



# WISCONSIN LEGISLATURE

P. O. Box 7882 Madison, WI 53707-7882

March 15, 2023

Attn: Robert M. Califf, M.D., MACC  
Commissioner of Food and Drugs  
Food and Drug Administration  
White Oak Campus  
10903 New Hampshire Avenue  
Silver Spring MD, 20993

RE: FDA-2023-D-0451 Draft Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements

Dear Dr. Califf:

On behalf of Wisconsin's Dairy Industry, which includes over 6,500 dairy farms and dairy processors, **we are contacting you to request revisions to the draft guidance for the labeling of plant-based milk alternatives (PBMA). Please revise the guidance to make it indisputable that products made from nuts, seeds, plants and algae are prohibited from using terms such as milk, yogurt or cheese.** Agriculture is the second leading industry in Wisconsin, contributing \$104.8 billion to our economy, and dairy accounts for almost half that total.

**The long awaited U.S. Food & Drug Administration (FDA) action on the labeling of PBMA fails to address the concerns of our constituents in the dairy industry and is a disservice to the consumers who may purchase these products.** The current Code of Federal Regulations—Title 21 FDA clearly defines milk products as originating exclusively or principally from animal sources:

“1240.3(j) Milk products. Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo,…”

Dairy products are often touted nutritionally as a source of calcium, and while dairy products are calcium-powerhouses, the other essential nutrients they provide are important in the overall diet. It is difficult to obtain those nutrients without drinking or eating real dairy. Protein is one of those important nutrients. For instance, almond beverages contain only 1-2 grams of protein compared to 8 grams of protein per each cup of cow's milk. Plus, cow's milk is a source of high-quality or complete protein, meaning it provides all of the essential building blocks to build and repair muscle, provide proper immune function, and support good health.

In the draft guidance, the FDA takes the position that PBMA are non-standardized foods because no definition or standard of identity has been prescribed for them by regulation. Accordingly, the FDA maintains PBMA must be labeled with their common or usual names, or in the absence

thereof, a statement of identity that accurately describes them. While "plant-based" or "plant" may be used to describe PBMA, the FDA, in the draft guidance, does not recommend using only these terms, since "plant-based milk" is not the common or usual name of PBMA.

Per the FDA, since PBMA are not milk, they may not be offered for sale as "milk," although they may use the word "milk" in labeling, as long as it is qualified by the plant source. Notably, however, with such usage of the word "milk," the FDA recommends that PBMA products that have a nutrient composition different than milk bear an additional nutrient statement on the product label. This statement, which is voluntary, should, according to the FDA, describe how the PBMA product compares with milk, based on the U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS) fluid milk substitutes nutrient criteria.

Many of the companies offering PBMA have to deal with these requirements in Europe. The European Union's (EU) top court has ruled that milk and dairy replacements that are being marketed and sold within the EU cannot have the word "milk" or "butter" in their names. This includes products such as soy milk, tofu butter, vegan cheeses, and other soy foods that act as dairy replacements. The court said, "Purely plant-based products cannot, in principle, be marketed with designations such as 'milk', 'cream', 'butter', 'cheese' or 'yoghurt', which are reserved by EU law for animal products."

The FDA should have been enforcing the current Code of Federal Regulations all along. The draft guidance recommendation for a voluntary statement on the nutritional differences is completely inadequate and contrary to federal code. **Please revise the guidance to make it indisputable that products made from nuts, seeds, plants and algae are prohibited from using terms such as milk, yogurt or cheese.** We urge you to heed our concerns and make wholesale revisions to the draft guidance.

Thank you for considering our request and we look forward to revised final guidance.

Sincerely,

Howard Marklein  
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Robert Cowles  
State Senator  
2<sup>nd</sup> Senate District

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