



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.
Dairymen's Marketing Cooperative, Inc.
Ellsworth Cooperative Creamery
Farmers 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 Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Swiss Valley Farms
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

February 8, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Dear Sir or Madam:

The following comments are submitted on behalf of the National Milk Producers Federation (NMPF) with respect to the Food and Drug Administration's (FDA) November 2015 document entitled *Questions and Answers on FDA's Fortification Policy: Guidance for Industry*.

- **Question A2: What is an example of rational addition?**

The answer provided cites the addition of calcium to soy beverages as an example of a "rational addition". NMPF respectfully objects to the wording of the answer to Question A2 in that it is not fully consistent with the most recent *Dietary Guidelines for Americans* (DGA).

The answer cites a universe of "people who do not drink milk" and then gives as the only example "those who are lactose intolerant". FDA should be aware that lactose-intolerant Americans can often consume dairy products, and that the DGA encourages dairy consumption as the preferred option: "Individuals who are lactose intolerant can choose low-lactose and lactose-free dairy products¹". (Also, NMPF notes that soy beverages are deficient in several of the nutrients found in milk, not just calcium, and must be fortified to specified levels of these nutrients in order to be eligible for a number of nutrition assistance programs administered by the U.S. Department of Agriculture.)

A variety of options – consuming smaller quantities of dairy products; consuming dairy with a meal; choosing lactose-free milk; and consuming dairy foods that naturally have less lactose, such as hard cheeses – are all viable strategies that still allow people with lactose intolerance to benefit from dairy's unique nutrient package. Since the DGA is a publication of FDA's parent department, NMPF was surprised by the guidance document's implication that lactose-intolerant individuals will naturally "not drink milk."

¹ Dietary Guidelines for Americans 2015-2020, 8th edition.

Should FDA continue with this beverage as an example of a rational addition, NMPF encourages FDA to modify the answer provided in the guidance document to clarify that dairy should be the first option for lactose-intolerant individuals.

- **Question A9: Can I fortify products in order to make a health claim?**

NMPF respectfully suggests that FDA consider modifying the answer to Question A9 to include the criteria of determining whether nutrient addition is appropriate (including nutrient stability, physiological availability, etc.), by referencing Question C4.

For example, as it specifically applies to soy beverages and other plant-based alternatives to milk, calcium added through fortification may be less bioavailable than the calcium found naturally in milk. Particularly since, as the 2015 Dietary Guidelines Advisory Committee noted, these beverages often provide substantially more calories for the same amount of nutrients, NMPF believes bioavailability is a relevant consideration for any food making a health claim, and should be considered by FDA in deciding whether to permit such a claim. While NMPF notes this concept is captured later in the document in Question C4, it may be helpful to include it through a cross-reference in the answer to A9 as well.

NMPF appreciates FDA's consideration of these comments. Please contact me for additional information (bbriczinski@nmpf.org, 703-243-6111).

Sincerely,



Beth Briczinski, Ph.D.
Vice President, Dairy Foods & Nutrition

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 more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.