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Upstate Niagara Cooperative, Inc.

> Zia Milk Producers, Inc.

August 1, 2014

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

Re: Docket No. FDA-2012-N-1210, RIN 0910-AF22; Food Labeling: Revision of the Nutrition and Supplement Facts Labels

Dear Sir or Madam:

The National Milk Producers Federation welcomes the opportunity to provide comments to the Food and Drug Administration (FDA) on the proposed rule to revise and update the Nutrition Facts label to assist consumers in maintaining healthy dietary practices. The National Milk Producers Federation (NMPF), 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.

The Nutrition Facts label is used by consumers in various ways, ultimately influencing or enabling them to make informed dietary choices and to develop healthful dietary habits. Toward that end, NMPF respectfully offers the following comments about FDA's proposed amendments to the current Nutrition Facts label.

# Mandatory and Voluntary Declarations for "Calories from Fat" and "Calories from Saturated Fat".

NMPF supports removing the current "calories from fat" declaration. As nutrition research expands, our understanding of the effect of nutrient intake on health improves, and dietary recommendations evolve. It is appropriate to consider changes to the Nutrition Facts label in light of such information. Therefore, as one example, NMPF agrees with FDA's conclusion that "calories from fat" no longer be a mandatory declaration. As further noted below in comments on the "alternative label" on which the agency seeks feedback, scientific views of fat's role in the diet have evolved and few, if any, experts would now claim that total fat calories are the most important data related to fat. Given that this declaration offers minimal utility for Americans in maintaining healthy dietary patterns, and that information about the amount of fat and

% Daily Value (%DV) would still appear on the label, NMPF supports deletion of the "calories from fat" as a mandatory declaration.

NMPF supports "calories from saturated fat" as voluntary declaration, and "saturated fat" as mandatory declaration. FDA has proposed not requiring "calories from saturated fat" to be declared, while maintaining "saturated fat" as a mandatory declaration. NMPF recognizes that, despite emerging scientific evidence questioning the link between saturated fat and heart disease as well as the complexities associated with attributing health outcomes to all types of fatty acids, the amount of saturated fat in a product may aid consumers in selecting or comparing foods. We support the mandatory declaration of saturated fat for this reason, and agree with FDA's determination that the calories derived specifically from saturated fat is information not necessary for consumers to maintain healthy dietary habits.

### 2. Declaration of *Trans* Fat.

Under the proposed rule, *trans* fat content would continue to be a mandatory declaration. **NMPF encourages FDA to carefully consider whether this is still necessary in light of changes in the food supply** during recent years, as well as pending regulatory action by the agency.

Concern about the effects of industrial *trans* fatty acids (iTFAs) has led to major reductions in their prevalence in the food supply. The *trans* fat content in American diets has decreased from 4.6 g per day in 2003 to about 1 g in 2012. In addition, FDA has proposed¹ to withdraw the Generally Regarded as Safe (GRAS) status from partially hydrogenated oils (PHOs). If FDA's tentative determination in this matter becomes final, the iTFA content of U.S. food will decline still more sharply, regardless of what appears on nutrition labels.

FDA has noted that it wants to avoid over-crowding the Nutrition Facts label, and NMPF shares this concern. Therefore, should FDA finalize the determination that PHOs not be GRAS, NMPF suggests that FDA reconsider the continued mandatory labeling of *trans* fat content given that, between current marketplace trends and regulatory changes, the presence of iTFAs in the food supply are likely to further diminish. Pending this decision, as well as FDA's stated lack of more-sensitive validated methods of analysis, we also see no justification for changing current FDA practice (levels <0.5 g/serving) with respect to rounding *trans* fat content in foods.

