

October 11, 2018

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

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

Dear Sir or Madam,

Prime Label Consultants, Inc. submits these comments in response to the FDA's Multi-Year Nutrition Innovation strategy. We appreciate the FDA's work on this program and support their goal to reduce the burden of chronic disease through improved nutrition. The suggestions we outline below are inspired by key elements of FDA's strategy – modernizing standards of identity, modernizing claims, and modernizing ingredient labels.

### **Modernizing Standards of Identity**

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#### *Peanut Butter* (21 CFR 164.150)

We suggest modernizing this standard by allowing the use of non-hydrogenated oils in peanut butter. Currently, the only oils permitted as optional stabilizing ingredients in peanut butter are hydrogenated and partially hydrogenated oils.

Solid fats, such as hydrogenated oils, are a source of saturated fat in the diet. Partially hydrogenated oils are a source of trans fat in the diet. Allowing the use of non-hydrogenated oils within standardized peanut butter would give manufacturers an opportunity to better align with the 2015-2020 Dietary Guidelines for Americans, which identifies saturated fat as a source of empty calories and recommends limited consumption of both saturated and trans fats.

Today, manufacturers who want to make peanut butter with lower saturated fat content through the use of non-hydrogenated oils must label their products as “peanut spread.”

*Whole Wheat Bread*  
(21 CFR 136.180)

We suggest modernizing this standard by allowing very small amounts of refined wheat in whole wheat bread. The FDA could also create a regulatory distinction between “whole wheat bread” (which could be made with very small amounts of refined wheat) and “100% whole wheat bread” (which could not be made with any amount of refined wheat). Currently, the standard does not allow for any amount of refined wheat.

Increasing whole grain consumption is one of the recommendations outlined in the 2015-2020 Dietary Guidelines for Americans. An updated whole wheat bread standard could help consumers identify products that are overwhelmingly whole wheat, but which contain a small amount of refined wheat.

This change is needed due to innovations in the food industry. Bread manufacturers increasingly utilize functional ingredients derived from refined wheat (e.g. cultured wheat flour) and functional ingredients premixed with small amounts of refined wheat (e.g. baking enzymes mixed with a wheat-based carrier, such as wheat starch). These minor sources of refined wheat often disqualify products from being labeled as “whole wheat” regardless of their total whole wheat content.

*Artificially Sweetened Canned Fruits*  
(21 CFR 145.116; §145.126; §145.131; §145.136; §145.171; §145.176; §145.181)

We suggest modernizing these standards by giving manufacturers more options for naming artificially sweetened canned fruits. Specifically, we propose manufacturers be allowed to identify the sweetener used in lieu of “artificially sweetened.” With this change, canned pears sweetened with saccharin could use either “pears sweetened with saccharin” or “artificially sweetened pears” for their statement of identity.

This change would give consumers additional information about the artificial sweetener used in the products. It may also make artificially sweetened canned fruits more attractive to consumers. The 2015-2020 Dietary Guidelines for Americans identifies added sugars as a source of empty calories and recommends limited consumption. Artificially sweetened canned fruit is lower in added sugars than traditional canned fruit.

*Milk Chocolate, White Chocolate, Sweet Chocolate, Semisweet, and Bittersweet Chocolate  
(21 CFR 163.130; §163.124; §163.123)*

We suggest modernizing these standards by permitting the use of non-nutritive sweeteners in standardized chocolate products, so long as the labeling makes this clear to consumers.

The 2015-2020 Dietary Guidelines for Americans identifies added sugars as a source of empty calories and recommends limited consumption. Non-nutritive sweeteners could be used to create standardized chocolate products with lower added sugars content.

## **Modernizing Claims**

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*New Sugar and Added Sugar Nutrient Content Claims*

We suggest the FDA establish additional nutrient content claims for sugar and added sugar, such as “low in sugar,” “low in added sugars,” “reduced sugar,” and “reduced added sugars.”

The 2015-2020 Dietary Guidelines for Americans identifies added sugars as a source of empty calories and recommends limited consumption. New nutrient content claims for sugar and added sugars could enable consumers to more easily identify products that are lower in sugar.

*“No Added Sugar”  
(21 CFR 101.60)*

We suggest revising this claim to allow its use whenever a product has a nutritionally insignificant level of added sugars per reference amount customarily consumed and per labeled serving. Negligible sources of added sugar could be identified within the ingredient listing using asterisks that refer to a statement such as “Adds a trivial amount of added sugars.” This would mirror the approach FDA uses for several other nutrient content claims, such as “fat free,” “saturated fat free,” and “cholesterol free.” Currently, even a trivial amount of added sugars disqualifies a product from using a “no added sugar” claim.

The existing requirements for “no added sugar” appear to treat added sugar as an ingredient, rather than as a nutrient. Because added sugars now appears in the Nutrition Facts label, we believe the claims’ requirements should more closely resemble other nutrient content claims.

The 2015-2020 Dietary Guidelines for Americans identifies added sugars as a source of empty calories and recommends limited consumption. An updated “no added sugar” claim could help consumers more easily identify products that are largely free of added sugars.

### *“Net Carbs”*

We suggest the FDA provide guidance on the use of “net carbs” claims. We have observed an increasing number of these claims in the marketplace and believe clear, consistent guidance from the FDA could help companies make truthful and not misleading labels. Thus far, guidance has come primarily through Warning Letters. The FDA currently appears to use enforcement discretion when net carbs claims are presented as factual statements and accompanied by an equation or explanation of how the net carbs are calculated.

## **Modernizing Ingredient Labels**

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### *Vitamins and Minerals*

We support the idea presented by FDA to allow vitamins and minerals to be declared by names more commonly understood by consumers. For example, using the name “vitamin B6” for “pyridoxine” and using the name “vitamin B12” for “cyanocobalamin.”

### *Oils*

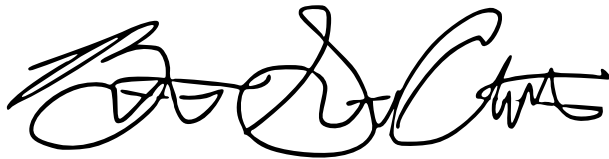
We request added clarity on whether the common and usual name of high oleic oils must include “high oleic.” Currently, some manufacturers are hesitant to use high oleic oils due to confusion concerning how they must be labeled. Other manufacturers worry consumers may misinterpret “high oleic” to be a negative attribute.

High oleic oils are often rich in monounsaturated and polyunsaturated fats. Many contain lower levels of saturated fat than their conventional counterparts. Increased use of high oleic oils aligns with the 2015-2020 Dietary Guidelines for Americans, which recommends replacing saturated fats in the diet with monounsaturated and polyunsaturated fats.

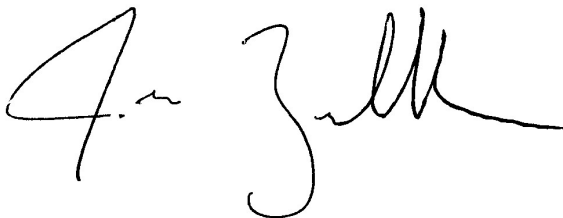
Regardless of the FDA’s decision in this case, more guidance on labeling high oleic oils may lead to more manufacturers using them to replace oils with higher saturated fat contents.

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We appreciate this opportunity to comment on FDA's Multi-Year Nutrition Innovation Strategy. Our hope is that these comments help the agency as they seek to reduce the burden of chronic disease through improved nutrition. Please feel free to reach out to Prime Label Consultants if you have any questions or concerns.



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