

**Citizen Petition Requesting Amendment of Federal Regulations to Allow Label Claims of “Less Sugar” on Beverages Marketed to All Children, Not Just Children Over the Age of Two Years**

May 20, 2010

Petitioner: David Glasser, Founder/CEO, First Juice, Inc.

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Subject of the Petition: Regulations governing label claims permitted on beverages for children under the age of two years

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857

The undersigned submits this petition under 21 CFR 10.30  
of the Federal Food, Drug, and Cosmetic Act.

***A. Action requested***

Given grave concerns about childhood obesity and the dire prediction that one in three children will develop diabetes if Americans continue to consume high levels of sugar, it is nonsensical to allow a truthful “less sugar” label claim on a beverage targeted to all adults and to all children two years and older, but to disallow the very same claim on a beverage intended for children under the age of two. [current 21 C.F.R. 101.13(b)(3)]

We recognize the rationale for not restricting calorie-providing macronutrients (i.e., fats, protein and carbohydrates) for children under the age of two years as they, of course, need macronutrients to properly develop. However, as to carbohydrates, the caloric intake (energy) needs of children under the age of two can be met in a variety of ways, many of which are far more healthful than the over-consumption of simple sugars.

As detailed below, the current regulation prohibiting the dissemination of information on lower sugar content on beverages intended for children under the age of two is clearly antithetical to the health of growing children and against the grain of current scientific wisdom.

Therefore, the undersigned requests the Commissioner of the FDA to amend the regulations cited in this petition pertaining to FDA's prohibition of claims such as "50% less sugar than the leading apple juice" on beverages intended for children under the age of two years.

Specifically, this petition solely requests an exception allowing label claims relating to the sugar content of beverages intended for children under the age of two years. The undersigned requests that these claims be permitted with the requirement that if the juice (or juice beverage) labeled under this exception contains added sugar or an added sweetener (e.g.: sucralose, aspartame, acesulfame potassium, etc...) that this must be written on the label together with the "less sugar" claim.

The regulation this petition seeks to amend is Title 21, CFR, section 101.13(b)(3) (21 CFR 101.13(b)(3)) which states that except for claims regarding the percentage of a vitamin or mineral in relation to its established Reference Daily Intake, a nutrient content claim cannot be made for a food that is intended for use by infants and children less than two years of age unless the claim is specifically provided for in parts 101, 105, or 107 of the regulations. **(Sugar is not a permitted exception under those parts.)**

### **B. Statement of Grounds**

In 2010 the incidence of obesity in children is a far greater global concern than it was in the early 1990s when the regulations in question were written. Parents today are serving significant and increasing amounts of juice to children under the age of two years, which science supports as a time in life when long lasting taste preferences are forming. All "juices," "juice drinks," and "juice beverages" are not created equally; however, current FDA regulations disallow the statement of an important differentiator amongst these products.

As detailed below in this statement, children under the age of two years are consuming increasing amounts of juice. Experts stress that this is the time in life when long-lasting taste preferences are developing. When children are under the age of two years is quite possibly *the most important time* during a child's development to permit producers of lower-sugar juices and juice beverages the right to communicate this important product benefit to parents, yet current FDA regulations expressly forbid this.

In their article, "Transitions in Infants' and Toddlers' Beverage Patterns," published January, 2004 in the Supplement to the Journal of The American Dietetic Association, and attached as Exhibit A hereto, researchers Skinner, Ziegler (a principal research scientist at Gerber Products Company) and Ponza report on the non-milk beverage consumption patterns of the 3,022 children ages four months to twenty-four months that participated in the 2002 Feeding Infants and Toddlers (FITS) study, sponsored by Gerber:

“About one-fifth of the infants four to six months of age drank 100% juice on the day of the 24-hour recall (Table 1), with the percentage increasing to about 60% of the sample at 19 to 24 months. Average amounts consumed by those drinking 100% juice more than doubled from 4.1 oz at four to six months of age to 9.5 oz at 19 to 24 months, and about 10% of toddlers 15 to 24 months of age had over 14 oz of 100% juice.”

“Beverages provided 84% of total daily food energy for infants 4 to 6 months of age, decreasing to 36% at ages 19 to 24 months. Apple juice and apple-flavored fruit drinks were the most frequently consumed beverages in the 100% juice and fruit drink categories, respectively. Juices, fruit drinks, and carbonated beverages appeared to displace milk in toddlers’ diets.”

“The severity of the obesity and diabetes epidemics have, understandably, caused lawmakers and policy experts to rethink nutritional labeling and to debate the merits of alternative means of providing information to consumers in a way that will change eating habits and lead to widespread improvements in the public health,” according to “Brain Food: Bringing Psychological Insights to Bear on Modern Nutrition Labeling Efforts,” by Jason Szanyi, and published in the most recent edition of the Food and Drug Law Journal (Volume 65).

The American Academy of Pediatrics published guidelines in 2001 saying that fruit juice should not be given to children younger than 6 months, and that there is no nutritional reason to give it to them before their first birthday. “Despite the guidelines, 60 percent of 1-year-olds drink juice, averaging 11½ ounces a day, according to 2002 USDA data. That's up from 57 percent less than a decade before. The USDA also found that more children younger than 1 are drinking juice, up from 35 percent to 39 percent, though they are drinking less of it,” according to the Associated Press in an article published in 2005. Children are clearly drinking significant amounts of juice, and there are often subtle differences in what parents perceive as “juice.”

Since 2005 there have been multiple introductions of new juice beverages designed for children that are lower in sugar than 100% juice, and these beverages are intended for, and are being consumed by, children under the age of two years. The petitioner believes that Gerber Products Company was the first to introduce a lower-sugar juice beverage intended for children under the age of two years, which petitioner also believes was a result of the knowledge derived from the Feeding Infants and Toddlers Study. In 2005 Gerber introduced “Fruit Splashers®,” which is a juice beverage specifically designed for children starting at age one, containing juice that is 40% juice/60% water, and on its front label panel is the claim “40% less sugar than the leading apple juice.” A sample of the current label is attached as Exhibit B.

