



National Milk Producers Federation

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Agri-Mark, Inc.
Associated Milk
Producers Inc.

Bongards' Creameries
Cooperative Milk
Producers Association
Cortland Bulk Milk
Producers Cooperative

Dairy Farmers of
America, Inc.

Ellsworth
Cooperative Creamery
FarmFirst Dairy
Cooperative
First District Assoc.

Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk
Producers

Maryland & Virginia
Milk Producers
Cooperative Association
Michigan Milk
Producers Association
Mid-West
Dairymen's Company
Mount Joy Farmers
Cooperative Association
Northwest Dairy Assoc.
Oneida-Madison Milk
Producers Cooperative
Association

Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto County
Cooperative Milk
Producers' Association
Select Milk
Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative
Creamery, Inc.
Tillamook County
Creamery Association
United Dairymen
of Arizona
Upstate Niagara
Cooperative, Inc.
Zia Milk
Producers, Inc.

April 17, 2018

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
Food and Drug Administration
Silver Spring, MD

**Re: Docket No. FDA-2017-P-6211-0001: Request that the FDA amend 21CFR
101.9(c)(8)(v) to allow for the use of simple vitamin letter names on both the
Nutrition/Supplement Facts label and Ingredient Declaration lines**

Dear Ms. Bigby:

The National Milk Producers Federation (NMPF) appreciates the opportunity to comment on a citizens' petition submitted by DSM Nutritional Products LLC, which the Food and Drug Administration (FDA) describes as a request "to allow for the use of simple vitamin letter names on both the Nutrition/Supplement Facts label and Ingredient Declaration lines." The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

NMPF encourages FDA not to consider this petition in isolation. The petition itself raises some significant issues, but other related issues that go beyond the petition's request also deserve careful consideration. Should FDA decide to move forward to address nomenclature regulations like those identified by the petition, NMPF strongly urges the agency to begin with an advance notice of proposed rulemaking (ANPR) to garner the widest possible public input.

Reducing consumer confusion and improving clarity of product labels is an admirable goal fully supported by NMPF. However, there is more than one kind of confusion. If the ingredient declaration list contains common vitamin names instead of chemical names, will consumers assume that these vitamins occur naturally in the food rather than being added, in the same way that vitamin C occurs naturally in citrus or vitamin B12 occurs naturally in milk? As a matter of general policy, NMPF does not believe that FDA should structure its regulations in ways that artificially or unintentionally encourage manufacturers to heavily fortify processed foods. One of the Dietary Principles to meet Key Recommendations of the 2015-2020 Dietary Guidelines for

Americans (DGA)¹ – which is the official nutrition guidance of the U.S. government – explicitly encourages us to get our nutrients primarily from foods; recommends nutrient-dense foods as the primary means of obtaining nutrients; and discusses fortification as a limited tactic that should focus on nutrients that are consumed in less than recommended amounts.

NMPF is also cognizant that numerous substances other than vitamins (e.g., minerals) must be listed as ingredients. How would an isolated change to the rules for vitamin naming affect public perceptions of these other ingredients? It would seem advisable for the agency to consider issues of nomenclature globally across all ingredients, not simply as to one class (vitamins).

In addition, there are practical issues. All food manufacturers must already re-design their Nutrition Facts labels, and are likely to do so before any rulemaking process on vitamin nomenclature could become final (FDA has proposed January 1, 2020, as the enforcement date for the Nutrition Facts label, although, as a practical matter, label re-design must be completed some months prior to that date). Yet another re-design of food packaging to accommodate new nomenclature for vitamins would increase food industry costs. FDA would need to identify benefits that would offset these added costs.

Of these issues, NMPF is most concerned about whether a change in nomenclature would serve as an unintended incentive for significantly expanded fortification of foods, and/or relatedly might confuse consumers about which nutrients are naturally occurring and which are added. NMPF urges FDA to consider issues of nomenclature in this context. The following are two examples where unintended consequences from the petition may occur:

- In comparing the vitamin declarations for whole milk and low-fat milk, the following would appear beneath the ingredient list:

VITAMINS: D.	(for whole milk)
VITAMINS: A, D.	(for low-fat milk)

¹ U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.

“Nutritional needs should be met primarily from foods. Individuals should aim to meet their nutrient needs through healthy eating patterns that include nutrient-dense foods. Foods in nutrient-dense forms contain essential vitamins and minerals and also dietary fiber and other naturally occurring substances that may have positive health effects. In some cases, fortified foods and dietary supplements may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts.” (page 16)

This type of labeling could be misinterpreted by consumers concluding that whole milk is not a source of Vitamin A because it is not specifically noted in the vitamin declaration line. In fact, whole milk contains Vitamin A naturally, and low-fat milk is fortified with Vitamin A to replace the amount lost when the milkfat is removed.

- As a second example, low-fat milk would be labeled beneath the ingredient statement with “**VITAMINS**: A, D.” By comparison, a vitamin-fortified water may have a much longer list of vitamins highlighted. However, consumers may not be aware that milk is a good or excellent source of nine essential nutrients – including vitamins B2, B3, and B12, which are naturally-occurring.

The grouping of vitamins at the end of the ingredient line may be interpreted by consumers as a special “call-out” or notification of the nutrients for which the food is a good or excellent source (much like how allergen statements on a separate line below the ingredients alert consumers to the presence of major food allergens). This oversimplification may falsely boost the perceived healthfulness of a heavily fortified product, while minimizing the presence of naturally-occurring nutrients in nutrient-dense foods for which consumption is encouraged by dietary guidance.

A broad-based public discussion of this and other questions is appropriate and, in NMPF’s view, necessary before FDA takes any action. The agency might also benefit from commissioning consumer research on perceptions not only of the proposed new names, but of perceptions of other nutrients that are not re-named.

For that reason, we reiterate that if FDA wishes to act on this petition, the agency should do so through issuance of an ANPR. The agency should not act in ways that circumscribe the public’s right to comment *before* a change in policy, such as through enforcement discretion or a notice of proposed rulemaking (NPR) without benefit of an ANPR.

NMPF looks forward to continuing to work with the agency to identify ways to provide greater clarity and strengthen the utility of food labels, and to encourage healthful food choices that improve the health of Americans. We appreciate the opportunity to provide these comments.

Respectfully submitted,

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