In the event that FDA should determine to maintain a mandatory *trans* fat declaration, **NMPF strongly urges FDA to consider excluding rTFAs from the declaration.** FDA has recognized that ruminant *trans* fatty acids (rTFAs), which occur naturally in meat and dairy products, are not the same as iTFAs. In proposing to withdraw GRAS status from

<sup>&</sup>lt;sup>1</sup> 78 Federal Register 67169, "Tentative determination regarding partially hydrogenated oils; Request for comments and for scientific data and information", November 8, 2013.

iTFAs, the agency wrote that "trans fat occurs naturally in meat and dairy products from ruminant animals and that naturally-occurring trans fat is unavoidable in ordinary, nonvegan diets without significant dietary adjustments that may introduce undesirable effects." Among these "undesirable effects" could be further worsening the existing under-consumption of calcium, potassium, and vitamin D – three of the four "nutrients of concern" identified in the 2010 Dietary Guidelines for Americans and three nutrients provided by milk and other dairy products. Indeed, as FDA is now proposing to increase the Daily Value (DV) for all three of these nutrients, it certainly seems unwise to inadvertently discourage Americans from getting adequate amounts, as might be the case if a continued focus on trans fat, where rTFA will be the predominant such fat, were to discourage dairy consumption. Finally, some studies indicate rTFAs are not nutrients of public health significance and may have potentially beneficial health impacts, further suggesting that they should not be grouped together with iTFAs.

As noted above, iTFAs and rTFAs have different impacts on human health and different causes for concern. The most recent DGAC report concluded, "Although total elimination of iTFA may be desirable, the elimination of rTFA would have wider implications for dietary adequacy and is not recommended. It is best to avoid iTFA while leaving small amounts of rTFA in the diet."

Should FDA conclude that excluding rTFAs from a *trans* fat declaration is inconsistent with current policy regarding nutrient definitions, NMPF refers to our comments submitted in response to the agency's tentative determination to remove the GRAS status of PHOs<sup>2</sup>. NMPF has provided several practical steps for FDA to clarify to Americans that rTFAs are not nutrients of public health significance, which should also be incorporated into education and outreach materials when the revisions to the Nutrition Facts label are finalized. Without such meaningful information, consumers may inadvertently assume there is something wrong with healthful dairy products that contain small amounts of rTFAs, the consumption of which is encouraged by federal dietary guidance.

### 3. Potassium and Vitamin D Daily Values and Nutrient Content Claims.

FDA has done valuable work in updating DVs for a variety of nutrients. In general, the proposed regulation follows the Institute of Medicine's (IOM) series of Dietary Reference Intakes (DRIs). This basic approach is sound, and allows FDA to use much more recent and complete science than is reflected in current DVs, which are often based on 40-year-old (or older) data. Thus, for instance, the new DVs reflect the establishment of a Recommended Dietary Allowance (RDA) for calcium, which is moderately higher than the current value, but more importantly reflects the IOM's most recent work on this critically important nutrient.

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<sup>&</sup>lt;sup>2</sup> Comments submitted by NMPF to Docket #FDA-2013-N-1317: Tentative determination regarding partially hydrogenated oils; request for comments and for scientific data and information.

Similarly, NMPF supports FDA's proposed increases in the DVs for potassium and vitamin D, and accepts that the agency has made use of the best science in arriving at these values. Milk is the #1 food source of potassium in the American diet; vitamin D-fortified dairy foods account for nearly two-thirds of total vitamin D intake from foods. Therefore, dairy foods are an indispensable part of the solution to Americans' underconsumption of these two nutrients.

Unfortunately, the dairy industry's ability to educate consumers about these nutrients will be limited by the proposed rule, since some products will lose the ability to make good or excellent source claims (for example, reduced-fat milk will no longer be an excellent source of vitamin D or a good source of potassium). This loss will occur because the percent thresholds for the claims will be applied to higher DVs than at present. Dairy foods will not be the only foods so affected. Under the proposed rule, for example, spinach would no longer be able to make a "good source" potassium claim, but potato chips would.

Although it would not be appropriate to change the qualifying criteria for good and excellent source claims, there is a real need to facilitate consumer education through a uniform, objective system for describing the nutrient content of foods. FDA's higher proposed DVs for such nutrients as potassium and vitamin D logically imply a need to encourage more consumption of these nutrients. Yet the proposed rule will severely limit such education, not only for dairy foods, but for other nutrient-dense foods such as some vegetables.