Additional similarly innovative products include First Juice® (introduced by the petitioner), Sensible Sippers (by J M Smucker Company), Motts for Tots (by Motts), Fruitables (by Apple & Eve) and Wadda Juice (highly successful at launch, however no longer in business).

In today's world, given the global concern about childhood obesity, we find aspects of the regulations, particularly regarding sugar, to be clearly at odds with current prevailing wisdom regarding the health needs of children under the age of two years.

We recognize the rationale for not restricting calorie providing macronutrients (which are fats, protein and carbohydrates) for children under the age of two years. However, when it comes to macronutrients, children can get their caloric intake (energy) needs met in a variety of ways, other than from simple sugars.

Science supports that the time in life when children are under the age of two years is when food taste preferences are developing. Sugar tends to create a sweet taste in beverages, regardless if the sugar is added or naturally occurring. According to Amy Lanou, a senior nutrition scientist for the Physicians Committee for Responsible Medicine, a Washington-based nonprofit, early exposure to intensely sweet foods has long-term consequences. Ms. Lanou says "When we're really young, our taste buds are especially attuned to sweet flavors. If you're offered bananas and berries at an early age, that level of sweetness will satisfy. But if you're given concentrated sweets, a taste for those intense sweets will follow you for the rest of your life."

**Ms. Lanou is not alone in her point of view:**

- ✓ **"The key thing is that children learn many of their food taste preferences early— below age 2."**-- Dr. Paula Ziegler, Principal Research Scientist, Gerber Products Company (SOURCE: Cruz, M.D., C.R.Y, Children must be taught healthy eating habits early, Medical Observer. Apr. 2005.)
- ✓ **An eight-year study of 70 baby-mother pairs at the University of Tennessee, published in 2002, confirmed that food preferences are established early: 8-year-olds usually like the same foods they did when they were 4, and preferences are often formed as early as age 2.**—Pamela Paul, Rethinking First Foods, Time Magazine, 6/11/06
- ✓ **Pediatricians do agree on one thing: the period before age 2 is critical for establishing healthy eating. "We need to send a message to new parents," says Dr. Ari Brown, of Austin, Texas. "Here's your opportunity to change the way a generation eats. By the time a child is 10, eating chips in front of the TV, it's almost too late."**—Pamela Paul, Rethinking First Foods, Time Magazine, 6/11/06
- ✓ **"It's important for parents to help teach children healthy eating patterns from the beginning. Juice has become such a staple in the daily diets of many young children these days. That said, offering them a juice that contains**

**significantly less sugar and the nutritional benefits of 100% fruit juice is a good way to help toddlers develop an appreciation for less sweet tastes.**"--Dr. Laura Jana, pediatrician and co-author of *Food Fights: Winning the Nutritional Challenges of Parenthood Armed with Insight, Humor and a Bottle of Ketchup* (American Academy of Pediatrics, Oct. 2007)

- ✓ **“To understand exploding obesity rates among the very young, researchers are looking into the critical period between breast or bottle and the school lunchroom, when lifelong food habits take shape.”**—Pamela Paul, Rethinking First Foods, Time Magazine, 6/11/06

In 2005 the Monell Chemical Senses Center in Philadelphia, PA published “Understanding the Origin of Flavor Preferences,” which is attached to this petition as Exhibit C.

The overall goal of the study was to understand if flavor acceptance patterns later in life are influenced by flavor experiences early in life, and the results were clear and the effects were proven to be lasting:

In summary, the researchers, “...hypothesized that there is an early sensitive period during which... the flavors of other foods and beverages—is established.”

“The research provided clear evidence in the affirmative: infants fed on one or another brand of hydrolysate formula significantly preferred that familiar formula to the alternative unfamiliar formula. In other words, the acceptance pattern that develops is specific to the flavor profile experienced.”

“The control infants, fed only on milk-based formula, were equally reluctant to accept either hydrolysate formula, a result consistent with previous research (Mennella and Beauchamp, 1996, 1998; Mennella et al., 2003).”

“The effects of these experiences appear to be long-lived. Children aged 4–5 years who were fed hydrolysates during their infancy exhibited more positive responses to sensory attributes associated with them (e.g. sour taste, aroma) several years after their last exposure to the formula when compared with same-aged children without such experience (Liem and Mennella, 2002; Mennella and Beauchamp, 2002).”

“In other words, the characteristic flavor of the formula experienced in early life is imprinted’ and remains as a preference for a considerable time.”

Current FDA regulations, specifically within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], prohibit informing parents that a juice or juice beverage, that is intended for children under the age of two years, has less sugar than 100% juice, because the regulations define such claims as “unauthorized nutrient content claims.”

- The petitioner does not believe that the spirit of this regulation is meant to protect the disclosure that a juice beverage for a child under the age of two years has less sugar than 100% apple juice.
  - Is sugar a nutrient that the regulations intend to protect?
  - If so, should there be a “Recommended Daily Intake” of sugar?

Title 21, Code of Federal Regulations, section 101.13(b)(3) (21 CFR 101.13(b)(3)) states that except for claims regarding the percentage of a vitamin or mineral in relation to its established Reference Daily Intake, a nutrient content claim cannot be made for a food that is intended for use by infants and children less than two years of age unless the claim is specifically provided for in parts 101, 105, or 107 of the regulations. **(Sugar is not a permitted exception under those parts.)**

- ✓ **“A number of scientific studies have found that the amount of sugar we consume is a major factor in how big Americans have become. In the last half-century, consumption of sugars by the average American has increased by more than 24 pounds a year, expanding waistlines and crowding out more nutritious foods.”**

**“Furthermore, the studies indicate that the main dietary culprit for both the increase in sugar and the weight of Americans has been the ever-growing consumption of sugary drinks, especially soda. These soft drinks contribute 7 percent of the calories Americans consume, making them the leading source of added sugar and the single largest source of calories in our diet.”** -- Jane Brody, How Sweet It Is, NY Times, April 6, 2010

Label regulations should support parents in making informed beverage choices for their young children. In research paid for by First Juice, Inc. (prior to the launch of our brand) and conducted in 2006 and 2007 by independent consumer research firms, it was found that 69% of 1,000 parents surveyed, all of whom had children ages 6 months to 36 months at home, diluted 100% fruit juice with water prior to serving it to their children. 97% of these same parents separately either “agreed” or “strongly agreed” with the statement, “I am concerned about my child’s intake of sugar.”

