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November 17, 2005

The Honorable Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

I am writing to express concern that the misleading marketing and labeling of popular rice-based beverages pose a serious risk to children's health. The products have been promoted as alternatives to cow's milk. Yet because rice is very low in protein, young children who consume these beverages in place of milk can develop a life-threatening syndrome of protein malnutrition known as kwashiorkor.

In recent years, at least a dozen infants and toddlers with kwashiorkor have been reported in Philadelphia, San Francisco, Atlanta, and other areas. In each case, children who should have been receiving infant formula or cow's milk were instead fed large quantities of a rice-based beverage. Medical complications have included delayed and stunted growth, behavioral changes, and impaired immunity associated with multiple infections. Two of the children died.

Under the Federal Food, Drug, and Cosmetic Act, it is unlawful for manufacturers to use misleading labels on food products. Yet the manufacturers of rice-based beverages have described their products as "a tasty alternative to dairy or soymilk" and "a creamy alternative to milk" without alerting consumers about the significant difference in protein content between rice-based beverages and cow's milk. This can seriously mislead consumers.

I have contacted four major manufacturers of rice-based beverages. Two of these manufacturers subsequently changed their products' labels or websites to reduce the possibility that misunderstanding could lead to harm. But the other two manufacturers have not yet made any changes to their promotions.

I urge FDA to warn consumers about the dangers associated with excessive consumption of rice-based beverages by infants and young children. FDA should also consider enforcement

action against makers of products that continue to sell rice-based beverages with misleading labeling.

Background

The National Academies of Science has recommended that infants and young children consume approximately 1-2 grams of protein per kilogram of body weight per day for healthy growth and development.[1] Proteins help build and repair muscles and bones and form skin and hair. They act as chemical messengers, providing essential signals to make the brain develop and function properly. They form critical blood products, create antibodies to fight infections, regulate water balance in the body, and provide energy if carbohydrates and fats from the diet are in low supply.[2] Young children require substantially more protein per unit of body weight in their diet than adults.

Infants consume virtually all of their protein from liquids, with the consumption of solids gradually increasing over the first several years of life.[3] Breast milk, infant formula, and cow's milk contain approximately 1 gram of protein per 1-2 ounces. As a result, a one-year-old child weighing ten kilograms (about 22 pounds) can obtain adequate protein each day in approximately 11 ounces (1.5 cups) of cow's milk.

In contrast, rice-based beverages contain approximately one gram of protein per *eight* ounces.[4] As a result, a one-year-old child might have to drink eleven cups, or more, every day for adequate protein.

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[1] National Academies of Science, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acid (Macronutrients)* (2002) (online at http://www.nap.edu/books/0309085373/html/) (accessed on June 13, 2005).

[2] *Id.*

[3] JD Skinner, P Ziegler, M Ponza, *Transitions in Infants' and Toddlers' Beverage Pattern*, Journal of the American Diet Association, 45-50 (Jan. 2004).

[4] Imagine Foods, *Rice Dream Original Enriched: Ingredients and Nutritional Information* (online at http://www.imaginefoods.com/pages/products/ricedream/rdoe.php) (accessed on Aug. 26, 2005); Pacific Natural Foods, *Nut and Grain Beverages, Low Fat Rice Plain-Nutrition Information* (online at http://www.pacificfoods.com/products-nut-grain.php) (accessed on Aug. 26, 2005); Whole Foods, *Organic Soy and Ricemilk-Ricemilk Original Nutrition Facts* (online at http://www.wholefoodsmarket.com/products/365organic/ricemilk.html)(accessed on Aug. 26, 2005).

When the diet of infants and young children fails to contain sufficient amounts of protein, the first clinical sign is often irritability. The next step is the development of skin rashes, characterized by redness and peeling. As muscle and blood proteins are lost, the body takes on water, leading to gross abdominal distension. Hair becomes thin, growth is stunted, and development is delayed.[5] Untreated severe protein malnutrition — even when children are eating adequate amounts of carbohydrates and fats — eventually causes immunodeficiency, heart failure and death. This medical syndrome is known as kwashiorkor.

