

Application No.	Drug	Applicant
ANDA 077312 ....	Fentanyl Citrate Troche/Lozenge, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base, EQ 1.2 mg, and EQ 1.6 mg base.	Par Pharmaceutical, Inc., One Ram Ridge Rd., Chestnut Ridge, NY 10977.
ANDA 077853 ....	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g .....	Provident Pharmaceutical, Inc., c/o Vintage Pharmaceuticals, LLC, 1400 Atwater Dr., Malvern, PA 19355.
ANDA 080355 ....	Hydrocortisone Tablets USP, 20 mg .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., Morris Corporate Center III, 400 Interpace Pkwy., Parsippany, NJ 07054.
ANDA 080377 ....	Lidocaine HCl with Epinephrine Injection, 1%; 0.01 mg/mL and 2%; 0.01 mg/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087100 ....	Chlorthalidone Tablets USP, 25 mg .....	Do.
ANDA 087211 ....	Methocarbamol and Aspirin Tablets, 400 mg/325 mg .....	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 090184 ....	Podofilox Topical Solution, 0.5% .....	Bausch & Lomb, Inc., Subsidiary of Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 202002 ....	Imiquimod Cream, 5% .....	Strides Pharma Global Pte Ltd., c/o Strides Pharma, Inc., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.
ANDA 203247 ....	Sodium Fluoride F-18 Injection, 10–200 millicurie (mCi)/mL ..	University of Texas MD Anderson Cancer Center, Cyclotron Radiochemistry Facility, 1881 East Rd., Unit 1903, Houston, TX 77054.
ANDA 203933 ....	Ammonia N-13 Injection, 3.75–37.5 mCi/mL .....	Do.
ANDA 205072 ....	Cefadroxil Capsules USP, EQ 500 mg base .....	CSPC Ouyi Pharmaceutical Co., Ltd., c/o Megalith Pharmaceuticals, Inc., 9625 Hillside Rd., Rancho Cucamonga, CA 91737.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 29, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on October 29, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 25, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–21199 Filed 9–27–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–3522]

#### Use of the Names of Dairy Foods in the Labeling of Plant-Based Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or we) invites comments on the labeling of plant-based products with names that include the

names of dairy foods such as “milk,” “cultured milk,” “yogurt,” and “cheese.” We are interested in learning how consumers use these plant-based products and how they understand terms such as, for example, “milk” or “yogurt” when included in the names of plant-based products. We also are interested in learning whether consumers are aware of and understand differences between the basic nature, characteristics, ingredients, and nutritional content of plant-based products and their dairy counterparts. We are taking this action to inform our development of an approach to the labeling of plant-based products that consumers may substitute for dairy foods.

**DATES:** Submit either electronic or written comments on this document by November 27, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 27, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 27, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2018–N–3522 for “Use of the Names of Dairy Foods in the Labeling of Plant-Based Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Mabel Lee, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Introduction*

Over the past several years, there has been an emergence and expansion of plant-based products labeled with names that include the names of dairy foods such as “milk” (e.g., “soy milk,” “almond milk”), “cultured milk” (e.g., “coconut kefir”), “yogurt” (e.g., “soy yogurt,” “almond milk yogurt”), and “cheese” (e.g., “vegan mozzarella cheese”). These products are often packaged in the same kinds of cartons, tubs, or bottles as their dairy counterparts and sometimes are sold in or adjacent to the dairy display in stores. However, these plant-based products may not have the same basic nature, essential characteristics, and characterizing ingredients as their dairy counterparts and may differ in their performance characteristics (e.g., physical properties, flavor characteristics, functional properties, or shelf life) such that they are not suitable substitutes for certain uses. Some plant-based products also may contain less nutrients than their dairy counterparts and may not meet the recommendation for dairy food group intake in the “2015–2020 Dietary Guidelines for Americans” (Dietary Guidelines) (Ref. 1).

We are interested in learning how consumers use these plant-based products and how they understand terms such as, for example, “milk” or “yogurt” when included in the labeling of plant-based products. We are interested in learning whether consumers are aware of and understand the basic nature, essential characteristics, characterizing ingredients, and nutritional differences between plant-based products and dairy foods.