According to FDA’s 2008 Health and Diet Survey, 54% of consumers said they read a products label the first time they buy the product. Information on the labels of beverages intended for children under the age of two years is often the only direct communication that the creators and marketers of the products have with the parents they are seeking to serve. This is especially true for the brands launched by small, entrepreneurial companies such as the one founded by the petitioner.

As the FDA Commissioner wrote in her “Open Letter to Industry” on March 3, 2010:

“...many use this nutrition information to make food choices. Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States. This need is highlighted by the announcement recently by the First Lady of a coordinated national campaign to reduce the incidence of obesity among our citizens, particularly our children. With that in mind, I have made improving the scientific accuracy and usefulness of food labeling one of my priorities as Commissioner of Food and Drugs.”

Given that there is not a “Recommended Daily Intake” for sugar, there is otherwise no permitted and regulated language for the marketer of a juice that has been blended with water to reduce its sugar content to communicate the reduced sugar content to the parents of a child under the age of two years.

- “It is well known that the nutritional needs of the very young are different than those of adults.”—from “Open Letter to Industry” by Dr. Margaret Hamburg, Commissioner of Food and Drugs, March, 2010
- Claims such as “50% less sugar than the leading apple juice” are currently permitted on products intended for children over the age of two years.

Petitioner agrees with Dr. Hamburg that the nutritional needs of the very young are different, and require special consideration, and that is precisely why this regulation should be amended. That said, petitioner does not understand why claims about lower sugar content are permitted on beverages intended for children age 25 months, but not for children age 23 months or 13 months or 11 months.

In lieu of this prohibition we believe FDA should permit such labeling in a regulated manner, as is suggested in this petition. Petitioner further believes that this would best match “the intention of Congress to provide consumers with labeling information that enables consumers to make informed and healthy food choices,” as Dr. Hamburg wrote in her “Open Letter to Industry” dated March 3, 2010.

The consumption of high-in-sugar, sweet-tasting, low-nutrient-dense foods and beverages can contribute to excess weight. Sweet tasting foods and beverages served to children under the age of two years can have the unintended side effect of encouraging a tendency to crave sugar-rich foods which does not support healthful eating practices.

Given the global concern regarding widespread childhood obesity, and the fact that 1 in 3 children born today are predicted to develop diabetes, we strongly urge FDA to revisit and revise its regulations with respect to sugar claims for children under the age of two years.

The need to permit the exception requested is clear.

**C. Environmental Impact**

None.

**D. Economic Impact**

None.

**E. 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 that it includes representative data and information known to the petitioner which are unfavorable to the petition.

This petition has been prepared in consultation with Scott Polisky, Esq., regulatory counsel, and Lauren Swann, MS, RD, LDN. Ms. Swann is a registered dietitian and food labeling specialist.

Respectfully submitted,



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# Exhibit A

# Transitions in Infants' and Toddlers' Beverage Patterns

JEAN D. SKINNER, PhD, RD; PAULA ZIEGLER, PhD, RD; MICHAEL PONZA, PhD

## ABSTRACT

**Objective** To describe transitions and patterns in infants' and toddlers' beverage intakes, with focus on nonmilk beverages.

**Design** A cross-sectional study was conducted by telephone to obtain a 24-hour dietary recall of infants' and toddlers' food intakes, as reported by mothers or other primary caregivers.

**Subjects** A nationwide sample of infants and toddlers ( $n=3,022$ ) ages 4 to 24 months, who participated in the Feeding Infants and Toddlers Study (FITS).

**Analyses** Beverages were categorized as total milks (ie, breast milk, infant formulas, cow's milk, soy milk, goat's milk), 100% juices, fruit drinks, carbonated beverages, water, and "other." Analyses included means  $\pm$  standard deviations, percentages, frequencies, nutrient densities, and linear regression.

**Results** Beverages provided 84% of total daily food energy for infants 4 to 6 months of age, decreasing to 36% at ages 19 to 24 months. Apple juice and apple-flavored fruit drinks were the most frequently consumed beverages in the 100% juice and fruit drink categories, respectively. Juices, fruit drinks, and carbonated beverages appeared to displace milk in toddlers' diets ( $P<.0001$ ).

**Applications/Conclusions** This research shows that beverages make important contributions to infants' and toddlers' energy and nutrient needs, but they must be wisely chosen. Registered dietitians should advise parents and caregivers that excessive intakes of any beverage, including milks and 100% juices, may displace other foods and beverages in the diet and/or contribute to excess food energy (kcal). Further research is needed to define excessive amounts in each beverage category, and such guidance could be very useful to parents and caregivers of infants and toddlers.

*J Am Diet Assoc. 2004;104:S45-S50.*

**B**everage patterns of US youth are of considerable concern to health professionals. Reasons for concern include the increasing consumption of beverages that are high in calories and sugars (1-3), the relation-

ships between these beverages (eg, carbonated beverages, sweetened fruit drinks) and childhood obesity/overweight (4,5), and the displacement of nutritionally desirable foods and beverages in the diet (1,3,6). Carbonated beverage consumption has been shown to be related to bone fractures in adolescents (7) and dental caries in preschool children (8). Beverage intakes in young children are of particular concern because daily intakes of high-calorie, high-sugar beverages appear to increase as children grow older (6,9). Food preferences at two and four years of age are highly predictive of food preferences at eight years of age (10). Thus, transitions in beverage patterns and the development of beverage patterns prior to two years of age may be important to the establishment of healthy patterns in childhood and adolescence, as well as affecting the current health of infants and toddlers. However, relatively few studies have investigated the beverage patterns of infants and toddlers less than two years of age (6,8,11-14). Thus, this portion of the Feeding Infants and Toddlers Study (FITS) was designed to describe beverage patterns of infants four to 11 months of age and toddlers 12 to 24 months of age. A secondary purpose was to investigate whether increased intakes of carbonated beverages and sweetened fruit drinks may displace 100% juice and milk in the diet, as suggested with previous studies with older children (1-3,6,9). The major focus of this paper is on nonmilk beverages; greater detail on intake patterns and transitions in intake of milks has been described in other papers in this supplement (15,16).

