



National Milk Producers Federation

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October 11, 2018

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

Re: Docket No. FDA-2018-N-2381, The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy

The National Milk Producers Federation (NMPF), established in 1916 and 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.

NMPF is pleased to offer its views in response to FDA's request for comments on the Comprehensive, Multi-Year Nutrition Innovation Strategy. NMPF Executive Vice President, Tom Balmer, also provided oral testimony at the July 26, 2018 public meeting. His testimony is attached here.

Standard Icon to Denote "Healthy" Claims

FDA is considering a standard icon or symbol that would be featured on packages of foods eligible to be called "healthy." Although NMPF believes such an icon could have merit in some circumstances at a future point in time, we submit three cautionary points for the agency's consideration:

1. Food packages are already crowded with a wide variety of information and symbols. The agency should ask itself whether one more icon would really stand out. At a minimum, FDA would be well-advised to carry out consumer testing of any proposed icon. We have our doubts about the utility of such an icon but advocate additional research to help bring clarity to the issue.

2. Will the "healthy" icon preclude, limit or discourage the use of other symbols that food manufacturers may already use? A number of graphic information systems, often conveying levels of specific nutrients, are already in use. Food manufacturers should not have to choose between these existing systems and a new, FDA-sanctioned icon.

3. Perhaps most importantly, it is difficult to evaluate the merits of a "healthy" icon without knowing what FDA intends "healthy" to mean. We commend the agency for announcing that it was working on a proposed rule to modify the "healthy" definition. We respectfully suggest that consideration of an icon should be part of the comment period for this proposed rule, rather than being carried out in isolation.

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 Dairyman'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.
Swiss Valley Farms
Tillamook County Creamery Association
United Dairyman of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

Further, some requirements for labeling foods as “healthy” are inconsistent with the latest science and the 2015-2020 Dietary Guidelines for Americans (DGA) and should be eliminated. More broadly, foods identified by the DGA as nutrient-dense and are recommended as part of one or more of the healthy dietary patterns recommended in the DGA should be able to use the term “healthy.” Otherwise, the FDA’s regulatory scheme may run at cross-purposes to the DGA, which is designated by statute as the official nutrition guidance and policy of the United States.

FDA’s work in this area should give priority to transparency. Food manufacturers need to be open and honest about the ingredients in their products. A well-informed consumer can make appropriate dietary choices even without a “healthy” label. FDA needs to ensure that its rules do not encourage manufacturers to “game” their product formulations, with the result that products are eligible to be called “healthy” even though they manifestly fail to meet the common-sense meaning of that word.

“Modernizing” Standards of Identity

In theory, few could oppose FDA’s goal of “provid[ing] more flexibility for the development of healthier products,” which the agency lists as its reason for revisiting long-established standards of identity for foods. However, we urge the agency to approach this topic with extreme caution, since some groups may have an agenda quite different from the agency’s.

Standards of identity, under the Federal Food, Drug and Cosmetic Act, are to be established whenever they will “promote honesty and fair dealing in the interest of consumers.” This statutory test is potentially consistent with “developing healthier products,” but the emphasis in the law is on how consumers are treated: The standards exist to ensure that commerce is conducted honestly and that transactions between buyers and sellers are fair.

Standards of identity permit consumers of common foods to have confidence that such foods will be what they purport to be. The consumer does not have to be concerned that the food’s nutrition, quality or sensory attributes will be compromised through the use of methods or ingredients not historically associated by consumers with those products or part of the recognized standard of identity.

Unfortunately, for years a number of products have been sold in violation of standards of identity. It is regrettable that FDA has generally failed to act against the manufacturers of these products. NMPF has repeatedly asked FDA to do so for nearly 40 years, and we will continue our plea for respect for the law and honesty and fair dealing in the marketplace.

We believe that in considering changes to standards of identity, two principles should guide FDA. First, in no case should standards be changed for economic reasons, in order to permit food companies to evade standards simply to lower their production costs. Second, the provisions of individual standards should only be changed where

there is a consensus among affected industries, including both manufacturers and the suppliers of major ingredients, that the change is warranted and that consumers will not be misled by such action.