*B. Legal Authority*

1. What is FDA’s statutory and regulatory authority relating to the naming of food?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides for two general categories of food: Standardized food and nonstandardized food. (See sections 401 and 403(g), (h), and (i) of the FD&C Act (21 U.S.C. 341 and 343(g), (h), and (i)).) Both standardized foods and nonstandardized foods are generally named by their common or usual names. When a food is standardized, the

standard is promulgated in a regulation under the common or usual name of the food under section 401 of the FD&C Act. The common or usual name of the food must be declared on the principal display panel of the label when the food is in package form. (See § 101.3(b)(1) (21 CFR 101.3(b)(1).) Foods that are not standardized are also required to bear the common or usual name of the food on their labels when such a name exists (section 403(i)(1) of the FD&C Act and § 101.3(b)(2)). The common or usual name of a food is the name by which it is known to the American public and is generally established by common usage (§ 102.5(d) (21 CFR 102.5(d)).

However, in certain instances where the common or usual name of a nonstandardized food is found to be misleading or to cause confusion,<sup>1</sup> we have established a new common or usual name by regulation (see 21 CFR part 102, subpart B). When establishing the name, we consider the principles set forward in § 102.5(a) through (c), such as whether the name accurately identifies the food or describes its basic nature or characterizing properties or ingredients. We also consider whether the name is uniform among similar products and is not confusingly similar to the name of any other food that is not reasonably encompassed within the same name. The common or usual name established by regulation is then the name required to be declared on the label of the food (§ 101.3(b)(1)).

2. What is FDA’s statutory and regulatory authority regarding food standards?

Our authority to establish food standards is set forth in section 401 of the FD&C Act, which provides, in part, that to promote honesty and fair dealing in the interest of consumers we can promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.

Under section 403(g) of the FD&C Act, a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulation, unless it conforms to such definition and standard. Misbranded food is prohibited from introduction or delivery for introduction into interstate commerce (section 301(a) of the FD&C Act) (21 U.S.C. 331(a)). The factors considered

<sup>1</sup> The FD&C Act prohibits labeling that is false or misleading (sections 403(a)(1) and 201(n) of the FD&C Act).

in determining whether a food purports to be or is represented as a standardized food are not limited to the name or labeling of the food; other factors (for example, location in the grocery store or appearance of the package or container) may be relevant.

### 3. FDA's Standard of Identity Regulations for Certain Dairy Foods: Milk, Cultured Milk, Yogurt, and Cheese

Standards of identity are established for milk and cream in 21 CFR part 131, subpart B. Each of these standards requires the use of milk or ingredients derived from milk (e.g., cream, nonfat milk). In this document, we discuss the standards of identity for milk, cultured milk, yogurt, lowfat yogurt, and nonfat yogurt for illustration purposes. We also discuss 21 CFR part 133, which sets forth definitions and standards of identity for cheeses and related cheese products.

Milk is a standardized food and is described in § 131.110(a) (21 CFR 131.110(a)), in part, as the lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy cows. Generally, milk serves as a dietary source of protein, calcium, vitamin A, and potassium. The standard of identity permits optional fortification with vitamins A and D to increase nutrient content (§ 131.110(b)). The common or usual name of food that purports to be or is represented as milk and conforms to the standard of identity is "milk."

Cultured milk is a standardized food and is produced by culturing cream, milk, partially skimmed milk, and/or skim milk with characterizing microbial organisms (§ 131.112(a) and (c) (21 CFR 131.112(a) and (c))). The standard of identity permits optional fortification with vitamins A and D to increase nutrient content (§ 131.112(b)). The common or usual name of a food that purports to be or is represented as cultured milk and conforms to the standard of identity is "cultured milk." However, the name of the food may be accompanied by a declaration such as the traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., "kefir cultured milk" (§ 131.112(f)).

Yogurt is a standardized food produced by culturing cream, milk, partially skimmed milk, and/or skim milk with a characterizing bacterial culture (§ 131.200(a) (21 CFR 131.200(a))). The common or usual name of a food that purports to be or is represented as yogurt and conforms to the standard of identity is "yogurt."

Lowfat yogurt and nonfat yogurt are also standardized foods produced by culturing cream, milk, partially skimmed milk, and/or skim milk with a characterizing bacterial culture (§ 131.203(a) and § 131.206(a) (21 CFR 131.203(a) and 131.206(a))); their common or usual names are "lowfat yogurt" and "nonfat yogurt," respectively. We note that certain provisions of the standards of identity for yogurt, lowfat yogurt, and nonfat yogurt have been stayed (47 FR 41519, September 21, 1982). We also note that, in the **Federal Register** of January 15, 2009 (74 FR 2443), we issued a proposed rule that would amend the standard of identity for yogurt and revoke the standards of identity for lowfat yogurt and nonfat yogurt. Revocation of the standards of identity for lowfat yogurt and nonfat yogurt would result in lower fat yogurt products being covered under the general standard in § 130.10 (21 CFR 130.10).