## METHODS

The sample included the entire group of 3,022 infants and toddlers in the FITS with the six age groupings, four to six, seven to eight, nine to 11, 12 to 14, 15 to 18, and 19 to 24 months. Mothers or other primary caregivers provided a 24-hour dietary recall of all foods and beverages consumed by the child on the previous day by telephone. Detailed information on food intake data collection, coding, and analyses are in a previous paper (17).

Beverages consumed by the FITS children were categorized into six groups: total milks, 100% juices, fruit drinks, carbonated beverages, water, and "other" drinks; similar groupings, excluding water, have been used previously (3,6,9). Total milks included breast milk, all kinds of infant formula, cow's milk with varying fat content, soy milk, and goat's milk. Although these milks may differ in nutrient composition and nutrient bioavailability, they are more similar to one another than to any of the remaining beverage categories, which also differ in nutrient content within each category. The 100% juice category included infant and adult fruit and vegetable juices that were 100% juice, including juices fortified with calcium and/or other nutrients; this categorization is consistent with food-labeling regulations. Fruit drinks as defined in this study included beverages with less than 100% juice, many of which had added sugars (eg, lemonade, punch),

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and some of which were fortified with one or more nutrients. Although the fruit drink category included many sweetened beverages that have low amounts of real juice, it also included some beverages with higher percentages of juice (eg, cranberry) that would be too tart for consumption without additional sweeteners. Sometimes these sweeteners were other naturally sweet juices. Carbonated beverages included carbonated mineral waters and "diet" and "regular" products that may or may not have contained sugars and caffeine. The water category included noncarbonated bottled water and tap water, both consumed plain or used to dilute other beverages, but excluded water used to prepare infant formula or reconstitute juices and fruit drinks. The "other" drink category included tea, cocoa and other dry milk mixtures, and electrolyte replacement beverages for infants.

Using the six age groupings in the FITS, the percentages of infants and toddlers in each age group who consumed any amount in a beverage category in one day were tabulated. Mean amounts consumed  $\pm$  standard deviations in each beverage category were calculated, including only those infants and toddlers who consumed a beverage from that category. Mean percentages of energy and selected nutrients provided by each beverage category at each age were calculated for the entire sample. Finally, the most frequently consumed beverages in each beverage category at each age were ranked based on frequency of consumption, regardless of amount served.

Because of the difficulty in estimating the quantity of breast milk for young infants who consumed breast milk and other nonmilk foods and beverages, nutrient intakes for four- to six-month-old infants were not included in these analyses (18). Although this same issue of estimating the quantity of breast milk also applies to older breastfed infants, two factors justify including older breastfeeding infants in the analysis. (a) The assumed quantity of breast milk consumed for these older infants (600 mL for breastfed infants older than 6 months) accounts for the fact that energy from solid foods replaces energy from breast milk as solids are introduced. (b) The proportion of infants breastfeeding is substantially lower among infants seven to 11 months of age, suggesting that the issue related to estimating the quantity of breast milk is less important for older infants.

To explore the notion that some beverages may displace others in the diets of toddlers, two linear regression models were developed using SAS, version 8.2, 2001 (Cary, NC). Analyses were limited to data from 15- to 24-month-old toddlers because the numbers of children consuming carbonated beverages at younger ages were too small for analyses with only 24-hour data. The dependent variable in model 1 was nutrient density for calcium (mg/1,000 kcal) with the following independent variables: mother's age (years), toddler's weight for age percentile, toddler's age in weeks, oz/day milk consumed, oz/day 100% juice consumed, oz/day fruit drinks consumed, and oz/day carbonated beverages consumed. The second model included these same independent variables, but the independent variable was nutrient density for vitamin C. A nutrient density approach was selected to control for energy intakes; thus, patterns of beverage consumption could be identified among toddlers whose energy intakes differed. The dependent variables (ie, nutrient densities for calcium and vitamin C) were selected because beverages provide substantial proportions of the total daily intake for these nutrients. The independent variables included

four beverage categories and other factors thought to possibly influence toddlers' diets. A significance level of  $P \leq .05$  was established.

## RESULTS

Beverages, including breast milk and formula, provided 84% of total energy (kcal) for infants four to six months of age, 43% at 12 to 14 months, and 36% at 19 to 24 months. Beverages also provided at least one-third of the daily intakes of calcium; vitamins A, C, and D; protein; and zinc (data not shown).

Some form of milk beverage was consumed by almost all children at each age, although total amounts of milk beverages decreased with increasing age (Table 1). Forty-nine toddlers (4.9% of the samples at 12 to 24 months of age) did not consume any type of milk beverage on the day described by the 24-hour recall. Most of these non-consumers of milk were consuming an electrolyte replacement beverage, which is often prescribed for illness. Along with changes in the percentage of total energy provided by the milks category, the types of milks also changed with increasing age (Table 2). Among infants, breast milk and infant formula were the most common beverages in the milks category, and whole cow's milk was the predominant choice among toddlers. By 19 to 24 months of age, however, over one-third of the sample consumed some form of reduced fat milk. Initially, breast milk and/or formula were the sole sources of energy and nutrients. By 19 to 24 months of age, milks contributed about one-third of the daily protein and vitamin A, more than half of the calcium and vitamin D, and less than one-fourth of the day's energy intake (data not shown).