Therefore, NMPF recommends that FDA establish a "source of" claim similar to one already permitted under Canadian regulations for certain nutrients. Such a claim could be made for foods with between 5% and 10% (or perhaps 7.5% and 10%) of the DV for nutrients such as potassium and vitamin D. Thus, dairy foods could be described as a "source of potassium" so that consumers are aware of the foods' content of that nutrient. NMPF is aware that FDA has stated that it will not modify nutrient content claims as part of this rulemaking, but we respectfully submit that the agency should reconsider that position in light of the presumably unintended consequences of DV changes for certain nutrients. We are not questioning the new, higher DVs – but the fact is that milk will have just as much potassium and vitamin D after the DVs are changed as it does now. It is not sound nutrition policy to remove the ability to inform consumers who need to increase their intake of these nutrients, whether through dairy or other foods.

### 4. Sodium Daily Value.

NMPF supports the proposal to reduce the DV for sodium from the current 2,400 milligrams (mg) to 2,300 mg, and opposes a further reduction in the DV to 1,500 mg. The 2,300 mg sodium level is consistent with recommendations in the 2010 *Dietary Guidelines for Americans* (DGA). It is true that the DGA recommend a lower 1,500 mg sodium level for several sub-populations, but DVs are appropriately set for the general

population, and the general-population recommendation in the DGA is in fact 2,300 mg sodium.

Moreover, recent scientific studies cast serious doubt on the wisdom of recommending 1,500 mg sodium for all Americans. As FDA itself pointed out, a committee of the IOM reviewed the science and, in 2013, concluded that available evidence did not justify the conclusion that sodium reductions below 2,300 mg will reduce cardiovascular disease (CVD) risk. In fact, the IOM found that sub-population recommendations for a 1,500 mg intake also could not be supported by the evidence. Even more recently, a meta-analysis published this year found that not only were very high sodium intakes associated with higher CVD risk, but so were very low intakes. In this analysis, the sodium intakes associated with the best health outcomes were actually higher than both the current and the recommended DV. The 2015 Dietary Guidelines Advisory Committee will certainly take these and other studies into account as it crafts recommendations for new dietary guidance, and it would be inappropriate (and inconsistent with the most recent science) for the FDA to anticipate either the committee's recommendation or the government's eventual disposition of that recommendation.

### 5. <u>Declaration of "Added Sugars".</u>

As proposed, FDA is requiring declaration of "added sugars" on the Nutrition Facts label. In reaching this determination, FDA acknowledged this decision was not based on relation of a specific nutrient to a chronic disease or health-related condition, but was based on consumers having nutrient information, citing a number of dietary recommendations encouraging consumers to limit their intake of added sugars which would otherwise displace the consumption of nutrient-dense foods. The purpose of including an "added sugars" declaration on the label is that consumers would be able to identify the presence of added sugars in foods and to compare products on a consistent basis.

NMPF recognizes the rationale for a mandatory declaration of "added sugars" is atypical, and is not based on a traditional nutrient-health outcome linkage; however, NMPF also recognizes that such a declaration would aid in clarifying the contribution of lactose, a naturally-occurring sugar, to dairy products. Therefore, NMPF supports the mandatory declaration of "added sugars", as a gram amount. Recognizing that calories from added sugars are no more likely to contribute to weight gain than from other sources of calories in foods, and that a gram declaration of added sugars on a product label will sufficiently allow consumers to identify the presence of and to compare the amounts of added sugars among products, NMPF further agrees that a "calories from added sugars" declaration would be unnecessary. NMPF also agrees with FDA's conclusion that there is no scientific consensus that would support establishing a %DV for added sugars.

