labeling decision concerning sugars was based in part on the agency's 1986 literature review, which, in turn, was based in part on 1977-78 consumption data.² Since then, new information about sugars consumption and the health consequences of consuming excessive levels of added sugars necessitates a revision of the 1993 policy. For example:

1. Consumption of added sugars is soaring. According to data published by FDA and USDA data, since 1977-78 the contribution of calories from added sugars to the American diet jumped from 11 percent to 16 percent.³ In 1996, the *average* teenager got 20 percent of his or her calories from the added sugars in soft drinks, cakes, cookies, and other foods. That's about 34 teaspoons for boys and 24 teaspoons for girls.

2. Added sugars squeeze nutrients and more healthful foods out of the diet. New USDA data indicate that people who consume diets high in added sugars consume lower levels of protein; fiber; vitamins A, E, C, B-2, B-3, B-6, B-12, and folate; calcium; iron; zinc; and magnesium. They also consume fewer servings of grains, fruits, vegetables, meats, and dairy products than people who consume less added sugars.⁴ A healthful diet -- including fruits, vegetables, whole grains, and low-fat dairy products -- appears to lower the risk of cancer, heart disease, stroke, and osteoporosis. Yet a recent study by the National Cancer Institute found that

only two percent of 2- to 19-year-olds met all of five federal recommendations for a healthy diet.⁵

3. Added sugars may contribute to obesity. Increasing consumption of foods high in added sugars may be contributing to the nation's epidemic of obesity because they are often calorie-dense. A recent review of clinical studies suggests that diets rich in calorie-dense foods promote obesity.⁶ It states "...when the fat content was controlled but the energy density varied, subjects ate a constant weight of food; therefore, the greater the energy density, the greater was the energy intake." Calorie-dense foods are typically high in fat and/or added sugars. For example, a Pepperidge Farm Black Forest Cake has 27 grams of sugar and a caloric density of 3.6 (290 calories per 2.9 oz.); a Cinnabon contains 49 grams of sugar and has a caloric density of 3.2 (670 calories per 7.5 ounces); an order of Burger King Cini-Minis with icing has 38 grams of sugar and a caloric density of 4.0 (530 calories per 4.7 ounces). Furthermore, soft drinks are the largest and fastest-growing source of added sugars in the average American's diet. New studies suggest that overweight children consume more soft drinks than their normal-weight counterparts and that people are less likely to compensate for excess calories consumed as liquid foods.^{7,8} An analysis of 1994 CSFII data found that school-age children who consumed non-diet soft drinks ingested more calories than children who did not consume soft drinks.

4. Added sugars may contribute to heart disease. Added sugars appear to raise triglyceride levels more than other carbohydrates, especially among people who are insulin-resistant.⁹ Elevated triglycerides may increase the risk of heart disease.

For those and other reasons, we urge the FDA to improve food labeling -- and the public's health -- by requiring disclosure of added sugars. While the naturally occurring sugars in fruit and dairy products may be chemically identical to added sugars, low-fat varieties of those foods clearly help prevent cancer, heart disease, stroke, osteoporosis and other diseases. In contrast, soft drinks, baked goods, candy, and other sources of added sugars may increase the risk of disease either by adding sugars to the diet or by displacing more nutritious foods from the diet.

It is vital that the FDA give consumers the information they need to reduce their intake of added sugars. Without added-sugars labeling, it is very difficult for consumers to know how much of those sugars has been added to yogurt, ice cream, puddings, frozen fruit bars, sorbet, canned or frozen fruit, fruit snacks, juice drinks, jams, breakfast cereals, cereal bars, muffins, cookies, and a host of other foods. Many of those products are marketed with claims like "made with real fruit," but they contain far more nutrient-devoid added sugars than nutrient-rich fruit.

Furthermore, the FDA should define claims such as "low in added sugars" and limit the added sugars in foods that make health claims or are labeled "healthy." The FDA currently limits other nutrients -- fat, saturated fat, cholesterol, and sodium -- in foods that make those claims.

Thank you for your prompt attention to this important public health matter. (Please respond to the cosigners by writing to the Center for Science in the Public Interest.)