About one-fifth of the infants four to six months of age drank 100% juice on the day of the 24-hour recall (Table 1), with the percentage increasing to about 60% of the sample at 19 to 24 months. Average amounts consumed by those drinking 100% juice more than doubled from 4.1 oz at four to six months of age to 9.5 oz at 19 to 24 months, and about 10% of toddlers 15 to 24 months of age had over 14 oz of 100% juice. Thus, the increase in the percentage of infants drinking juice occurred by seven to eight months of age, and the major increase in the amount of juice consumed occurred between 12 to 14 and 15 to 18 months of age. Apple juice was the most frequently consumed juice for each age group (Table 2), with baby food apple juice the predominant choice in the four to 11 months of age samples and regular apple juice in the 12- to 24-month samples. Frequencies for apple juice were approximately double that of orange juice, which was ranked second. As shown in Table 2, there was little variety in the kinds of juices offered to infants and toddlers. From seven to 11 months of age, 100% juices provided about 20% of the daily intake of vitamin C and about 4% of daily energy; for toddlers 100% juices provided 32% to 38% of the daily vitamin C and 5% to 7% of energy. Less than 1% of daily vitamin A and less than 5% of daily folate were provided by 100% juices.

The percentage of very young children consuming fruit drinks was less than 10% at four to eight months of age (Table 1), but rose to over 40% at 19 to 24 months. Amounts of 100% juice and fruit drinks consumed were similar, as were the increases with age in the percentages of infants and toddlers consuming these beverages, and the mean amounts consumed per child (Table 1). However 5% of the sample reportedly consumed  $\geq 16$  oz of

**Table 1.** Consumption of beverages by infants and toddlers

Beverage category	Age (mo)											
	4-6 (n=862)		7-8 (n=483)		9-11 (n=679)		12-14 (n=374)		15-18 (n=308)		19-24 (n=316)	
	Consumers % <sup>a</sup>	Mean±SD oz/d	Consumers % <sup>a</sup>	Mean±SD oz/d	Consumers % <sup>a</sup>	Mean±SD oz/d	Consumers % <sup>a</sup>	Mean±SD oz/d	Consumers % <sup>a</sup>	Mean±SD oz/d	Consumers % <sup>a</sup>	Mean±SD oz/d
Total milks <sup>b</sup>	100	26.3±8.7 <sup>c</sup>	100	23.4±8.7	99.7	22.3±9.6	98.2	20.9±9.9	94.2	19.6±10.3	93.4	18.0±9.5
100% juice <sup>d</sup>	21.3	4.1±3.0	45.6	4.9±3.7	55.3	5.4±4.3	56.2	6.3±4.9	57.8	9.3±6.4	61.6	9.5±6.4
Fruit drinks <sup>e</sup>	1.6	3.4±2.6	7.1	3.3±2.6	12.4	5.3±4.7	29.1	7.8±6.3	38.6	8.8±7.8	42.6	10.3±10.4
Carbonated	0.1	2.9±0	1.1	0.2±0.3	1.7	3.0±3.1	4.5	3.9±2.8	11.2	5.3±3.6	11.9	5.5±5.8
Water	33.7	5.5±7.8	56.1	5.9±7.4	66.9	7.1±7.9	72.2	10.2±10.7	74.0	10.6±8.8	77.0	11.4±8.3
Other <sup>f</sup>	1.4	6.8±6.5	2.2	6.8±7.4	3.5	5.7±5.6	6.6	8.5±12.8	12.2	6.7±7.8	11.2	5.6±8.4
Total beverages	100	29.2±8.6	100	29.3±10.5	100	30.8±12.2	100	34.4±13.5	100	36.5±13.5	100	37.1±16.3

<sup>a</sup>Weighted percentages, adjusted for over sampling, nonresponse, and under representation of some racial and ethnic groups.

<sup>b</sup>Includes breast milk, infant formula, cow's milk, soy milk, and goat's milk.

<sup>c</sup>Amounts consumed only by those children who had a beverage from this beverage category.

<sup>d</sup>Fruit or vegetable juices with no added sweeteners.

<sup>e</sup>Includes beverages with less than 100% juice and often with added sweeteners; some were fortified with one or more nutrients.

<sup>f</sup>Other beverages category included tea, cocoa and similar dry milk beverages, and electrolyte replacement beverages for infants.

fruit drinks in one day (data not shown). Apple-based fruit drinks were most popular at each age group, and, as with 100% juices, there was little variety (Table 2). For the samples over 15 months of age, the percentages of daily vitamin C, folate, and vitamin A provided by fruit drinks were 6% to 15%, less than 1%, and less than 1% to 4%, respectively. Fruit drinks provided 4% to 6% of total daily energy.

Although the percentage of infants and toddlers drinking carbonated beverages was less than 5% from four to 14 months of age, the percentages more than doubled to over 11% from 15 to 24 months (Table 1). Types of carbonated beverages consumed included colas, fruit-flavored carbonated drinks, and carbonated mineral waters (Table 2). Diet and regular, caffeinated and caffeine-free carbonated beverages were consumed by children in this sample. Carbonated beverages did not contribute to nutrient and energy intakes for the sample as a whole because relatively small amounts of carbonated beverages were consumed; only 1% of the sample had ≥10 oz.

Percentages of infants and toddlers consuming water ranged from 34% at four to six months of age to 77% at 19 to 24 months (Table 1). Toddlers (12 to 24 months of age) had mean intakes of about 11 oz water per day. Tap water had the highest frequency of consumption at each age category (Table 2).

The "other" beverage category was dominated by various types of tea and by fluid and electrolyte replacement beverages formulated for infants. Average amounts ranged from about six to 12 oz/day for those children consuming "other" beverages.

The regression models developed to explore the notion of substitutions among beverage categories are shown in Table 3. In model 1, variables positively related to the calcium density (mean=763 mg/1,000 kcal) in diets of toddlers ages 15 to 24 months were milk consumption and mother's age (mean=30.2±6.4 years). Intakes of 100% juice, fruit drinks, and carbonated beverages were negatively related to calcium density, indicating intakes of these beverages decreased calcium density in the diet. In model 2, variables positively related to density of vitamin C (mean=65 mg/1,000 kcal) were intakes of 100% juice and fruit drinks; negatively related variables were the child's age (mean=19.3±2.7 months) and milk intake. The data support the hypothesis that some beverages displace others in the diet.