Regarding the definition of "added sugars" as proposed by FDA, NMPF offers comment specifically on the part of the definition that identifies added sugars as "naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component". Presumably, this would not include any dried and concentrated dairy ingredients where lactose is the constituent present in the largest quantity, such as non-fat dry milk powder (51% lactose), whole milk powder (37% lactose), buttermilk powder (49% lactose), whey powder (70% lactose), etc. that have been incorporated into the basic dairy substrate (i.e., milk) used to manufacture products such as cheese, yogurt and ice cream. NMPF maintains that the lactose contributed by dried and concentrated dairy ingredients should be excluded from the definition of "added sugars" on the Nutrition Facts label of dairy products for the following reasons:

1. Lactose is not primarily added to dairy foods (for example, yogurt, ice cream) for the purpose of sweetening. Lactose differs from other nutritive carbohydrate sweeteners used in foods in that it has a much lower relative sweetness (15-20% compared to 100% for sucrose on a typical sweetness scale) and is much less soluble (approximately 16 grams lactose per 100 grams water compared to 67 grams of sucrose per 100 grams of water). Both of these properties limit the functionality of lactose in dairy foods.

Put simply, while milk-derived ingredients that contain lactose are added to a variety of dairy foods, they are not primarily added because the lactose serves as a sweetener. The other milk components serve a variety of functional purposes (e.g., milk proteins contribute to aeration and gelation; milk salts often serve as sodium substitutes) and provide a "dairy flavor" to products. Likewise, lactose also contributes functional properties to dairy foods (e.g., contributing to viscosity and mouthfeel, serving as a fermentation source in yogurt).

In FDA's discussion of "added sugars", yogurt and dairy-based desserts were cited as examples of foods that contain both naturally-occurring sugar (i.e., lactose) and added sugars. The functional properties of lactose are so different from other sugars used as sweeteners in the food industry that it would not be possible to make these foods if lactose were used as the sole sweetener in the formulation, replacing the traditional sugar (i.e., sucrose). The amount of lactose required to achieve the same level of sweetness would compromise basic attributes of the product itself. For example, if lactose were added to a typical ice cream – at a level to replace the sweetness contributed by sucrose – the amount of lactose that would have to be added (roughly 5 to 6 times the amount of sucrose) would either depress the freezing point of the ice cream mix such that the product would not be able to freeze under normal conditions or, if it did freeze, would result in an extremely "sandy" texture defect (lactose crystallization because of poor solubility) which would make the product unacceptable to consumers.

2. The standard of identity for many dairy products does not require sweeteners to be added, but does allow for lactose-containing dairy-based ingredients in "unsweetened" products. For standardized dairy products like milk and yogurt, current regulations do not require that a sweetener be added; the products may be manufactured and sold "unsweetened". In the case of yogurt, per the standard, yogurt may be made by culturing cream, milk, partially skimmed milk, or skim milk<sup>3</sup> and other optional dairy ingredients, and without sweeteners. Not including dairy-based ingredients<sup>4</sup> (for example, concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, or modified whey) as "sweeteners" in the standard is tacit acknowledgement by FDA that the lactose in these dairy-derived ingredients is not primarily added to provide sweetness – dairy-based ingredients containing lactose and sweeteners are two clearly different categories of ingredients.

Similarly, "unsweetened" milk may be fortified by increasing the milk solids content with the addition of concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk<sup>6</sup>. The addition of dry whole milk or nonfat dry milk (containing 37% and 51% lactose, respectively) would not result in a "sweetened milk" simply because lactose-containing dairy-based ingredients were added to the milk. Likewise, "no-sugar-added" ice creams have been available in the marketplace for over two decades, despite the fact that many are formulated with dairy-based ingredients that contain lactose as the primary component (i.e., nonfat dry milk powder). This strongly suggests that the inherent lactose in dairy-based ingredients is different from "added sugars" from a regulatory perspective as well.