The need for consensus seems particularly clear in the case of dairy standards of identity, where formal rather than informal rulemaking is required for a change. If a particular change is highly controversial among dairy producers (farmers) and processors, FDA is likely to consume an unnecessary amount of resources in a protracted process. It is much better to be sure that dairy producers and processors are aligned on any changes before initiating them.

At FDA's public meeting, there was discussion of "horizontal" changes in standards of identity that would apply across a variety of different foods. We would seriously question whether such an approach comports with the law if it had the effect of allowing a *de facto* change in dairy standards of identity without meeting the requirement for formal rulemaking.

Consumers Need to be Educated About the Nutritional Inferiority of Plant Based Imitators

All fake dairy beverages start with a single ingredient – water. To this fundamental non-nutritive ingredient, plant-based beverage manufacturers add nut, seed or other vegetable or grain-based powders, emulsifiers, stabilizers and a host of other ingredients until they have products that purport to be a "milk". They are not milk; They are highly-processed formulations of water with added ingredients. In decades past, FDA took issue with the practice of nutritional fortification of nutritionally inadequate foods, which were then held out as healthy nutritionally sound foods. FDA took action and issued what has been colloquially known as the "jelly bean rule." In essence, this "rule" conveys that one cannot take a jelly bean (or similarly unsuitable foods) and fortify it with nutrients and then advertise that it was a "good source of...". The plant-based beverage manufacturers are doing precisely this. They start with water, a substance with no nutrient content, add a concoction of powders and chemicals and then call it "milk" – one of the most wholesome and nutritious food products known to man. Real milk contains nine essential nutrients and is an especially important source of nutrients in a child's diet. Plant-based food manufacturers have been making implied nutrient source claims by labeling their products as "milk" and have marketed these products without fear of retribution. This deceptive practice needs to cease.

FDA Commissioner Gottlieb appears to recognize this marketplace misconduct when he pointed out this summer that children are suffering from diseases such as kwashiorkor and rickets because the improper use of dairy terminology on plant-based imitation dairy products conveyed a nutrition benefit that was sorely lacking. He stated:

One area that needs greater clarity – and which has been the subject of much discussion of late – is the wide variety of plant-based foods that are being positioned in the marketplace as substitutes for standardized dairy products. Many of these plant-based foods use traditional dairy terms (e.g., milk,

yogurt, cheese) in the name of the product. For instance, we've seen a proliferation of products made from soy, almond or rice calling themselves milk. However, these alternative products are not the food that has been standardized under the name "milk" and which has been known to the American public as "milk" long before the 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) was established. In addition, some of these products can vary widely in their nutritional content – for instance in relation to inherent protein or in added vitamin content – when compared to traditional milk.

We intend to look at these differences in relation to potential public health consequences. Numerous reports indicate this issue needs examination. For example, case reports show that feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of severe protein malnutrition. There has also been a case report of a toddler being diagnosed with rickets, a disease caused by vitamin D deficiency, after parents used a soy-based alternative to cow's milk. Because these dairy alternative products are often popularly referred to as "milk," we intend to look at whether parents may erroneously assume that plant-based beverages' nutritional contents are similar to those of cow's milk, despite the fact that some of these products contain only a fraction of the protein or other nutrients found in cow's milk.¹

NMPF looks forward to FDA more fully exploring the health consequences for which these mislabeled foods are possibly responsible. In the interim, we provide the following citations of several tragic outcomes.

1. **"Parents convicted over baby killed by 'alternative' diet"** - Belgian court hands suspended sentence to mother and father after seven-month-old infant dies from malnutrition and dehydration. June 15, 2017 ²

2. **"An Italian baby raised on a vegan diet is hospitalized for severe malnutrition and removed from parents"** - The baby was severely malnourished and suffering from dangerously low calcium levels. July 11, 2016 ³

3. **"Parents of toddler whose vegan diet led to death sentenced to 30 months"** – Canadian toddler died of chronic malnutrition from a vegan diet devoid of Vitamin D, B12 and enough protein. April 10, 2015 ⁴

¹ Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency's standards of identity for dairy products, July 26, 2018