## DISCUSSION

This study confirms that children were consuming a wide variety of beverages prior to two years of age. Milks including breast milk and formula as well as other milks remained the major beverage in children's diets prior to age two years and were the major source of many nutrients. It is appropriate that more milks were consumed than any other beverage category because it is difficult for children to meet daily needs for calcium and vitamin D without some type of milk in the diet (19). The findings that 100% juice appeared to displace milk in the diet and also that milk displaced juice emphasizes the importance of dietary balance. Both milk and 100% juice are nutritious beverages; therefore, parents may not believe that restrictions are necessary (20). Usually they are not, but excessive amounts of any food or beverage must be avoided.

Although the American Academy of Pediatrics (AAP) recommends that juices not be introduced before six

**Table 2.** Most frequently consumed beverages<sup>a</sup> at ages 4 to 24 months

Beverage category	Age of infant/toddler (mo)					
	4-6	7-8	9-11	12-14	15-18	19-24
Milks	Breast milk <sup>b</sup> Formula	Breast milk Formula	Formula Breast milk Milk, whole	Milk, whole milk, 2% Breast milk Formula	Milk, whole Milk, 2% Soymilk Breast milk	Milk, whole Milk, 2% Breast milk Milk, skin
100% juices <sup>c</sup>	Apple <sup>d</sup> White grape <sup>d</sup> Pear <sup>d</sup> Apple, regular	Apple <sup>d</sup> White grape <sup>d</sup> Pear <sup>d</sup> Apple, regular	Apple <sup>d</sup> Apple, regular White grape <sup>d</sup> Grape, regular Pear <sup>d</sup>	Apple, regular Orange, regular Apple <sup>d</sup> Grape, regular	Apple, regular Orange, regular Grape, regular Apple <sup>d</sup>	Apple, regular Grape, regular Orange, regular Mixed berry
Fruit drinks <sup>e</sup>	Apple, sweet	Apple, sweet Dry pkg mix	Apple, sweet	Apple, sweet Punch, regular Dry pkg mix Sports drink	Apple, sweet Punch	Apple, sweet Orange Dry pkg mix Punch
Carbonated	Mineral water	Mineral water Cola	Mineral water Citrus flavor	Cola Mineral water Citrus flavor	Citrus flavor Cola	Cola Citrus flavor Mineral water

<sup>a</sup>Frequencies, product not included if consumed by <10% of sample within an age category; calculations excluded non consumers of that beverage category.

<sup>b</sup>Beverages rank ordered within each category at each age.

<sup>c</sup>Includes only unsweetened products.

<sup>d</sup>Baby food products.

<sup>e</sup>Includes beverages with less than 100% juice and often with added sweeteners; some were fortified with one or more nutrients.

**Table 3.** Influences of toddlers<sup>1a</sup> beverages on nutrient densities for calcium and vitamin C<sup>b</sup>

Variable	Parameter estimate+SE	t-Value	P value
<b>Model 1. Dependent variable: Calcium density (mg/1,000 kcal/d); F=44.61, P&lt;.0001, R<sup>2</sup>=.36.</b>			
Mother's age, y	3.37±1.55	2.17	.03*
Wt/age, percentile <sup>c</sup>	0.40±0.32	1.27	.21
Age, wk	-1.47±0.86	-1.72	.09
Milk, oz	14.26±1.01	14.09	.0001***
100% juice, oz	-6.60±1.62	-4.09	.0001***
Fruit drink, oz	-8.92±1.40	-6.37	.0001***
Carbonated beverage, oz	-9.03±3.75	-2.41	.02*
<b>Model 2. Dependent variable: Vitamin C density (mg/1,000 kcal/d) F=23.94, P&lt;.0001, R<sup>2</sup>=.23.</b>			
Mother's age, y	0.57±0.30	1.90	.06
Wt/age, percentile <sup>b</sup>	-0.11±0.06	-1.72	.09
Age, wk	-0.43±0.17	-2.59	.01**
Milk, oz	-0.59±0.20	-3.01	.003**
100% juice, oz	3.58±0.31	11.46	.0001***
Fruit drink, oz	1.60±0.27	5.91	.0001***
Carbonated beverage, oz	-1.21±0.72	-1.66	.10

<sup>a</sup>Toddlers 15-24 months, only; n=561.

<sup>b</sup>From a 24-hour recall provided by mothers or other primary caregiver.

<sup>c</sup>From Center for Disease Control percentiles.

\*≤.05.

\*\*≤.01.

\*\*\*≤.0001.

months of age (20), it appears that some infants in this study may have had 100% juice earlier than age 6 months (ie, 21% of infants age four to six months drank 100% juice). AAP also recommends that daily juice intake be limited to four to six oz for children one to six years of age; high intakes by a few infants and toddlers suggest that some of the FITS parents did not heed that advice. Other researchers also have reported early introduction of 100%

juices (12,14) and daily amounts over six oz consumed by some children (9). From the data presented in this study, we can conclude that, although 100% juices provide concentrated energy (kcal) and sugars to the diet, they also make significant contributions to daily vitamin C intake. The low contributions of dietary folate by 100% juices reflect the popularity of apple juice, which is low in folate compared with orange juice. Dietitians can help parents

and caregivers recognize the health advantages of juices that provide an array of nutrients. Most parents and caregivers of infants appear to be following AAP recommendations about juice. Among toddlers, the variety of juice consumed could be improved, and amounts should be limited to avoid excessive intakes.

The AAP does not make any recommendations about limiting amounts of fruit drinks or carbonated beverages in the diets of infants and toddlers. Perhaps such guidance is needed. AAP does state that fruit drinks are not nutritionally equivalent to 100% juice, and fruit drinks cannot be considered as a fruit serving (20). However, fruit drinks vary considerably in nutritional quality. In general, fruit drinks with higher percentages of real juice are more nutritious than those with lower percentages of juice; parents and caregivers may be in need of dietary advice about selecting fruit drinks that are beneficial to the diet. Factors to consider are percentages of juices, energy and nutrient content, and limited amount of added sweeteners. Among the FITS toddlers, fruit drinks contributed significantly to vitamin C density.