Standards of identity are established for cheeses and related cheese products in 21 CFR part 133, subpart B. Each of these standards requires the use of milk or ingredients derived from milk (e.g., cream, nonfat milk). Milk is defined in § 133.3(a) (21 CFR 133.3(a)), in part, as the lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy cows. However, some standardized cheeses (e.g., Caciocavallo siciliano cheese (§ 133.111 (21 CFR 133.111)) and mozzarella cheese (§ 133.155 (21 CFR 133.155)) allow for the use of milk from other mammals like sheep, goat, or water buffalo. When cheese is made from sheep's milk, goat's milk, or water buffalo's milk, the animal source of the milk is often declared on the label in conjunction with the name of the cheese (e.g., see § 133.111(e)). The common or usual name of a food that purports to be or is represented as a standardized cheese or cheese product and conforms to the standard of identity is the name specified in the corresponding standard (e.g., cheddar cheese, provolone cheese, and swiss cheese).

Standardized foods that have been modified in accordance with a nutrient content claim defined by regulation (e.g., "low fat," "skim") and that substitute for the standardized food are subject to the general standard under § 130.10. If the modification results in loss of essential nutrients, the general standard requires the nutrients to be restored so that the modified food is not nutritionally inferior to the standardized food (§ 130.10(b)). Both the nutrient content claim and the name of the standardized food are included in the

name of the modified food (e.g., "low fat milk," "skim milk"). In general, a standardized food that has been modified in accordance with a nutrient content claim defined by regulation and that substitutes for the standardized food is subject to the general standard under § 130.10, unless a specific standard of identity related to the modification exists (e.g., lowfat yogurt, nonfat yogurt, low sodium cheddar cheese).

Plant-based products that resemble dairy foods, such as milk, cultured milk, yogurt, and cheese do not have standards of identity, and therefore are nonstandardized foods. Thus, these foods are subject to section 403(i)(1) of the FD&C Act and their labels must bear the common or usual name of the food.

## II. Additional Issues for Consideration and Request for Information

We invite comment, particularly data and other evidence, about: (A) The current market conditions and labeling costs of plant-based products; (B) consumer understanding, perception, purchase, and consumption of plant-based products, particularly those manufactured to resemble dairy foods such as, for example, milk, cultured milk, yogurt, and cheese; (C) consumer understanding regarding the basic nature, characteristics, and properties of these plant-based products; (D) consumer understanding of the nutritional content of plant-based products and dairy foods and the effect, if any, on consumer purchases and use; and (E) the role of plant-based products and dairy foods in meeting the recommendations in the Dietary Guidelines (Ref. 1). Specifically, we are interested in responses to the following questions. In responding to these questions, please identify the question by its associated letter and number (such as "B.1") so that we can easily associate your response with a specific question.

### A. The Current Market Conditions and Labeling Costs of Plant-Based Products

1. How many different types of plant-based products that are manufactured to resemble dairy foods such as, for example, milk, cultured milk, yogurt, and cheese, are on the market? Please provide any data or evidence to support your answer.

2. What percentage of each subclass (e.g., soy or almond) of plant-based products is marketed as a substitute for its dairy counterpart (e.g., milk, cultured milk, yogurt, or cheese)? What percentages of each subclass of plant-based products are marketed with names that include the name of a dairy

food (e.g., “milk”) versus names that include another term (e.g., “beverage” or “drink”)? Please provide any data or evidence to support your answer.

3. What are the costs associated with label changes? How often are labels revised?

4. How are plant-based products displayed in stores? For example, are they sold in grocery stores next to or mixed with their dairy counterparts or are they sold in areas of the store that are separate or distinct from the areas where their dairy counterparts are sold? Does the packaging or display of these plant-based products affect consumers’ perception or expectation about the nutritional properties or performance of these products?

*B. Consumer Understanding, Perception, Purchase, and Consumption of Plant-Based Products, Particularly Those Manufactured To Resemble Dairy Foods Such as, for Example, Milk, Cultured Milk, Yogurt, and Cheese*

1. Why do consumers purchase and consume these types of plant-based products? How do they use these products? Specifically, do consumers purchase these plant-based products for use as substitutes for their dairy counterparts, or do consumers purchase these plant-based products for distinct uses? If consumers use these plant-based products as substitutes for dairy foods (for example plant-based beverages as alternatives to milk), what are their reasons? Do consumers think they are healthier, and if so, why? Are consumers purchasing these plant-based products because they may be allergic to dairy or are lactose-intolerant? Are consumers purchasing these plant-based products for reasons related to their personal consumption habits, such as a vegan diet? If consumers do not use these plant-based products as substitutes for dairy foods, what are their reasons for choosing these products? (For example, do these products provide unique taste, flavor, or texture?) Does consumer purchasing behavior differ if the consumer is purchasing the product for himself/herself as opposed to purchasing the product for a family member? Please provide any data or evidence to support your answer.

