NMPF
NATIONAL MILK PRODUCERS FEDERATION

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
California Dairies, Inc.
Cayuga Marketing
Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Ellsworth Cooperative Creamery
First District Association
Foremost Farms USA
Lanco Pennland
Land O'Lakes, Inc.
Lone Star Milk Producers
Maola Local Dairies
Michigan Milk Producers Association
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Scioto Cooperative Milk Producers' Association
Southeast Milk, Inc.
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.

July 11, 2025

Docket No. AHRQ-2025-0001: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again

Dear Sir or Madam:

The National Milk Producers Federation's (NMPF) 24 cooperatives represent 20,000 dairy producers who collectively produce two-thirds of the U.S. milk supply. NMPF was organized in 1916 to provide a forum for dairy producers and the cooperatives they own to participate in public policy discussions. NMPF advocates policies to Congress, U.S. and foreign government agencies, industry organizations, the news media, and the public.

NMPF offers these comments in response to the request for information entitled "**Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again,**" specifically regarding the proposed guidance entitled "Labeling of Plant-based Milk Alternatives (PBMA) and Voluntary Nutrient Statements" published in the Federal Register on February 23, 2023 and the proposed guidance "Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry" published in the Federal Register on January 7, 2025.

NMPF strongly supports efforts to improve Americans' diets and increase transparency in food labeling. However, we are concerned that the "Labeling of Plant-based Milk Alternatives (PBMA) and Voluntary Nutrient Statements" guidance and the "Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry" will fail to achieve FDA's stated goals. More critically, these documents mislead consumers, distort public understanding of healthful eating, and are both unlawfully promulgated and otherwise unlawful on numerous grounds. For these reasons and the reasons set forth below, NMPF requests both guidances be revoked in their entirety.

Specifically, we believe the guidances are unlawful and meet several of the criteria identified in the RFI that warrant repeal. The guidances are:

- Unconstitutional regulations that raise serious constitutional difficulties, because a federal agency cannot rewrite a Congressional statute and both are doing so in numerous instances,
- Unlawful regulations because they contradict existing regulations that were properly promulgated under the Administrative Procedures Act,
- Unlawful regulations because they did not follow the notice and comment provisions of the Administrative Procedures Act,
- Unlawful regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition, and
- Unlawful regulations that are based on unlawful delegations and/or usurpations of legislative power.

The "Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements" draft guidance provides information on the labeling of plant-based alternatives that include the names of dairy foods, with the goal of "empowering consumers with more informative and accessible labeling to choose healthier diets." However, this guidance does the opposite, by creating more uncertainty on the nutritional differences between these products and real dairy milk, which is a key source of calcium, vitamin D, protein, and many other nutrients. Allowing these products to use the term "milk" is misleading to consumers, even with the recommendation for "voluntary" nutrient statements.

Similarly, the "Labeling of Plant Based Alternatives to Animal Derived Foods" draft guidance claims to emphasize the importance of "clear labeling" for consumers to make educated choices, yet creates more confusion by misinterpreting nutritional information, blurring standards of identity, and undermining the importance of dairy in a healthy diet.

As Secretary Robert F. Kennedy noted:

> *"As Secretary, I believe that an important component of Making America Healthy Again is making sure that providers and caretakers can focus on preventing and treating chronic diseases instead of having to do unnecessary or burdensome paperwork and otherwise comply with Administrative burdensome requirements with no clear health benefit."*

Eliminating the plant-based labeling guidance documents directly aligns with the Secretary's mission of "making sure that providers and caretakers can focus on preventing and treating chronic diseases." There is plenty of

evidence that mislabeling has led to confusion among consumers regarding the nutritional deficiencies of plant-based alternatives.

According to a 2018 survey by IPSOS, a global market research and consulting firm, 62% of plant-based beverage buyers cite nutrition as important to their purchase decision. Additionally, more than 70% of consumers thought plant-based, non-dairy substitutes have the same or more protein than dairy milk. However, an actual comparison of nutritional profiles shows that most types of non-dairy substitutes are almost uniformly nutritionally inferior to their nutrient-dense dairy counterparts.

The inconsistency between consumer perception and reality of the nutritional profiles of dairy and plant-based substitutes has potentially grave consequences, given the important role that dairy plays in contributing to human nutritional needs. Many scientists, doctors, and even some in the non-dairy substitute industry have recognized the risks to individual health and public health that are presented by the proliferation of these misbranded imitation products.