² <https://www.independent.co.uk/news/world/europe/baby-dies-diet-parents-convicted-lucas-dendermonde-belgium-malnutrition-dehydration-a7790916.html>

³ https://www.washingtonpost.com/news/morning-mix/wp/2016/07/11/italian-baby-fed-vegan-diet-hospitalized-for-malnutrition/?noredirect=on&utm_term=.fd48490d2d2e

⁴ <https://ottawasun.com/2015/04/10/parents-of-toddler-whose-vegan-diet-led-to-death-sentenced-to-30-months/wcm/64f62d5b-8e45-4ebd-b1d5-4be4d2fb1c7c>

4. **“Vegan Couple Sentenced to Life Over Baby’s Death”** - 6-week-old baby boy was fed a diet largely consisting of soy milk and apple juice. May 9, 2007 ⁵

5. **“Health food is out of control’: Doctors warning over vegan diets as more malnourished children seen in hospitals”** - Parents were prosecuted when their child died as a result of being fed a gluten-free diet - which included quinoa milk. August 22, 2017 ⁶

This is a short list sampling of related stories that are available. These are easily found because of the egregious nature and outrageous circumstances surrounding the cases. NMPF asserts that while these cases made headlines, it is highly likely that there are many cases here in the US that are going unnoticed and occur because consumers simply don’t know they are buying highly-processed waters that are not nutritionally sound in accordance with their labeling.

Substitute and Alternative Foods Violate FDA’s Nutrition Quality Guidelines for Foods

FDA’s Nutrition Quality Guidelines were recently updated and reissued on April 1, 2018. In the opening paragraph those guidelines state:

The fundamental objective of this subpart is to establish a uniform set of principles that will serve as **a model for the rational addition of nutrients to foods**. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or under fortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods. **The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. [Emphasis Added]** ⁷

As mentioned above, plant-based beverages start out as water. If the FDA does not consider it appropriate to fortify fresh produce, meat, poultry or fish products, sugars or snack foods such as candies and carbonated beverages, why should the indiscriminate fortification of water be permitted to the point that it may be labeled as “milk”? NMPF is at a loss as to how FDA can support such a contradiction. If the fundamental objective of the April 1, 2018, Nutrition Quality Guidelines is to establish a uniform set

⁵ http://www.nbcnews.com/id/18574603/ns/us_news-crime_and_courts/t/vegan-couple-sentenced-life-over-babys-death/#.W6E-5Mvrupo

⁶ <https://www.mirror.co.uk/news/world-news/health-food-out-control-doctors-11033265>

⁷ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=104.20>

of principles that will serve as a model for the rational addition of nutrients to foods, based on the current state of affairs in the marketplace, NMPF believes that FDA has failed in its mission and needs to rethink it, revise and reissue it -- and ultimately, enforce it.

Plant-Based Imitators, Substitutes and Alternatives Lack More Than Nutrition

In an August 14, 2017, *Federal Register* notice, FDA noted that while there should be some flexibility in food standards, the basic nature and the essential characteristics need to be preserved. FDA also clarified that certain ingredients were required and that the overall physical, chemical and organoleptic properties were not to be affected. Here the discussion involved the use of a dairy ingredient, ultrafiltered milk, not provided for in the standard of identity for a standardized dairy food. Under extraordinary circumstances FDA chose to exercise enforcement discretion relating to the use of and labeling of the product that minimally deviated from the standard. See below.

FDA believes that food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved [emphasis added]. Given the oversupply of UF milk and the pending rulemaking, through this guidance we are announcing our intent to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products under part 133, **in addition to the other required dairy ingredients, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected** [emphasis added]. FDA is also announcing its intent to exercise enforcement discretion with respect to the labeling of standardized cheeses and related cheese products, when, in addition to milk or nonfat milk, fluid UF milk or fluid UF nonfat milk is used as an ingredient, but is not declared in the ingredient statement, provided that milk or nonfat milk is declared in the ingredient statement. We are exercising enforcement discretion with respect to the labeling of fluid UF milk and fluid UF nonfat milk in recognition of the costs and logistics involved in label changes; however, we encourage industry to identify these ingredients as “ultrafiltered milk” and “ultrafiltered nonfat milk” to the extent feasible and appropriate. We intend to exercise enforcement discretion until we have completed a rulemaking process amending our regulations with respect to the issues covered by this guidance, or announce in the Federal Register our determination not to proceed with such a rulemaking.