Sincerely,

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Organizations

American Association for Health Education

American Association of Family &
Consumer Sciences

American Chiropractic Association Council
on Nutrition

American Chiropractic Board of Nutrition

American College of Preventive Medicine

American Medical Student Association

American Public Health Association

American Society of Bariatric Physicians

Association of Schools of Public Health

Association of State and Territorial Chronic
Disease Program Directors

Association of State and Territorial
Nutrition Directors

Cancer Research Foundation of America

Center for Communications, Health and the
Environment

Child Health Foundation

The Children's Foundation

Citizens for Public Action on Blood
Pressure and Cholesterol

Consumer Federation of America

Cornell University Medical College
Nutrition Information Center

Girl Scouts of the USA

Harlem Consumer Education Council

International SPA Association

Meals on Wheels Association of America

National Association of School Nurses

National Association of WIC Directors

National Black Nurses Association

National Black Women's Health Project,
Inc.

National Consumers League

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National Council of Senior Citizens

People's Medical Society

National Education Association's Health
Information Network

Produce for Better Health Foundation

National Student Nurses Association

Produce Marketing Association

National Women's Health Network

Shape Up America!

Oldways Preservation and Exchange Trust

Texas Dept. of Health, Bureau for Disease
and Injury Prevention, Chronic Disease
Community and Worksite Wellness Program

Pacific Health Education Center

YMCA of the USA

Endnotes

1. DHHS and USDA noted in "Dietary Guidelines for Americans" (p. 34) that added sugars include brown sugar, corn sweetener, corn syrup, fructose, fruit juice concentrate, glucose (dextrose), high-fructose corn syrup, honey, invert sugar, lactose, maltose, molasses, raw sugar, [table] sugar (sucrose), and syrup. "Added sugars" does not include sugars that occur naturally in foods such as fruit and milk.
2. Glinsmann WH, Irausquin H, Park YK. "Evaluation of health aspects of sugars contained in carbohydrate sweeteners." *J Nutr.* 1998;116(11S):S1-S216
3. Glinsmann WH, Irausquin H, Park YK. "Evaluation of health aspects of sugars contained in carbohydrate sweeteners." *J Nutr.* 1998;116(11S):S1-S216. USDA, Agricultural Research Service. 1997. Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals, [Online]. ARS Food Surveys Research Group. Available (under "Releases") <<http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm>> (visited Oct. 7, 1998).
4. Testimony by Rachel Johnson, Dietary Guidelines Advisory Committee Meeting, Washington, D.C., March 9, 1999, p. 364.
5. Munoz KA, Krebs-Smith SM, Ballard-Barbash R, et al. "Food intakes of U.S. children and adolescents compared with recommendations." *Pediatrics.* 1997;100:323-9. 1998;101:952-3.
6. S.B. Roberts et al. "Physiology of fat replacement and fat reduction: effects of dietary fat and fat substitutes on energy regulation," *56 Nutrition Reviews* S29-41 (1998).
7. Personal communication from Troiano RP. *Am J Clin Nutr* (forthcoming).
8. Hamack L, et al. "Soft Drink Consumption Among U.S. Children and Adolescents: Nutritional Consequences." *J Am Diet Asso.* 1999;99:436-41.
9. Daly ME, et al. "Dietary Carbohydrates and Insulin Sensitivity: A Review of the Evidence and Clinical Implications." *Am J Clin Nutr.* 1997;66:1072-85. Hollenbeck CB. "Dietary Fructose Effects on Lipoprotein Metabolism and Risk for Coronary Artery Disease." *Am J Clin Nutr.* 1993; 99:800S-809S; Frayn KN, et al. "Dietary Sugars and Lipid Metabolism in Humans." *Am J Clin Nutr.* 1995;62:250S-261S.

Exhibit 2

Nutrition Facts

Serving Size 1 cup (228g)

Amount Per Serving

Calories 260 Calories from Fat 120

% Daily Value*

Total Fat 13g 20%

Saturated Fat 5g 25%

Cholesterol 30 mg 10%

Sodium 660mg 28%

Total Carbohydrate 31g 10%

Dietary Fiber 0g 0%

Total Sugars 15g

Added Sugars 10g 25%

Protein 5g

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

*Percent daily values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Added sugars	Less than	40g	60g

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Exhibit 3

Added Sugars Contained in 28 Different Foods

WHERE ARE THE ADDED SUGARS?