Results of this study indicate that milk may be displaced in toddlers' diets by 100% juice, fruit drinks, and carbonated beverages. In studies with older children, milk intake decreased as fruit drinks and carbonated beverages increased (3,6,9). The decreasing milk intake and increasing intakes of fruit drinks and carbonated beverages with increasing age in this study may be cause for concern. Infants and toddlers are developing food preferences and food patterns that are likely to carry over to preschool and early school age years (10,21).

This study is among the first to document water intake in infants and toddlers. Water is an appropriate choice for quenching thirst and does not contribute to excessive energy intake. Breastfed and formula-fed infants usually do not need additional water. It has been estimated that infants need 1.5 mL water/kcal of energy expenditure for adequate intakes; this water-to-energy ratio corresponds to that found in breast milk and common infant formulas (22). Caution also must be used so that water does not displace needed energy and nutrients in the diet (23). However, infants are particularly susceptible to dehydration because of their large surface area per unit of body weight, their higher percentage of body water, and their inability to communicate thirst (22). Thus, in unusually hot weather, infants may need some additional water (23). Introducing infants to sips of water also may help them learn to drink water to quench thirst. Of course, these recommendations are based on the availability of a safe water supply.

Excessive amounts of any beverage, including milk, 100% juice, and even water, should be avoided because other foods and beverages may be displaced in the diet, and dietary variety may be decreased (21,24). Further research is needed to define excessive beverage intakes for each type of beverage at various ages, and such definitions would be very helpful to parents of infants, toddlers, and young children. The definitions of excessive intakes of various beverage categories are beyond the scope of this study. The water-energy ratio of 1.5 mL/kcal energy expenditure is a recommendation for adequacy rather than a maximum level. Factors to consider in developing excessive guidelines include toxicity issues (such as those with water), desirable ranges of proportions of solid food to liquid foods in the diet, nutrient needs (especially those provided primarily by beverages),

displacement issues, and the percentage of daily intake that can be allowed for beverages low in nutrients but high in calories.

## APPLICATIONS

- Breast milk and formula are important sources of energy and nutrients for infant; milks also are so for toddlers.
- In addition to milk, wisely chosen juices and fruit drinks with substantial portions of real juice can provide many nutrients and varied flavors to the diets of older infants and toddlers.
- Water is a good choice to quench toddlers' thirst.
- Milk was displaced in toddlers' diets by 100% juice, fruit drinks, and carbonated beverages. However, parents and caregivers should limit excessive intakes of any beverage. The definition of "excessive" will vary among beverage categories.

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# Exhibit B

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Saturated Fat 0g

Trans Fat 0g

Cholesterol 0mg

Sodium 10mg

Potassium 50mg

Total Carbohydrate 16g

Dietary Fiber 0g

Sugars 15g

Protein 0g

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Vitamin A 0% • Vitamin C 100%

Calcium 10% • Iron 0% • Niacin 10%

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# Exhibit C

## Understanding the Origin of Flavor Preferences

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**Key words:** development, flavor, infants, programming, smell, taste

### Introduction

Food traditions mirror a people's beliefs and values and are among the last characteristic of a culture that is lost during the immigration of an individual or group into a new culture (Rozin, 1996). However, the origins of preferences and aversions for flavors and food in humans have elicited much speculation but, until recently, remarkably little experimental investigation (Ganchrow and Mennella, 2003). We now know that initial experiences with flavors occur prior to birth when the flavor of amniotic fluid changes as a function of the mothers' dietary choices (Mennella *et al.*, 1995). Some of these same flavors continue to be experienced in mother's milk (Mennella and Beauchamp, 1991). Because early flavor experiences have been shown to enhance acceptance and enjoyment of foods during weaning and childhood (Mennella *et al.*, 2001), culturally determined flavor preferences, one of the most enduring characteristic of an ethnic group, can be understood in the context of early flavor exposure.

The major factor that has inhibited even greater progress in understanding the origin of flavor preference is the absence of a robust paradigm to investigate the role of infant experience. Practically, it is difficult experimentally to vary the flavor experiences of infants and children over long time periods and so few studies investigating consequences of major differences in feeding experience have been conducted (Mennella *et al.*, 2001). What is needed is a naturally occurring flavor variation that can be exploited to investigate the effects on subsequent acceptance.

During the past decade, we have identified a convenient and powerful model system to study the origin of flavor preferences—infants' acceptance of formulas containing protein hydrolysates, the feeding regimen of choice for formula-fed infants who cannot tolerate cows' milk and other intact proteins (American Academy of Pediatrics, Committee on Nutrition, 1989). It is perhaps one of the most striking examples of a developmental change in chemical sensory perception. Although this type of formulas is extremely unpalatable to older children and adults because of its offensive flavor, infants 4 months of age or younger accept it without difficulty (Mennella and Beauchamp, 1991, 1996). However, if infants receive exposure by the third month of life, they continue to accept these formulas for a considerable period of time thereafter (Mennella *et al.*, 2003). From these data, we hypothesized that there is an early sensitive period during which the hedonic value of this formula—and likely the flavors of other foods and beverages—is established.

The overall goal of the present study was to explore the specificity of the flavor experience during this sensitive period. Although all brands of protein hydrolysate formula share common flavor attributes and are judged unpleasant by adults, they differ in their flavor profiles. Here we exploit the inherent flavor variation of different brands of formulas to determine whether experience with one brand of protein hydrolysate formula influences acceptance of another brand that differs in flavor. In other words, is the acceptance pattern that develops specific to the flavor profile experienced? Or does the infant, regardless of the brand of formula currently being fed, prefer the one that tastes sweeter or the one that tastes less bitter?

To this aim, we studied infants' acceptance of two commercial brands of hydrolysate formulas widely used in the Philadelphia area of the United States: Alimentum™ and Nutramigen™.

### Materials and methods

#### Subjects

Three groups of healthy infants, whose ages ranged from 5 to 11 months, were formed on the basis of the type of formula they were being fed. Group 1 infants ( $n = 20$ ) were being fed Nutramigen, Group 2 ( $n = 16$ ) were being fed Alimentum, whereas Group 3 ( $n = 13$ ) were being fed a milk-based formula and had never experienced hydrolysate formulas. As expected, those who were fed hydrolysate formulas (Groups 1 and 2) were often fed a milk- or soy-based formula during the first months ( $1.9 \pm 0.2$ ) of life and then, usually following their pediatrician's recommendation, switched to hydrolysate. However, none of the Group 1 infants were ever fed Alimentum and none of the Group 2 infants were fed Nutramigen. All testing procedures were approved by the Office of Regulatory Affairs at the University of Pennsylvania and informed consent was obtained from mothers prior to testing.

