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January 23, 2019

The Honorable Scott Gottlieb, MD
C/O Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2018-N-3522 Use of the Names of Dairy Foods in the Labeling of Plant-Based Products

Dear Commissioner Gottlieb:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, I write to respond to FDA's Request for Comment on the Use of the Names of Dairy Foods in the Labeling of Plant-Based Products.

The AAP is pleased by the efforts FDA has undertaken in recent years to modernize regulations for nutrition-related labeling to reflect current science, provide information in ways that are understandable and useful to consumers, and encourage industry efforts to develop and introduce healthier food products through innovation or reformulation.

Dairy products play an important role in the diet of children. Milk, yogurt, cheese, and other milk products supply calcium for building and maintaining strong bones and teeth and protecting bones from osteoporosis.^{i,ii} They also provide children with the protein, vitamins, and minerals that they need to thrive including phosphorous, vitamin A, vitamin D, riboflavin, vitamin B12, potassium, zinc, choline, magnesium, and selenium.ⁱⁱⁱ In fact, milk is the leading food source of three of the four nutrients of public health concern (calcium, vitamin D, and potassium) in the diet of American children 2-18 years.^{iv}

AAP recommends that children consume two to three servings per day of milk and milk products.^v For adolescents, three or more servings per day of milk and milk products are recommended.^{vi} These recommendations are consistent with those of the Dietary Guidelines for Americans (DGA).^{vii} The DGA also notes that while average dairy intake for most young children ages 1-3 meets recommended amounts, all other age groups have average intakes that are below recommendations.^{viii}

Dairy-free alternatives to milk are becoming increasingly popular, even among

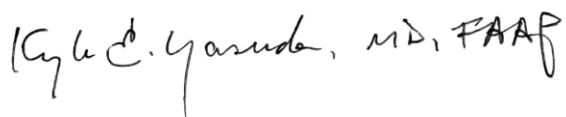
children who do not have a medical condition that prevents the consumption of dairy.^{ix} While some of these products are fortified with calcium and protein, many of these products lack the essential nutrients that dairy products contain to promote the healthy development of children, notably protein, calcium, and vitamin D.^x These essential nutrients can be difficult to replace in a healthy dietary pattern, and if plant-based alternative beverages are substituted in place of milk without the addition of other foods to supply the missing nutrients, Americans may move further away from dietary recommendations.^{xi}

Pediatricians report that using the term “milk” in the labeling of dairy-free alternatives has caused parental confusion, leading to the purchase of products that they assume contain traditional dairy ingredients and, thereby, unintentionally causing harmful nutritional deficiencies in their children. Consumer studies reinforce these anecdotal reports, indicating that consumers do not understand the nutritional differences between milk and plant-based alternative beverages labeled “milk”.^{xii} Further, many of these plant-based alternative products are perceived as having the same or more vitamins, protein, or other key nutrients as compared to milk.^{xiii}

Given the importance of dairy products in the diet of children and the confusion that parents exhibit with regards to the nutrients contained in plant-based alternative products, the AAP recommends that FDA reserve the label of “milk” solely for traditional dairy products to ensure that children receive the optimal nutrition they need to thrive.

Thank you for the opportunity to respond to this request for comments. The AAP looks forward to working with FDA to ensure that the nutritional needs of all children and families are met. If we may be of further assistance, please contact Tamar Magarik Haro in our Washington, DC office at 202-347-8600 or tharo@aap.org.

Sincerely,

A handwritten signature in black ink that reads "Kyle E. Yasuda, MD, FAAP". The signature is written in a cursive, flowing style.

Kyle E. Yasuda, MD, FAAP

KEY/mrc

ⁱ Holt, K, et al, *Bright Futures Nutrition*, 3rd Edition. 2011.

ⁱⁱ Golden, N.H. and S.A. Abrams, *Optimizing bone health in children and adolescents*. Pediatrics, 2014. **134**(4): p. e1229-43.

ⁱⁱⁱ U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015-2020 Dietary Guidelines for Americans*. 2015; Available from: <http://health.gov/dietaryguidelines/2015/guidelines/>.

^{iv} O'Neil, C.E., T.A. Nicklas, and V.L. Fulgoni, 3rd, *Food Sources of Energy and Nutrients of Public Health Concern and Nutrients to Limit with a Focus on Milk and other Dairy Foods in Children 2 to 18 Years of Age: National Health and Nutrition Examination Survey, 2011-2014*. Nutrients, 2018. 10(8).

^v American Academy of Pediatrics Committee on Nutrition, *Pediatric Nutrition*. 2014, Elk Grove Village, IL: American Academy of Pediatrics.

^{vi} American Academy of Pediatrics Committee on Nutrition, *Pediatric Nutrition*. 2014, Elk Grove Village, IL: American Academy of Pediatrics.

^{vii} U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015-2020 Dietary Guidelines for Americans*. 2015; Available from: <http://health.gov/dietaryguidelines/2015/guidelines/>.

^{viii} U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015-2020 Dietary Guidelines for Americans*. 2015; Available from: <http://health.gov/dietaryguidelines/2015/guidelines/>.

^{ix} Bridges, M, *Moo-ove Over, Cow's Milk: The Rise of Plant-Based Dairy Alternatives*. Nutritional Issues in Gastroenterology, 2018.

^x U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015-2020 Dietary Guidelines for Americans*. 2015; Available from: <http://health.gov/dietaryguidelines/2015/guidelines/>.

^{xi} Fulgoni, V.L., 3rd, et al., *Nutrients from dairy foods are difficult to replace in diets of Americans: food pattern modeling and an analyses of the National Health and Nutrition Examination Survey 2003-2006*. Nutr Res, 2011. 31(10): p. 759-65.

^{xii} Midwest Dairy Association, *Clean and Clear Labeling Survey (March-April 2016)*; *National Osteoporosis Foundation (NOF) member-survey (July 2017)*.

^{xiii} National Dairy Council, *Consumer Perceptions: Dairy Milk and Plant-based Milk Alternatives* (October 2019).