Food Groups *Added Sugars (teaspoons)*

Bread, Cereal, Rice, and Pasta

Bread, 1 slice	0
Muffin, 1 medium	* 1
Cookies, 2 medium	* 1
Danish pastry, 1 medium	* 1
Doughnut, 1 medium	** 2
Ready-to-eat cereal, sweetened, 1 oz.	* *
Pound cake, no-fat, 1 oz.	** 2
Angelfood cake, 1/12 tube cake	***** 5
Cake, frosted, 1/16 average	***** 6
Pie, fruit, 2 crust, 1/6 8" pie	***** 6

Fruit

Fruit, canned in juice, 1/2 cup	0
Fruit, canned in light syrup, 1/2 cup	** 2
Fruit, canned in heavy syrup, 1/2 cup	**** 4

Milk, Yogurt, and Cheese

Milk, plain, 1 cup	0
Chocolate milk, 2 percent, 1 cup	*** 3
Lowfat yogurt, plain, 8 oz.	0
Lowfat yogurt, flavored, 8 oz.	***** 5
Lowfat yogurt, fruit, 8 oz.	***** 7
Ice cream, ice milk, or frozen yogurt, 1/2 cup	*** 3
Chocolate shake, 10 fl. oz.	***** 9

Other

Sugar, jam, or jelly, 1 tsp.	* 1
Syrup or honey, 1 tbsp.	*** 3
Chocolate bar, 1 oz.	*** 3
Fruit sorbet, 1/2 cup	*** 3
Gelatin dessert, 1/2 cup	**** 4
Sherbet, 1/2 cup	***** 5
Cola, 12 fl.oz.	***** 9
Fruit drink, ade, 12 fl.oz.	***** 12

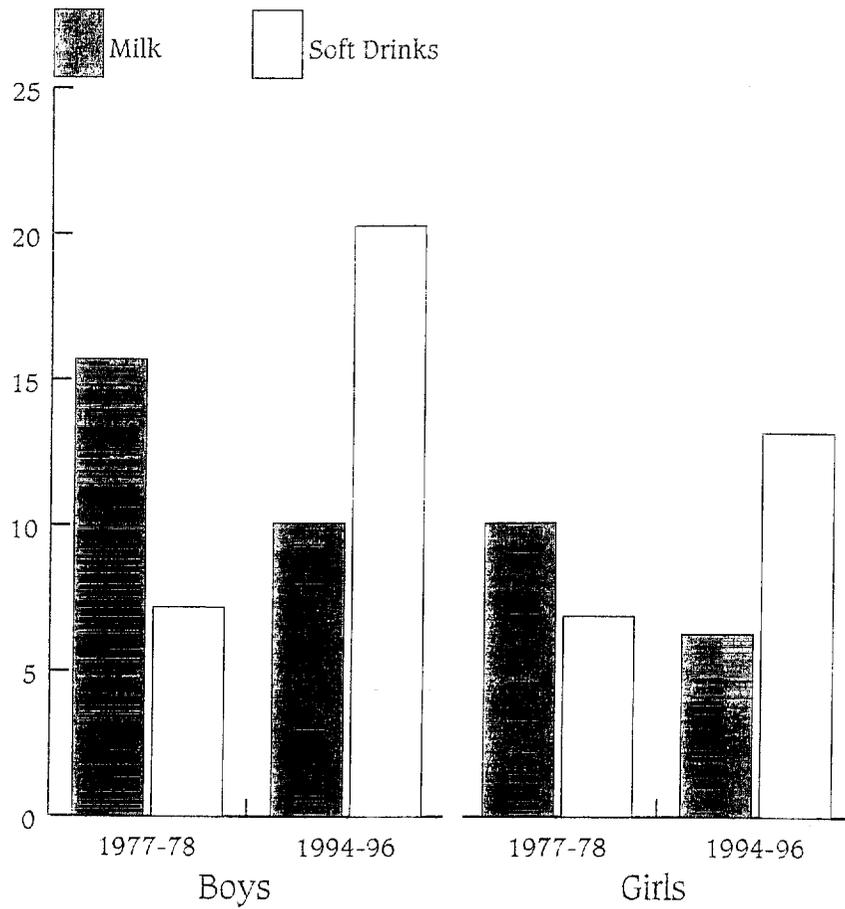
*Check product label. * = 1 teaspoon sugar

Note: 4 grams of sugar = 1 teaspoon

Source: United States Department of Agriculture, *The Food Guide Pyramid* (1996) at 16.