2. Do consumers perceive these plant-based products to be more nutritious, as nutritious, or less nutritious than their dairy counterparts? If consumers perceive these plant-based products to be more nutritious or as nutritious as their dairy counterparts, to what extent does this affect their decision to buy plant-based products? Please provide

any data or evidence to support your answer.

3. Do consumers perceive or expect these plant-based products to perform in the same manner as their dairy counterparts? For example, milk can be an ingredient in preparing other foods. Do consumers expect plant-based beverage products to perform in the same manner as milk when preparing other foods or in recipes that use milk? Please provide any data or evidence to support your answer.

4. How do consumers perceive or understand labeling of these plant-based products? For example, do consumers perceive the labeling as suggesting that these plant-based products are equivalent to or can be substituted for their dairy counterparts? Do consumers perceive the labeling as suggesting that plant-based products are different or distinct from their dairy counterparts? Please provide any data or evidence to support your answer.

5. We are aware that some plant-based beverage manufacturers use the term “milk” as part of the name of these foods while other manufacturers use terms such as “beverage” or “drink” as part of the name of these foods. Do consumers perceive plant-based beverages to be different if the term “milk” is used instead of “beverage” or “drink”? For example, how do consumers perceive or understand “soy milk” in comparison to “soy-based beverage” or “soy drink”? Please provide any data or evidence to support your answer.

*C. Consumer Understanding Regarding the Basic Nature, Characteristics, and Properties of Plant-Based Products*

1. What do consumers believe to be the basic nature, characteristics, or properties of plant-based products manufactured to resemble dairy foods such as, for example, milk, cultured milk, yogurt, and cheese? Is consumer understanding of the basic nature of plant-based products influenced by inclusion of terms such as milk, cultured milk, yogurt, and cheese in the names in the labeling of these products? Do consumers expect plant-based products labeled with such names to have physical characteristics, performance characteristics, or properties of their dairy counterparts? If so, in what ways? Please provide any data or evidence to support your answer.

2. What do consumers believe are the main ingredients of plant-based products? What do consumers understand/think about the different protein sources being used to make these plant-based products? Do they

understand that some of these plant-based products contain proteins from more than one plant source (e.g., almond and pea protein)? Are these beliefs or understanding influenced by the inclusion of dairy food names, particularly “milk,” “cultured milk,” “yogurt,” or “cheese,” in the product name? Please provide any data or evidence to support your answer.

3. What is consumers’ understanding of the amount or proportion of plant-based ingredient(s) relative to other ingredients in plant-based products? Are consumers aware that other ingredients (e.g., emulsifiers, thickeners, sweeteners, and added nutrients such as vitamins and minerals) are used in the manufacture of these plant-based products? How does the use of these ingredients impact consumer perception of these products? Please provide any data or evidence to support your answer.

4. Do these plant-based products vary in ingredients, even when manufactured using the same type of plant source (e.g., soy or almond)? If so, how? What are consumers’ expectations regarding the ingredients of different brands of each subclass (e.g., soy or almond) of plant-based products? What impact, if any, does the compositional variation have on purchase and consumption decisions? Please provide any data or evidence to support your answer.

*D. Consumer Understanding of the Nutritional Content of Plant-Based Products and Dairy Foods and the Effect, if Any, on Consumer Purchases and Use*

1. Dairy foods, such as milk, cultured milk, yogurt, and cheese, may differ in nutritional content compared to plant-based products manufactured to resemble these dairy foods. What nutrients, if any, do consumers believe to be provided from dairy foods such as milk, cultured milk, yogurt, and cheese? What nutrients, if any, do consumers believe to be in plant-based products that resemble dairy foods, such as milk, cultured milk, yogurt, and cheese? Do consumers expect certain nutrients to be present in both plant-based products and their dairy counterparts, and, if so, what nutrients do they expect? Do these expectations change depending on the terms included in the names of plant-based products, e.g., “milk,” “beverage,” “drink,” “yogurt,” “yogurt alternative,” “vegan cheddar cheese,” “cheese shreds”? Please provide any data or evidence to support your answer.

2. Do parents and caregivers who purchase these plant-based products for young children or other family members

believe that these plant-based products are nutritionally equivalent to their dairy counterparts and can replace them as a food choice? Are expectations of nutritional equivalency a factor in parents' and caregivers' decisions to purchase these plant-based products as part of young children's or other family members' balanced diet? Please provide any data or evidence to support your answer.