3. FDA's common or usual names for dairy ingredients would cause confusion with "added sugars" declarations. NMPF urges FDA to clarify how the proposal to label added sugars would operate in situations involving dairy foods with lactosecontaining milk-based ingredients. Otherwise, dairy products having identical compositions and identical ingredient statements would have different nutrition labels based on which ingredients are sourced. For example, FDA allows manufacturers to identify skim milk, concentrated skim milk, and nonfat dry milk as "skim milk" or "nonfat milk" in an ingredients listing<sup>7</sup>. Two nonfat yogurt products could be formulated to the same final product composition, and the ingredient statements for both could read "nonfat milk and culture". However (as stated above regarding standard of identity implications), with the definition of "added sugars" as proposed, a yogurt made using fluid skim milk as the sole dairy ingredient would have zero added sugars, while a yogurt made using nonfat dry milk powder as the sole source of dairy solids would have to declare "added sugars" on the nutrition label. Not only would this require manufacturers to constantly have to adapt their nutrition labels due to sourcing different ingredients, this would also be

<sup>&</sup>lt;sup>3</sup> 21 CFR 131.200 (c)

<sup>&</sup>lt;sup>4</sup> 21 CFR 131.200 (d)(1)

<sup>&</sup>lt;sup>5</sup> 21 CFR 131.200 (d)(2)

<sup>&</sup>lt;sup>6</sup> 21 CFR 131.110 (a)

<sup>&</sup>lt;sup>7</sup> 21 CR 101.4 (b)(3)

confusing to consumers who would see different nutrient declarations that are not reflected with differences either in the final product (i.e., no differences in taste or sweetness level) or in the ingredient statement.

While we recognize that FDA wanted to include products like fruit juice concentrates in the definition for "added sugars", it would be easier to simply specify that fruit juice concentrates are included in the definition of "added sugar" (which is the example of "naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component"). In addition to being used in formulations for dairy foods, lactose-containing dairy-based ingredients are also used in a variety of other non-dairy applications. The primary use of these dairy-derived ingredients is not for the sweetening power of lactose (as noted above), but for the functional properties of the other dairy components (proteins, milk salts) or for other functional properties of lactose (e.g., the browning on the crust of baked goods). Clearly, it is unreasonable to categorize the lactose in dairy-based ingredients as an added sugar in non-dairy foods as well. Therefore, FDA should amend the proposed rule to provide that the lactose in dairy-derived ingredients is not considered an added sugar.

FDA has noted that the justification for requiring an "added sugars" declaration is a departure from the typical rationale in that there is no scientific consensus that added sugars are directly linked with increased risk of chronic disease, a health-related condition, or a physiological endpoint. Therefore, FDA should also be equally justified in changing their definition of "added sugars" to exclude lactose. With respect to the definition and methods for quantification, there are suitable methods<sup>8</sup> as well as food composition databases for quantifying lactose in foods, the amount of which can be excluded from the "added sugars" declaration on the nutrition label. As the "Total Sugars" declaration would still be required, natural sugars (like lactose) would still be identified on the label and would not go un-reported. Consumers trying to limit total sugar intake would still have the information to be able to do so.

Lactose-containing dairy-based ingredients are not primarily used for sweetening purposes but for other reasons of functionality. The lactose in nonfat dry milk and other ingredients *is not added to* these ingredients – it is a naturally-occurring component of the ingredient. Thus, lactose in dairy ingredients does not fit the profile of an "added sugar" as discussed by FDA, and should not be so classified.

#### 6. Alternative Label.

NMPF opposes the alternative label published by FDA, which would group some nutrients under an "Avoid Too Much" heading. We believe there are two basic weaknesses in this approach. First, such a focus on saturated fat, sodium and other so-called "avoidance" nutrients would put consumers at risk of losing sight of the unique

<sup>&</sup>lt;sup>8</sup> Validated methods include ISO/IDF methods for lactose determination in dairy products, AOAC methods for lactose determination in milk and cream, and *Standard Methods for the Examination of Dairy Products* methods for lactose determination in milk and other dairy products.

nutrient package supplied by dairy foods. This is a real concern since Americans already under-consume dairy, achieving only about half the intake recommended by the 2010 DGA. It would be unsound nutrition policy to risk discouraging consumption of nutrient-dense dairy foods at the same time that FDA's proposed rule recognizes the need to increase consumption of potassium, for which dairy is the #1 food source, and of vitamin D, two-thirds of the dietary intake of which is supplied by dairy.