Injuries from Rice-Based Beverages

In recent years, doctors have reported at least twelve cases of kwashiorkor associated with excessive consumption of rice-based beverages by infants and young children. These cases have included:

- A seventeen-month-old girl from Rochester who presented to the Mayo Clinic with a three month history of itchy skin eruptions, hair "falling out in clumps," lack of weight gain, body swelling, imbalance, and the bone density of a seven-month old.[6] This child's daily diet consisted of a rice-based beverage and one to two tablespoons of baby food or solid foods.

- A fourteen-month-old girl from Philadelphia who was admitted to the hospital with a two-week history of a generalized rash, an increasingly swollen body, lighter hair and pale skin after transitioning from breast milk to a rice-based beverage.[7]

- A seven-month-old boy who presented to a Philadelphia hospital with several weeks of irritability, decreased feeding, a severe rash, and a week of generalized body swelling.[8] This child had been fed only a rice-based beverage, small amounts of baby food, and an iron supplement.[9]

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[5] Irene J. Buno, *The Enamel Paint Sign in the Dermatologic Diagnosis of Early-Onset Kwashiorkor*, Archives of Dermatology, 107-108 (Jan. 1998); Michael Krawinkel, *Kwashiorkor is Still Not Fully Understood*, Bulletin of the World Health Organization, 81 (2003).

[6] J. Kuhl et. al., *Skin Signs as the Presenting Manifestation of Severe Nutritional Deficiency: Report of 2 Cases*, Archives of Dermatology, 521-524 (May 2004).

[7] KA Katz et al., *Rice Nightmare: Kwashiorkor in 2 Philadelphia-Are Infants Fed Rice Dream Beverage*, Journal of the American Academy of Dermatology, S69-S72 (May 2005).

[8] *Id.*

[9] *Id.*

- A ten-month-old girl from Ontario was assessed for a severe rash and generalized swelling after her mother switched from cow's milk to a rice-based beverage in an attempt to resolve constipation.[10]

- A four-month-old boy from an unidentified U.S. city who presented to the hospital with a diffuse, red, crusty and erosive rash, swelling and irritability. His parents had switched to a rice-based beverage "as a treatment for colic at the suggestion of a popular women's magazine."[11]

- A five-month-old girl from San Francisco who fell ill with irritability, a three-day history of generalized swelling, vomiting, and a three-week history of a worsening diffuse rash. She was being fed a rice-based beverage for chronic constipation.[12]

- A twenty-two-month old boy from Atlanta who was admitted to the hospital for irritability, generalized body swelling, skin lesions throughout his body, abdominal distention, and thin sparse hair. He had been weaned from breast milk and started on a rice-based beverage.[13]

- A five-and-a-half month old girl from Australia who died of kwashiorkor associated with excessive consumption of a rice-based beverage.[14] Her parents were charged but not convicted of manslaughter.

- An eight-month-old girl from an unidentified U.S. city who died of heart failure associated with kwashiorkor in the pediatric intensive care unit.[15] She was found to have an enlarged fatty liver, pneumocystis infection of her lungs, herpes esophagitis, and a bacterial and fungal infection of the skin and esophagus.[16]

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[10] Badr Al Saleem, Robert Issenman, *Kwashiorkor in a Canadian Child Fed Commercial Rice Milk*, Canadian Digestive Diseases Week Abstract) (2003) (online at http://www.pulsus.com/cddw2003/abs/abs242.htm) (accessed on July 18, 2005).

[11] Theodore Liu et al., *Kwashiorkor in the United States: Fad Diets, Perceived and True Milk Allergy, and Nutritional Ignorance*, Archives of Dermatology, 630-636 (May 2001).

[12] *Id.*

[13] Norman Carvallo et al., *Severe Nutritional Deficiencies in Toddlers Resulting from Health Food Milk Alternatives*, Pediatrics, E46 (Apr. 2001).

[14] *Rice Drink Tied to Rare Disease in 2 Infants*, Philadelphia Inquirer (June 28, 2005).

[15] Theodore Liu et al., *supra* note 11.

[16] *Id.*

Other affected children have been reported in Georgia[17] and Europe.[18] It is highly likely that other cases have occurred but not been reported in the medical literature.

The Marketing of Rice-Based Beverages

An important question is why parents substitute rice-based beverages for breast milk, infant formula, or cow's milk. One important reason may be that the labeling and advertising of these products encourages them to do so.

