# FDA ISSUES DRAFT GUIDANCE ON NAMING AND VOLUNTARY NUTRIENT STATEMENTS FOR PLANT-BASED MILK ALTERNATIVES

By Ralph Simmons

Foster Garvey

# OVERVIEW

On February 23, 2023, the Food and Drug Administration (FDA) announced the issuance of a draft guidance document entitled "Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry." FDA is requesting public comment by April 24, 2023 (although FDA guidance documents are open for public comment at any time, submission of comments by April 24 assures that the comments will be considered prior to issuance of "final guidance"). Comments may be submitted electronically at https://www.regulations.gov, or in paper form sent to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments must reference the docket number – FDA-2023-D-0451.

As with all FDA guidance documents, these are only recommendations by the Agency, not rules. In accordance with FDA's Good Guidance Practices Regulation, 21 CFR § 10.115, guidance, even when final, "does not establish any rights for any person and is not binding on FDA or the public."

## NAMING OF PLANT-BASED MILK ALTERNATIVES

Plant-based milk alternatives (PBMA – our acronym, not FDA's) are non-standardized foods, meaning that they are not subject to an FDA-established standard of identity, unlike milk (see 21 CFR § 131.110 for the milk standard of identity). Therefore, PBMA must be labeled with their common or usual name, since they do not have names designated in a standard of identity. 21 U.S.C. § 343(i)(1). FDA is advising that common or usual names have been established for PBMA by common usage to be names including milk, qualified with the plant source of the product (e.g., "soy milk" or "almond milk"). This guidance applies only to products with milk in the name, not to plant-based alternatives for other dairy foods.

FDA indicates in the guidance that "plant-based milk" by itself is not an appropriate name, because it is not the common or usual name of a specific food. FDA is concerned that omitting the specific plant source of the PBMA may be confusing to consumers, as the product would not be readily distinguishable from other types of PBMA.

If a PBMA is derived from different plant sources, FDA recommends that the different plant sources be included in the name. The Agency also recommends that the predominant plant source be stated first in the name.

## RECOMMENDATIONS FOR VOLUNTARY NUTRIENT STATEMENTS

FDA recommends that PBMA that use the term "milk" in their name and have nutrient composition that is different from milk with respect to calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, or vitamin B12, bear an additional nutrient statement describing how it is nutritionally different. It is interesting that FDA describes this nutrient statement as "voluntary," emphasizing that aspect, since everything in a guidance document is "voluntary," consisting of recommendations only. In this context, however, it should be noted that FDA's "recommendations" in this guidance with respect to product naming are not really "voluntary" since non-standardized food products such as PBMA are required by law to be labeled with their common or usual name, and FDA has specified the common or usual names for PBMA

For the voluntary nutrient statements, FDA suggests use of language such as – "Contains lower amounts of [nutrient name(s)] than milk." The recommended placement of the statement is on the principal display panel (PDP) near and visually connected to the name of the product if space allows. The nutrient statement does not need to accompany the product name every time the name appears on the label, just once on the PDP.

To determine if a PBMA is nutritionally different from milk, FDA recommends using the US Department of Agriculture Food and Nutrition Service's (FCN) fluid milk substitutes nutrition criteria provided in the following table:

| Nutrient | Per cup (8 fl oz) |
|---|---|
| Calcium | 276 mg |
| Protein | 8g |
| Vitamin A | 500 International Units (IU)* |
| Vitamin D | 100 IU |
| Magnesium | 24 mg |
| Phosphorous | 222 mg |
| Potassium | 349 mg |
| Riboflavin | 0.44 mg |
| Vitamin B12 | 1.1 µg |

**USDA has proposed a rule (85 Fed. Reg. 4094) to update the units of measure for vitamins A and D to align with how they are declared on the updated Nutrition Facts label, which is in micrograms.*

You will note that the USDA list includes nutrients that are not required by FDA on the Nutrition Facts label, which is because that label does not include all the important nutrients found in milk.

## BACKGROUND

The process that resulted in this draft guidance began with a September 28, 2018 notice published by FDA (83 Fed. Reg. 49103) requesting public comment on the labeling of PBMA that include the names of dairy foods. FDA invited comment on issues including how consumers use PBMA, how consumers understand terms included in the names of PBMA, and whether consumers are aware of and understand differences between PBMA and their dairy counterparts. In addition to the request for comment, FDA conducted focus groups.