The second problem with the "Avoid Too Much" category is that by enshrining it in regulation, FDA would make it difficult to account for changing science. It has already been noted that recent science casts doubt on the movement to cut sodium to everlower levels. Perhaps more significantly, scientific views of the role of fat in the diet are also evolving. Already, FDA has recognized in the proposed rule that a focus on total fat is of lesser importance than was believed just a few years ago. Recent scientific studies have questioned the connection between saturated fat and CVD outcomes. And, though further research is needed, there are reasons to believe that dairy sources of saturated fat are not linked to CVD risk and may in fact be associated with reduced risk. In this regard, FDA should be extremely cautious about designating some nutrients as always "bad" when science may say otherwise in coming years. In that event, the alternative label might actually mislead consumers for the several years it would take FDA to change it.

We realize FDA has not proposed the alternative label, and submit that **the label proposed by the agency is far preferable to the alternative label.** 

## 7. <u>Dual Column Labeling.</u>

FDA has proposed to require dual column labeling for containers with between two and four servings of a food. In some cases, this concept may be sensible. However, in others, it leads to unintended and illogical results. FDA has already proposed an exemption from the requirement for some foods, like butter, that are typically used as ingredients. NMPF requests that the agency address two additional issues specific to dairy.

First, the agency should clarify in the final rule that its exemption applies to buttermilk. While earlier generations once consumed buttermilk as a beverage, it is now used almost exclusively as an ingredient, such as in baking. It should clearly fit within the universe of products FDA is proposing to exempt, but a specific acknowledgment of that fact would provide clarity to milk processors. Likewise, other dairy ingredients primarily used as ingredients and should receive recognition as such would include mascarpone, ricotta, and cheeses that are sold in shredded or grated forms.

Second, FDA may not have considered that, since a serving of milk is 8 ounces or one cup, a quart of milk is four servings and therefore would trigger a requirement for dual column labeling. This result seems anomalous in light of FDA's rationale for the dual column requirement. The agency wants to address situations where it is reasonable to

expect that people might consume an entire package, even though a serving size is less than the full package. However, NMPF is aware of no evidence that people drink an entire quart of milk at a single setting with any frequency at all. Indeed, the unfortunate decline in fluid milk consumption over recent decades is indicative that average quantities consumed have been shrinking. Thus, to require a label that provides information for the entire container risks misleading consumers. Since no one associates a quart of milk with a single drinking occasion, consumers may infer that the amount of fat (for example) listed for the container is the amount they would consume by drinking one glass of milk, and this may discourage consumption. NMPF would argue similarly for a pint of cottage cheese (which represents four servings) and is not aware of consumption data to suggest such a container size represents a single eating occasion for this food. In fact, with respect to the issue of product density and satiety, NMPF would maintain it is, in fact, unreasonable to expect that a person would consume four servings of either of these nutrient-rich products at a single eating occasion.

NMPF submits that if a proposed regulatory requirement triggers a result which nearly everyone would agree is not realistic, the solution is to modify the requirement. Therefore, NMPF respectfully requests that FDA exempt dairy foods primarily used as ingredients (butter, mascarpone, ricotta, shredded/grated cheeses), fluid milk in one-quart or larger containers, and cottage cheese in one-pint containers from the dual column labeling requirement.

### 8. Statements of Identity.

Finally, NMPF would be remiss if we did not point out one aspect of labeling that also does convey key nutrition information to the consumer – the statement of identity on the front of the package. Through multiple communications<sup>9</sup>, NMPF has raised the issue of existing regulations pertaining to the identity of foods as found in 21 CFR 101.3. Nonetheless, the Agency has blatantly disregarded the names displayed on the labels of imitation dairy products (e.g., "soy milk", "rice yogurt", etc.) in the current marketplace. NMPF has repeatedly urged the agency to address the issue of misbranded foods misusing names of standardized dairy products. However, by remaining nearly silent on the topic of these inappropriate common or usual names<sup>10</sup>, FDA has essentially created

<sup>&</sup>lt;sup>9</sup> Letter dated May 5, 2014 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2009-D-0430.