The labeling of rice-based beverages typically includes a picture of a white liquid, appearing to be milk, being poured out of a container. The products are generally sold in the supermarkets adjacent to other dairy and soy milk products, often next to the cereals section.

In addition to such generic signals, specific claims by the manufacturers present the products as nutritionally equivalent alternatives to cow's milk or soy milk. Examples of such claims are described below.

1. Rice Beverage Products Made by Hain Celestial

The recent packaging of Rice Dream, made by Hain Celestial, described the product as having "Complete Nutrition — Rice Dream is enriched with the same amount of Calcium, Vitamins A, D & B_{12} found in milk."[19] The package further stated:

> There are many reasons people reduce their milk consumption — approximately 50 million Americans are sensitive to milk. But that's not the only reason to enjoy the clean, lightly sweet taste of Rice Dream. Gentle on the system and easily digested, it's enriched with the same amount of Calcium, Vitamins A, D, & B_{12} as milk and has no artificial flavors, colors, hormones or preservatives.[20]

WestSoy Rice Beverage, another Hain Celestial product, contained the following statement on its packaging:

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[17] Centers for Disease Control and Prevention, *Severe Malnutrition Among Young Children — Georgia, January 1997-June 1999*, Morbidity and Mortality Weekly Report, 224-7 (Mar. 30, 2001).

[18] G. Massa et al., *Protein Malnutrition due to Replacement of Milk by Rice Drink*, European Journal of Pediatrics, 382-4 (June 2001).

[19] Hain Celestial, Rice Dream Rice Drink, 1.89 liter

[20] *Id.*

> Exploring alternatives to milk? Don't skip our delicious WestSoy Rice Beverage or you'll miss out on a refreshing, nutritious drink you're sure to love! It tastes so good, and it's enriched with calcium and vitamins A and D, making it a perfect choice for people who don't drink dairy milk.[21]

Until recently, Hain Celestial's website included a description of a segment on lactose intolerance that NBC's Matt Lauer hosted on the television show "Later Today."[22] The company described Rice Dream as an "excellent alternative" for people with lactose intolerance because Rice Dream had a nutritional profile that was "similar to milk."[23] Additionally, the website included a comment from parents who had given Rice Dream to their 15-month old son, who was "allergic to all milk and all soy products."[24]

2. "Drink Rice" Made by Lundberg Farms

Lundberg Farms manufactures "Drink Rice." The packaging describes both the plain and vanilla "Drink Rice" beverages as being "made from 100 percent organic whole grain rice," and "a healthy, non-allergenic alternative to dairy, soy or nut beverages. A tasty drink everyone can enjoy."[25]

Until June 2005, the product's website included the statement that "Lundberg Family Farms' Organic Drink Rice is a creamy alternative to milk." [26] The website also included the same description of the product as a "healthy, non-allergenic alternative to dairy, soy or nut beverages" found on the package labeling.[27]

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[21] Hain Celestial, WestSoy Rice Beverage, 32 fl. oz.

[22] Imagine Foods, The Hain Celestial Group, Inc., Media Center, *Imagine Foods Products Make News! Winning Brands catch the eye of NBC's Later Today & Prominent Print Media* (online at http://www.imaginefoods.com/pages/mediacenter/mediacenter.php) (accessed May 31, 2005).

[23] *Id.*

[24] Imagine Foods, The Hain Celestial Group, Inc., "Your Voice."(online at http://www.imaginefoods.com/pages/yourvoice/yourvoice.php)(accessed on May 31, 2005).

[25] Lundberg Family Farms, Drink Rice Beverage, 32 fl. oz.

[26] Lundberg Family Farms, Drink Rice (online at http://www.lundberg.com/products/drink.shtml) (accessed on June 28, 2005).

[27] Lundberg Family Farms, Drink Rice (online at http://www.lundberg.com/products/drink_original.shtml) (accessed on June 28, 2005).