By extension, one would have to believe that a dairy imitator, substitute or alternative using the name of a standardized dairy food would at the very least have to follow the same general rules. Are plant-based dairy imitators, substitutes and alternatives following these same rules? Do they provide a product that preserves the basic nature and essential characteristics of the standardized dairy food? Do plant-based dairy

imitators, substitutes and alternatives contain any of the required dairy ingredients? Do plant-based dairy imitators, substitutes and alternatives ensure that the physical, chemical, and organoleptic properties of their products are not affected compared to a real standardized dairy product? Of course, the answer to all these question is “NO.” For that reason they do not merit the use of standardized dairy nomenclature, and they should not be able to position themselves in that manner in the marketplace. The bottom line is that standards of identity are about more than nutrition, they are about the basic nature of the food and its essential characteristics. They are about the inclusion of required ingredients and ensuring that physical, chemical and organoleptic properties are consistent among products bearing the same standardized names. As we apply these concepts to the plant-based products it is clear they fail across the board in these important areas.

Educational Campaign on Nutrition Facts Label

NMPF strongly supports educating consumers about the new Nutrition Facts label. We offer two suggestions for this campaign.

1. FDA should work with the private sector, including non-profit industry groups, to amplify the education campaign. NMPF would welcome the opportunity to engage with FDA to help the agency convey important information to consumers.
2. The agency should use the educational campaign to remind consumers that dietary guidance on fat consumption has changed over time. In particular, the campaign will be a good opportunity to inform the public that dietary guidance no longer emphasizes reductions in total fat, but rather in the types of fats consumed. In addition, FDA could inform consumers of the multiple new scientific studies that show either beneficial or neutral effects of dairy foods at *all* fat levels, not just low-fat and fat-free.

There Should Be No Confusion About NMPF’s Position

As the Commissioner indicated in his July 26, 2018 remarks, there has been considerable attention to NMPF’s position on the labeling of plant-based dairy imitators and substitutes. At times, the media and the plant-based foods industry have criticized NMPF for not taking action sooner and for trying to eliminate competition. In fact, neither of those assertions is true. First, as indicated in these comments, NMPF has repeatedly asked FDA to take action and enforce its own rules and regulations since the late 1970’s. Second, NMPF welcomes competition from plant-based food manufacturers – our real dairy products are superior in taste, quality and nutrition. What we object to is plant-based food manufacturers misappropriating the nutrition halo and the dairy industry’s good name to market plant-based products. We have no problem with the marketing of Soy Beverages, Almond Beverages and similarly named products but do note that in addition to misappropriating dairy’s good name, plant-based food manufacturers also misappropriate the look and feel of dairy products with the packaging, promotion and placement of these products with the consuming public. For absolutely clarity, the misappropriation of dairy terminology on plant-based products is not permitted in other countries and those laws are enforced. And, those properly labeled products can and do compete in the marketplace.

NMPF opposes false and misleading labeling advertising and marketing practices and we concur with the American Butter Institute's (ABI) complaint filed with FDA on or about September 13, 2018, which lays out, in detail, the legal basis of why these products are misbranded, see attached.

NMPF also opposes the double standard that applies to labeling. The dairy industry is expected to follow the letter of the law - and does. When we make a mistake FDA never hesitates to point it out and we act to correct it immediately. FDA should treat the labeling of all food products equally and enforce its rules in a fair and even-handed manor.

In conclusion, we appreciate the opportunity to share our views on these important topics and we commend FDA's initiation of a comprehensive, multi-year strategy to promote public health by ensuring consumers have reliable evidence-based information to enable them to make informed decisions about the food they purchase. NMPF believes that there is, and has been, considerable mischief and misinformation in the marketplace for many years and we are optimistic that with this action, the wrongs of the past will be remedied.

Sincerely,



Clay Detlefsen
Senior Vice President, Environmental and
Regulatory Affairs & Staff Counsel

Attachment - ABI Complaint
Attachment - Statement of Tom Balmer