Letter dated July 28, 2010 from Dr. Beth Briczinski, Director, Dairy Foods & Nutrition, NMPF to Docket #FDA-2010-N-0210;

Letter dated April 28, 2010 from Jerry Kozak, President and CEO, NMPF to Margaret A. Hamburg, Commissioner, FDA;

Letter dated November 2, 2001 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Dr. Christine Lewis, Director of Office of Nutritional Products, Labeling and Dietary Supplements; Letter dated February 14, 2000 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Joseph Levitt, Director, CFSAN.

<sup>&</sup>lt;sup>10</sup> FDA has, in fact, issued a few warning letters over more than three decades: FDA Warning Letter dated August 8, 2008 from Alonza E. Cruse, District Director, FDA Los Angeles District to Mr. Long H. Lai, Lifesoy, Inc.;

an "anything goes" attitude in the marketplace where misbranding and mislabeling is without true regulatory consequence.

The inaction by FDA to address the category of plant-based imitation dairy products that are marketed using the names of standardized dairy products has only allowed these manufacturers to continue to mislead and confuse consumers as to the nutritional content of their products. NMPF strongly maintains that consumers are being defrauded by the inferior nutrient content of these misbranded non-dairy products compared to their true dairy counterparts (21 CFR 101.3 (e)(1)).

The name of a food as it appears on the front of a package does convey nutritional information to the consumer about the product. Consumers think non-dairy alternatives with the term "milk" or "yogurt" in their name represent a nutritional profile equivalent to what is present in dairy milk or yogurt, respectively. It has been recognized that many consumers rely on visual cues from the front of the package (the product imagery, style of packaging, nutrient claims) and the name of the food to make inferences about the nutrient content of the product. Given their physical state, similar packaging, images on the label, recommended uses, label claims (e.g. "as much calcium as milk"), along with the inclusion of the term "milk" in the name of the product on the principal display panel, consumers are being misled into thinking these imitation beverages are nutritionally equivalent to dairy milk.

Considering the limited agency resources available, while the current proposal addresses modifications to the Nutrition Facts panel, it is disingenuous for FDA to continue to ignore the nutritional inferences of the name of the food on the front of the package when the agency's overall goal is to provide accurate and meaningful nutrition information to consumers so they can make positive dietary choices and establish healthful eating patterns. NMPF would again strongly urge the agency to consider enforcing established food labeling policies, including the statement of identity. It is not reasonable for American consumers to have to turn a package over and perform a side-by-side comparison of these imitators and wholesome, nutritious dairy products to discover the many ways in which the plant-based mimics are inferior, when the very name of the food itself – the first thing a consumer sees when looking at a package – is misbranded.

#### Conclusion.

NMPF commends the efforts of FDA to update the Nutrition Facts labels, with the overall goal of assisting American consumers in maintaining healthy dietary practices. Overall, the proposed label will have a positive impact and will provide accurate and meaningful nutrition information. A few aspects of the proposed rule may result in

Letter dated July 18, 1985 from Lillie Taylor, Assistant to the Director, Division of Regulatory Guidance, CFSAN to C. Hwang, Dr. Chung's Foods Company, Ltd.;

Letter dated September 29, 1983 from James R. Taylor, Jr., Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods to Mr. Kok Ee Lynn, Senior Officer, Singapore Institute of Standards and Industrial Research.

unintended consequences with respect to dairy foods to which NMPF respectfully calls attention. Specifically, NMPF would suggest FDA re-evaluate their proposal with respect to the declaration of *trans* fat, the definition of "added sugars", the impact of dual column labeling with respect to dairy foods, and the statement of identity. We look forward to continuing to work with the agency to provide Americans with a variety of dairy foods and to effectively communicate nutrition information through accurate labeling.

Thank you for the opportunity to share our perspectives. Please contact us if you have additional questions.

Sincerely,

Beth Panko Briczinski, PhD

Vice President, Dairy Foods & Nutrition

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