3. "Rice" Beverages Made by Pacific Foods

Pacific Foods makes "Rice" beverages in plain and vanilla flavors. The packaging of the product states that Rice has "the same amount of calcium and vitamin D as milk."[28] According to the website: "It's the freshest ingredients that give both non-dairy alternative drinks that light, creamy and refreshing taste." [29]

4. "Ricemilk" Made by Whole Foods Market

Whole Foods Market manufactures a rice beverage called "Ricemilk." The product's packaging states:

> Ricemilk makes a tasty alternative to dairy or soymilk. Our 365 Organic Ricemilk is made from organic rice, grown from non-genetically engineered seed stock. We fortify our recipe with calcium and vitamins, for a healthful drink that is lactose-free. [30]

The packaging for "Vanilla Ricemilk," another Whole Foods product, similarly calls it "an alternative to dairy or soymilk." [31]

Other Information on the Packages

While the labels of rice-based beverages contain some additional information relevant to protein content and appropriate use, none of the additional information is adequate to warn parents not to use these products as milk alternatives in young children. All of the brands of rice-based beverages list the amount of protein per serving in the "Nutrition Facts" box on the package. However, the labels do not provide the percentage of recommended daily intake of protein represented by a serving size, distinguish between the protein content of the beverage versus cow's milk, or explain the importance of adequate protein intake.

The packages all also contain a statement that the drinks are not intended to be used as a replacement for "infant formula." However, these statements generally have appeared in

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[28] Pacific Natural Foods Low Fat Vanilla Rice Beverage, 32 fl. oz.

[29] Pacific Natural Foods, Nut & Grain Beverages (online at: http://www.pacificfoods.com/products-nut-grain.php) (accessed on Aug. 10, 2005)

[30] Whole Foods Market, "Organic Ricemilk-Original" 32 fl.oz. (online at http://www.wholefoodsmarket.com/products/365organic/ricemilk.html) (accessed on June 17, 2005).

[31] Whole Foods Market, "Organic Ricemilk-Vanilla" 32 fl. oz. (online at http://www.wholefoodsmarket.com/products/365organic/ricemilk_van.html) (accessed on June 17, 2005).

relatively small print in obscure places on the packages and say nothing about the dangers of use in toddlers and young children. For example:

- Hain Celestial's "Rice Dream's" recent packaging contained the statement "Not for Use as an Infant Formula" in small, black print and on a panel separate from the Nutrition Facts panel.[32]

- The packaging on Whole Foods' "Ricemilk" and Pacific Foods' Rice contains the statement "Not a Replacement for Infant Formula" in small print below the Nutrition Facts panel.[33]

- Lundberg Farms' "Drink Rice" states "Not for Use As Infant Formula" on the same package panel containing the Nutrition Facts. However, this language is separated from the Nutrition Facts and located at the bottom of the packaging, below the statement "Product of USA".[34]

Even if it were prominent, the statement "not for use in infant formula" does not address the full potential for misuse of rice-based beverages. Parents typically transition infants at age one year from formula or breastmilk to cow's milk. The statement "not for use in infant formula" could suggest that it is acceptable to transition a baby from infant formula to a rice-based beverage. Yet one-year-old children still require substantial amounts of protein in their liquid diets. Transitioning from infant formula or cow's milk to a rice-based beverage could lead to kwashiorkor even in children as old as two or three years, depending on the child's diet.

Response of Manufacturers

Over the past four months, I have made the results of our investigation known to the four major manufacturers of rice-based beverages. Two of these companies have responded by making changes to the package labeling of their rice-based beverages or to their websites. Two have failed to make any changes.

1. Hain Celestial

Hain Celestial promptly responded to the concerns I raised about its labeling.

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[32] Hain Celestial, Rice Dream Beverage, 32 fl. oz.

[33] Whole Foods Market, Organic Ricemilk Beverage, 32 fl.oz; Pacific Natural Foods Low Fat Vanilla Rice Beverage, 32 fl. oz

[34] Lundberg Family Farms, Drink Rice Beverage, 32 fl.oz.