#### Test stimuli

Prior to the start of the study, we had a trained sensory panel of seven adults (three women, four men) evaluate the sweetness, sourness, bitterness, saltiness and unpleasantness of Nutramigen and Alimentum. Evaluation was done with nostrils pinched closed with a nose clip. This revealed that these two brands differed in their characteristic flavor profile such that Alimentum was judged to taste significantly sweeter [paired  $t(6) = 4.55$ ,  $P = 0.001$ ] and less sour [paired  $t(6) = 3.29$ ,  $P = 0.01$ ] and tended to be judged less bitter [paired  $t(6) = 1.93$ ,  $P = 0.05$ ] than Nutramigen, while both formulas retained the distinct, unpleasant casein-like flavor, possibly due to the volatiles since this was evident when the nostrils were not pinched closed.

#### Testing procedures

The infants' responses were monitored during an entire feed under naturalistic conditions in which infants determined the pacing and duration of feeding. Mothers, who were blind to the hypotheses and brand of formula in the bottle, fed their infants Nutramigen on one test day and Alimentum on the other; the order was counter-balanced within groups. The amount of formula consumed by the infant was recorded and the entire feeding was videotaped (for all but three infants) to determine the length of each feed.

#### Statistical analyses

To determine whether there were significant differences among the three groups, a repeated measures analysis of variance (ANOVA) was conducted with formula group as the grouping factor and type

of formula fed during the feed as the within-subjects factor. All summary statistics are expressed as mean  $\pm$  SEM.

## Results

### Subject characteristics

There was no significant difference among the groups in the ages of the mother. Nor were there differences in the ages, weights and lengths of the infants.

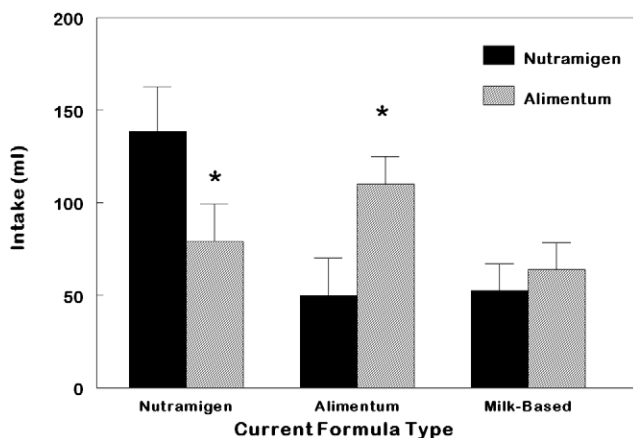
### Infants' feeding behaviors

There was a significant interaction between the feeding history of the infants and their acceptance of the two hydrolysate formulas [ $F(2,46) = 8.96, P < 0.0005$ ]. Infants who were currently being fed the milk-based formulas rejected both brands of the hydrolysate formulas equally [intake, paired  $t(12) = 0.61, P = 0.55$ ; length of feed, paired  $t(12) = 0.54, P = 0.60$ ]. These infants drank significantly less Nutramigen than Nutramigen-exposed infants ( $P < 0.01$ ) and less Alimentum than Alimentum-exposed infants ( $P = 0.04$ ).

As shown in Figure 1, the protein-hydrolysate-fed infants preferred the brand of hydrolysate that they were currently being fed. That is, infants who were currently being fed Alimentum preferred Alimentum to Nutramigen [intake, paired  $t(15) = 2.70, P = 0.016$ ; duration of feed, paired  $t(12) = 43.40, P = 0.005$ ]. In contrast, infants who were currently being fed Nutramigen ingested significantly more of [paired  $t(19) = -2.87; P = 0.009$ ] and spent a longer time feeding [paired  $t(19) = -2.37; P = 0.029$ ] the Nutramigen when compared to the Alimentum.

## Discussion

The present study was designed to ask whether early feeding with two separate varieties of hydrolysate formulas would differentially modify flavor acceptance. The research provided clear evidence in the affirmative: infants fed on one or another brand of hydrolysate formula significantly preferred that familiar formula to the alternative unfamiliar formula. In other words, the acceptance pattern that develops is specific to the flavor profile experienced. The control infants, fed only on milk-based formula, were equally reluctant to accept either hydrolysate formula, a result consistent with previous



**Figure 1** The amount (ml) of Nutramigen (black bars) and Alimentum (hatched bars) consumed during a single feed by infants whose regular formula was Nutramigen, Alimentum or a milk-based formula. \* $P < 0.05$  when compared to Nutramigen.

research (Mennella and Beauchamp, 1996, 1998; Mennella *et al.*, 2003).

The effects of these experiences appear to be long-lived. Children aged 4–5 years who were fed hydrolysates during their infancy exhibited more positive responses to sensory attributes associated with them (e.g. sour taste, aroma) several years after their last exposure to the formula when compared with same-aged children without such experience (Liem and Mennella, 2002; Mennella and Beauchamp, 2002). Consistent with these findings is a recent study on children and adults with phenylketonuria (PKU). The dietary regimen to treat PKU consists of a hydrolysate formula that is specifically treated with charcoal to remove most of the phenylalanine. When given a choice, PKU children and adolescents preferred their bad-tasting formula to that of the new formulation that was more palatable to naive children and adults (Owada *et al.*, 2000). In other words, the characteristic flavor of the formula experienced in early life is 'imprinted' and remains as a preference for a considerable time.

These findings demonstrate that exposure to the specific flavors (tastes, retronasal olfactory stimuli) that differentiate the two commercial infant formulas influences relative acceptance of the formula. Still to be determined are the effects of varying the timing of the experience, the sensory components that are critical to modifying acceptance and the long-term effects of such exposure.

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