3. Do these plant-based products vary in nutrient composition, even when manufactured using the same type of plant ingredients (e.g., soy or almond)? If so, how? What are consumers' expectations regarding the nutrient compositions of different brands of each subclass (e.g., soy or almond) of plant-based products? What impact, if any, does the compositional variation have on purchase and consumption decisions? Please provide any data or evidence to support your answer.

4. We are aware that the United States Department of Agriculture's National Nutrient Database for Standard Reference (USDA Nutrient Database) provides information about the nutritional content of dairy foods as well as some plant-based products that resemble dairy foods (Ref. 2). However, we believe the USDA Nutrient Database may not be a full representation of all the varieties of dairy foods, including milk, cultured milk, yogurt, cheese, and of the plant-based products manufactured to resemble these dairy foods, currently in the United States marketplace. We are interested in any data regarding the nutritional profiles of different dairy foods, such as, for example, milk, modified milk, cultured milk, yogurt, and cheese products, and any data regarding the nutritional profiles of the various plant-based products that resemble dairy foods, including fortified versions of those plant-based products. We are particularly interested in obtaining data that compares the amounts of protein, calcium, vitamin D, and potassium in these plant-based products and their dairy counterparts.

5. How do the protein qualities of plant-based products compare to their dairy counterparts? How does the variation, if any, impact consumer perception, and purchasing and consumption decisions? Please provide any data or evidence to support your answer.

#### *E. The Role of Plant-Based Products and Dairy Foods in Meeting the Recommendations in the Dietary Guidelines*

The Dietary Guidelines contain nutritional and dietary information and

guidelines for the public. The Dietary Guidelines are based on the preponderance of current scientific and medical knowledge and are intended to help individuals ages 2 years and older consume a healthy, nutritionally adequate diet. As part of these recommendations, the Dietary Guidelines refer to several "food groups," including a "dairy group," which includes fortified soy beverages. [Note: Although the Dietary Guidelines refer to a "dairy group," as indicated in section I.A., by "dairy foods," FDA is referring to foods such as milk, cheese, and yogurt, and not to their plant-based counterparts.]

The Dietary Guidelines state that healthy eating patterns in the dairy group include fat-free and low-fat (1 percent) dairy, including milk, yogurt, cheese, or fortified soy beverages (see Ref. 1 at page 23). The Dietary Guidelines explain that soy beverages fortified with calcium, vitamin A, and vitamin D, are included as part of the dairy group because they are similar to fortified low- and non-fat milk based on nutrient composition and in their use in meals. The Dietary Guidelines also state that other plant-based beverages sold as "milks" (such as almond, rice, coconut, and hemp "milks") are not included as part of the dairy group because their overall nutritional content is not similar to that of milk and fortified soy beverages (id.).

According to the Dietary Guidelines, the key nutrient contributions in the dairy group include calcium, phosphorus, vitamin A, vitamin D (in products fortified with vitamin D), riboflavin, vitamin B12, protein, potassium, zinc, choline, magnesium, and selenium (id.).

1. Do consumers understand that certain plant-based products might have a nutritional content that is not adequate to place them in the dairy group as described in the Dietary Guidelines? How does this influence their purchasing behavior with respect to plant-based products and dairy foods? Please provide any data or evidence to support your answer.

2. Do consumers who purchase or consume plant-based products instead of dairy foods, such as yogurt or cheese, believe that these plant-based products meet the dairy group recommendation described in the Dietary Guidelines? Please provide any data or evidence to support your answer.

#### **III. References**

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between

9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans, 2015–2020." Eighth Edition, December 2015. Accessed online at <https://health.gov/dietaryguidelines/2015/guidelines/>.
2. U.S. Department of Agriculture. National Nutrient Database for Standard Reference (Release 23), Food items with NDB Numbers: 01077, 01079, 01082, 01085, 16222, 16229, 16230, 14091, and 14639 accessed online at <http://www.nal.usda.gov/fnic/foodcomp/search> on August 1, 2018.

Dated: September 25, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–21200 Filed 9–27–18; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket Nos. FDA–2018–N–0073; FDA–2018–N–0074; FDA–2010–N–0155; FDA–2014–N–0987; FDA–2016–D–1164; FDA–2014–N–2029; FDA–2012–N–0369; FDA–2017–N–6730; FDA–2009–N–0025; FDA–2014–N–2294; and FDA–2018–N–1129]

### **Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for