Exhibit 4

Figure 3. Teens' (ages 12-19) consumption of milk and soft drinks (ounces per day).



USDA: NFCS, CSFII

FRUIT ROLLUPS

PEEL 'N BUILD

MADE WITH REAL FRUIT
EXCELLENT SOURCE OF VITAMIN C
LOW FAT

Nutrition Facts

Serving Size 1 roll (14g)
Servings Per Container 10

Amount Per Serving	
Calories	50
Calories from Fat	5
% Daily Value*	
Total Fat 0.5g	1%
Sodium 55mg	2%
Total Carbohydrate 12g	4%
Sugars 5g	
Protein 0g	
Vitamin C	25%

Not a significant source of saturated fat, cholesterol, dietary fiber, vitamin A, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: PEARS FROM CONCENTRATE, MALTODEXTRIN, SUGAR, CORN SYRUP, PARTIALLY HYDROGENATED COCONUT OIL, CITRIC ACID, GLYCERIN, SODIUM CITRATE, PECTIN, MONOGLYCERIDES, MALIC ACID, VITAMIN C (ASCORBIC ACID), NATURAL FLAVOR, COLOR (RED 0, YELLOWS 5 & 6, BLUE 1).

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(NET WT 14 oz) 397g

Strawberry/Orange

GEL SNACKS

Hunt's®
Juicy Gels®
GEL SNACKS

Nutrition Facts

Serving Size 1 Gel Cup (99g)
Servings Per Carton 4

Amount Per Serving

Calories 100

% Daily Value**

Total Fat 0g 0%

Sodium 40mg 2%

Total Carbohydrate 25g 8%

Sugars 24g

Protein 0g

Vitamin C 2%

**Percent Daily Values are based on a 2,000 calorie diet.

ORANGE INGREDIENTS: FILTERED WATER, SUGAR, FRUIT JUICE FROM CONCENTRATE (WATER, APPLE, PEAR, PINEAPPLE, PEACH), CARRAGEENAN, NATURAL FLAVOR, ADIPIC ACID, CITRIC ACID, POTASSIUM CITRATE, LOCUST BEAN GUM, SODIUM CITRATE, COLORED WITH YELLOW 6 AND RED 40.

STRAWBERRY INGREDIENTS: FILTERED WATER, SUGAR, FRUIT JUICE FROM CONCENTRATE (WATER, APPLE, PEAR, PINEAPPLE, PEACH), CARRAGEENAN, ARTIFICIAL AND NATURAL FLAVORS, ADIPIC ACID, CITRIC ACID, POTASSIUM CITRATE, LOCUST BEAN GUM, SODIUM CITRATE, COLORED WITH RED 40.



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LOW FAT

Nutrition Facts

Serving Size 1 pouch (25g)
Servings Per Container 6

Amount Per Serving
Calories 90
Calories from Fat 10
% Daily Value*

Total Fat 1g 2%
Sodium 45mg 2%
Total Carbohydrate 20g 7%
Sugars 13g
Protein 0g

Vitamin C 25%

Not a significant source of saturated fat, cholesterol, dietary fiber, vitamin A, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: PEARS FROM CONCENTRATE, SUGAR, DRIED CORN SYRUP, MODIFIED CORN STARCH, CORN SYRUP, GRAPES FROM CONCENTRATE, FRUCTOSE, PARTIALLY HYDROGENATED COTTONSEED OIL, GRAPE JUICE FROM CONCENTRATE, MALTODEXTRIN, CARRAGEENAN, CITRIC ACID, GLYCERIN, MONOGLYCERIDES, SODIUM CITRATE, MALIC ACID, VITAMIN C (ASCORBIC ACID), DEXTROSE, POTASSIUM CITRATE, AGAR-AGAR, NATURAL FLAVOR, XANTHAN GUM, YELLOW 5 AND BLUE 1.

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