While health experts and industry executives know that non-dairy substitutes are generally nutritionally inferior to their dairy counterparts, consumers are not as well informed, and misleading labels reinforce the false perception that nutritionally inferior imitations are equivalent or even superior to their dairy counterparts. Indeed, there have been numerous reports of health incidents such as malnutrition associated with replacement of dairy beverages with nutritionally inferior imitations. These potentially grave public health consequences are precisely why the FDA regulations require truthful and non-misleading common or usual names and require nutritionally inferior substitutes to be labeled as "imitation" products.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Fair Packaging and Labeling Act, FDA must enforce fair and accurate labeling of products within its jurisdiction. These laws reflect deliberate actions taken by Congress to promote fair trade and consumer understanding. Under the law, "A food shall be deemed to be misbranded… If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard…"

In the case of dairy products, there are well-established Standards of Identity (SOIs) for products including "milk," "yogurt," "cheese," "ice cream,"

"butter," and others. This latest guidance inappropriately relaxes these SOIs and others in conflict with the laws passed by Congress.

SOIs are not merely a matter of nomenclature for nomenclature's sake. SOIs are an important tool to ensure clear and accurate labels in the interest of consumer understanding. Terms such as "yogurt," "cheese", "butter" and others, have distinct meaning in the minds of consumers and often reflect information about a product's nutritional composition. Consumers may, for instance, seek out yogurt for its protein content or probiotic benefit, both of which have established thresholds specified in the standard of identity. Plant-based imitation products, by contrast, have a substantially different chemical (i.e. nutritional) composition, and yet benefit from the nutritional expectations inherent with the term "yogurt." This is precisely the type of consumer confusion Congress sought to remedy through the FFDCA and Fair Packaging and Labeling Act. Yogurt is a particularly apt example, as FDA modified the SOI for yogurt in 2023. To do so, the agency utilized its authority under section 701(e) of the FFDCA and ultimately finalized a modernized SOI for yogurt through a full rulemaking process that included an Advanced Notice of Proposed Rulemaking (ANPR), a proposed final rule, and accompanying notices in the Federal Register to provide for stakeholder input.

In contrast to the process FDA followed to modify an individual SOI, the proposed guidance "Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry" creates a sweeping policy change for an entire category of products (plant-based alternatives to animal-derived foods) through guidance rather than rulemaking. In doing so, the FDA is attempting to revise its own regulations with guidance documents which is in violation of the Administrative Procedures Act. Further, as noted above, Congress defined when products are misbranded. With this guidance, FDA once again chooses to ignore the congressional definition and substitute its own policy. FDA does not have the legal authority to rewrite a federal statute, only Congress does. Federal courts have reinforced this point through the case American Academy of Pediatrics (AAP) v. FDA (Case No.: PWG-18-883) in which the courts determined that:

> *"The power of an agency like the FDA "is 'not the power to make law. Rather, it is "the power to adopt regulations to carry into effect the will of Congress as expressed by the statute … and moreover, "neither federal agencies [like the FDA] nor the courts can substitute their policy judgments for those of Congress."*

Given the conflict with the underlying statute and the Administrative Procedures Act, NMPF respectfully requests that both guidance documents related to the labeling of plant-based alternatives be withdrawn immediately. If the FDA wishes to change the FFDCA, it can work with Congress to amend the statute itself. If the FDA wishes to change its regulations, it can do so by following the notice-and-comment requirements established by the Administrative Procedures Act. In the development of both guidance documents focused on plant-based labeling, FDA has egregiously ignored the laws and its duties as a federal agency.

Note that this is not the first time NMPF has raised concerns of consumer misinformation in labeling. To further highlight our concerns regarding the legality, consumer misinformation and ultimately, concerns of public health, we are providing a copy of previous comments made in response to "Labeling of Plant-based Milk Alternatives (PBMA) and Voluntary Nutrient Statements" **(Attachment 1), and "**Labeling of Plant-Based Alternatives to Animal Derived Foods: Draft Guidance for Industry" **(Attachment 2).**

If NMPF can answer any additional questions regarding our concerns, please contact me at 703-294-4355 or cdetlefsen@nmpf.org.

Sincerely,

Clay Detlefsen, Esq.
Senior Vice President and Staff Counsel