

May 11, 2023

Robert M. Califf, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Califf,

We write to you today regarding the Food and Drug Administration's (FDA) Draft Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements. We are disappointed because under this guidance we expect the agency will continue to neglect to enforce standards of identity for plant-based products that mimic or imitate dairy products such as milk, cheese, yogurt and butter. The inaction by FDA harms public health as a result of consumer misperception over dairy products' inherent nutritional value. As a result, it is imperative that FDA enforce its existing standards of identity for dairy in both current and future guidance.

The draft guidance released on February 23, 2023 provides only voluntary options for the plant-based industry to disclose their products' nutritional inferiority relative to their dairy counterparts. Additionally, the draft guidance does not enforce standards of identity for dairy, allowing some imitation products to continue to use dairy terms. In doing so, FDA is failing to address the root cause of consumer confusion over nutritional content. Studies have demonstrated that consumers incorrectly believe non-dairy, plant-based substitutes are nutritionally equivalent or even nutritionally superior to their dairy counterparts. For example, according to a 2018 survey by IPSOS, more than 70% of consumers believed that plant-based, non-dairy substitutes contain equivalent or greater amounts of protein than dairy milk. However, an actual comparison of nutritional profiles shows that most types of non-dairy substitutes are nutritionally inferior to their nutrient-dense dairy counterparts. This confusion over nutrition is especially stark among those who are purchasing imitation dairy products, as the same IPSOS survey shows that 62% of plant-based beverage buyers cite nutrition as important to their purchase decision.

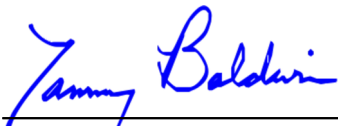
Given the central role dairy plays in providing essential nutrients, the consumer misperception of nutritional equivalency between imitation products and dairy products can lead to serious health consequences. Doctors and health scientists have reported on these risks, including increasing rates of malnutrition and nutrition-related diseases associated with consuming nutritionally inferior imitation products as a replacement for dairy beverages. The most recent Dietary Guidelines for Americans explicitly addresses nutritional inferiority by grouping dairy products and plant-based products separately, and providing the following explanation: "[o]ther products sold as 'milks' but made from plants (*e.g.*, almond, rice, coconut, and hemp 'milks') may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy

beverages.” It is precisely these type of nutritional content concerns that FDA regulations are supposed to prevent.

FDA’s lack of enforcement, and now its recent draft guidance, both fail to provide Americans with the transparent and truthful labeling necessary for preventing such misperceptions that have been demonstrated to lead to harmful nutrition-related health consequences. Due to the proliferation of the plant-based alternative market, and the potential for consumer confusion over the nutritional content of these products compared to the original dairy products, we request that any final guidance clearly define the nutritional differences between plant-based imitation products and dairy products, and require accurate labeling requirements for plant-based producers to use in the marketplace that are compliant with the agency’s own standards of identity for dairy.

Thank you for your consideration of our request.

Sincerely,



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Tammy Baldwin  
United States Senator



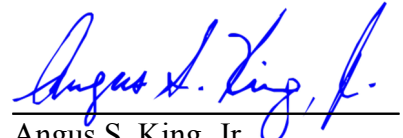
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James E. Risch  
United States Senator



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Mike Crapo  
United States Senator



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Angus S. King, Jr.  
United States Senator



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Roger Marshall M.D.  
U.S. Senator



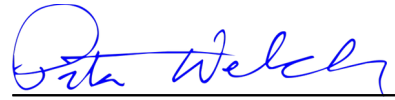
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Susan M. Collins  
United States Senator



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M. Michael Rounds  
United States Senator



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Peter Welch  
United States Senator



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John Fetterman  
United States Senator



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Tina Smith  
United States Senator



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Amy Klobuchar  
United States Senator