In response to the notice, FDA received over 13,000 comments, most of which focused on PBMA. The comments and other research reviewed by FDA suggest a potential public health concern related to the substitution of milk with PBMA that contain lower amounts of certain nutrients than found in milk. Therefore, the draft guidance focuses only on PBMA and not plant-based alternatives to other dairy products.

FDA found from the comments, consumer studies, and focus groups that, while consumers appear to understand that PBMA are distinct products from milk, they do not understand the nutritional differences between milk and PBMA. Research indicates to FDA that a majority of consumers who purchase PBMA do

so, because they believe the products are healthier than milk. Consumer survey data also indicates that respondents expect that PBMA are comparable in nutrition to milk, and this belief is stronger in those who purchase PBMA.

FDA finds the nutritional value of milk and its role in healthy eating patterns to be well documented, while the nutritional content of PBMA varies considerably across types (e.g., "almond milk" vs. "oat milk"") and within the same type depending on the raw materials used, processing, fortification with vitamins and minerals, and addition of other ingredients, such as sugar and oil.

FDA is concerned that consistently consuming PBMA that do not have a similar nutritional composition to milk in place of milk, without the addition of other foods to supply the missing nutrients could lead to further inadequate intakes of nutrients of public health concern and other nutrients that pose a special public health challenge.

## FIRST AMENDMENT CONSIDERATIONS

FDA recognizes in the draft guidance that there are First Amendment considerations when government seeks to regulate commercial speech such as food labeling. The Agency is aware of current lawsuits that challenge state legislative limits on the use of words associated with traditional food products on alternative food product labels.

Some courts have found that, under the First Amendment, the states have failed to justify bans on plant-based alternatives using names associated with meat and/or dairy products. However, some courts have found that a state can require that the labeling on the plant-based alternatives include a prominent disclosure indicating that the product is plant-based.

FDA concludes by stating that, as of February 2023, some cases remain pending, without providing an analysis of the draft guidance with reference to the First Amendment. In that regard, an important fact is that this is only guidance, not a binding regulation. Indeed, FDA puts extra emphasis on the voluntary nature of the supplemental nutrition statements. FDA also has many food labeling regulations issued over many years. The Federal Food, Drug and Cosmetic Act itself provides that non-standardized foods be labeled with their common or usual name, as discussed above, and FDA is interpreting that requirement in this guidance with respect to the naming of PBMA. An in-depth analysis of the application of the First Amendment to this guidance is beyond the scope of this summary. FDA is correct in noting that there are First Amendment "considerations," which may well be the subject of comments.

## ABOUT THE AUTHOR

Ralph Simmons leverages more than four decades of federal and state regulatory experience to help clients navigate the ever-evolving, complex web of key regulatory issues involving food packaging, labeling and safety.

Ralph regularly assists corporate and individual clients, including food and beverage companies, in a wide variety of matters, including corporate formation and governance, commercial contracts, regulatory and legislative proceedings.

## CONTACT

Tel: 202.965.7375
Fax: 202.965.1729
ralph.simmons@foster.com

Foster Garvey PC
1000 Potomac St. NW, Suite 200
Washington, DC 20007

Foster Garvey

| SEATTLE | PORTLAND | WASHINGTON, D.C. | NEW YORK | SPOKANE | BEIJING |
|---|---|---|---|---|---|
| 1111 Third Avenue<br>Suite 3000<br>Seattle, WA 98101 | Bank of America<br>Financial Center<br>121 SW Morrison Street<br>11th Floor<br>Portland, OR 97204 | Flour Mill Building<br>1000 Potomac Street<br>N.W., Suite 200<br>Washington, D.C. 20007 | 100 Wall Street<br>20th Floor<br>New York, NY 10005 | 618 West Riverside<br>Avenue, Suite 300<br>Spokane, WA 99201 | 821 South Tower Beijing<br>Kerry Center 1 Guang<br>Hua Road Chaoyang<br>District Beijing, PRC<br>100020 |
| T: 206.447.4400<br>F: 206.447.9700 | T: 503.228.3939<br>F: 503.226.0259 | T: 202.965.7880<br>F: 202.965.1729 | T: 212.431.8700<br>F: 212.334.1278 | T: 509.777.1600<br>F: 509.777.1616 | T: 86.10.8529.9880<br>F: 86.10.8529.9881 |