The company immediately changed its products' website to include the statement "For Children Under Age 5, Consult Your Child's Doctor." This statement appears in red, bold print and accompanies the words, "Not For Use as an Infant Formula."[35]

Hain Celestial also added a "frequently asked question" on its website stating:

> ***Which Rice Dream products can be used as an infant formula?***
> No Rice Dream products are for use as an infant formula. Rice Dream products are low in protein.[36]

In addition, Hain Celestial immediately removed from its site consumer comments praising Rice Dream as an alternative to dairy and soymilk[37] and the claim that Rice Dream is nutritionally similar to milk.[38]

Hain Celestial also ordered new packaging that states in red bold print, "Not for use as infant formula. For Children Under Age 5, Consult Your Child's Doctor." The company expects this packaging to be available nationwide later this fall.[39]

2. Lundberg Farms

Lundberg Farms also promptly responded to the concerns raised about its labeling. The company changed its website to state:

> Lundberg's Drink Rice™ is not for use as infant formula and should not be used as the primary source of protein in any individual's diet.[40]

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[35] Imagine Foods, The Hain Celestial Group, Inc., Rice Dream (online at http://www.imaginefoods.com/pages/products/ricedream.php) (accessed on Oct. 5, 2005).

[36] *Id.*

[37] Imagine Foods, The Hain Celestial Group, Inc., "Your Voice" (online at http://www.imaginefoods.com/pages/yourvoice/yourvoice.php) (accessed on Aug. 30, 2005)

[38] Imagine Foods, The Hain Celestial Group, Inc., Media Center, *Imagine Foods Products Make News! Winning Brands catch the eye of NBC's Later Today & Prominent Print Media* (online at http://www.imaginefoods.com/pages/mediacenter/mediacenter.php) (accessed on Aug. 30, 2005)

[39] Phone communication with Hain Celestial and staff of Congressman Henry A. Waxman (Oct. 2005).

[40] Lundberg Family Farms, Drink Rice (online at: http://www.lundberg.com/products/drink.shtml) (accessed on Sept. 30, 2005).

The website also now states:

> Because [Drink Rice] does not contain a significant amount of protein, it should not be used as the primary source of protein in an individual's diet. Especially in growing children, care should be taken to ensure that all nutritional needs are met and they are consuming a balanced diet.[41]

A company representative also stated that Lundberg Farms is committed to changing the packaging to emphasize these points.[42] The company intends to remove the statement on the current labeling describing Drink Rice as "a healthy, non-allergenic alternative to dairy, soy or nut beverages."[43] The labeling will include the statement above warning that Drink Rice "should not be used as the primary source of protein in any individual's diet."[44]

3. Pacific Foods

Pacific Foods, the manufacturer of "Rice," has not made any changes to its packaging or website. A company representative stated that while the company recognized that the problem of rice beverage-associated kwashiorkor was a serious one, it was caused by a misuse of the product. The company representative stated that Pacific Foods will continue to assess the problem to determine if any changes are appropriate.[45]

4. Whole Foods Market

Whole Foods Market, the manufacturer of "Ricemilk," has not yet made changes to its packaging or website in response to my inquiries.

In a phone conversation, a company representative took the position that the current labeling was sufficient to address the nutritional concern.[46] While the representative stated that

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[41] *Id.*

[42] Phone communication with Lundberg Farms and staff of Congressman Henry A. Waxman (Oct. 6, 2005).

[43] *Id.*

[44] *Id.*

[45] Phone communication with Pacific Foods and staff of Congressman Henry A. Waxman (Aug.10, 2005)

[46] Phone communication with Whole Foods and staff of Congressman Henry A. Waxman (June 22, 2005)

Whole Foods Market would continue to look into the issue, he stated the company believed that the cases reported were not "statistically significant."[47]

Conclusion

Each case of kwashiorkor associated with rice-based beverages is a preventable tragedy. Parents need to understand basic nutritional facts about the foods they provide their children. Manufacturers have an obligation under the law not to mislead consumers that rice-based beverages are adequate alternatives for dairy products for young children.

FDA's responsibility is to set clear standards that protect consumers from misleading food labels and provide a level playing field for companies. Otherwise, as is apparently the case with rice-based beverages, some companies may make legitimate attempts to address concerns, while others irresponsibly ignore the problem or blame consumers.

I urge FDA to warn consumers about the dangers associated with excessive consumption of rice-based beverages by young children. FDA also should review the responses of the manufacturers and consider enforcement action against companies with misleading labeling.

I request a response to this letter by December 16, 2005.

Sincerely,

Henry A. Waxman

[47] *Id.*