

Docket No. FDA-2018-N-3522

BEFORE

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

**USE OF THE NAMES OF DAIRY FOODS IN THE LABELING OF PLANT-BASED
PRODUCTS**

January 28, 2019

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Prefatory remarks

On September 28, 2018, the Food and Drug Administration (FDA or the Agency) issued a Federal Register notice (the September 28 Notice¹) in which the Agency invited 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.”

In the September 28 Notice FDA notes that foods, including both standardized foods and nonstandardized foods, are generally named by their common or usual names; are required to bear on their labels the common or usual name of the food when such a name is established by regulation (for standardized foods) or otherwise exists (for nonstandardized foods); that 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 (citing 21 C.F.R. § 102.5(d)); and that in certain instances where the common or usual name of a nonstandardized food has been found to be misleading or to cause confusion, the Agency has established a new common or usual name by regulation.²

In the September 28 Notice the Agency also expressed its interest 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, and 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. Of particular relevance to the present comments, the Agency states it is taking this action “to inform our development of an approach to the labeling of plant-based products that consumers may substitute for dairy foods” (emphasis added).

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products. AHPA’s

¹ 83 FR 49103. A subsequent notice of extension of time for submission of comments to this Docket was issued by the Agency on November 21, 2018 (83 FR 58775).

² The relevant rule at 21 CFR Part 102 Subpart B includes 16 such common or usual names established by regulation between 1977 and 1993 with several amended as recently as 2001.

members' herbal products are marketed as foods, dietary supplements, cosmetics, and occasionally as nonprescription drugs or in other product categories.

Since all herbs are plants, herbal products may be considered to be “plant-based products.” These comments are therefore submitted on behalf of AHPA’s members. These comments are narrowly focused on herbal ingredients that include in their common or usual names the names of dairy foods, and that are usually, but not always, found in products that are not generally used as substitutes for dairy foods or marketed to resemble dairy foods.

Recommendation and request

AHPA is recommending and requesting by these comments that FDA ensure that any rule or guidance document that results from the September 28 Notice makes completely clear that the Agency’s “approach to the labeling of plant-based products” applies only to any plant-based product and ingredient therein that is used as a substitute for or marketed to resemble a dairy product. AHPA is concerned that the absence of perfect clarity on this detail may result in regulatory uncertainty for companies that manufacture and market other products subject to FDA’s enforcement authority, or may present unwarranted opportunities for frivolous lawsuits.

AHPA’s concern in this matter is based on a review of how FDA uses the term “plant-based products” in the September 28 Notice. Most mentions of this term are modified to read, for example, “plant-based products that consumers may substitute for dairy foods” or “plant-based products that resemble dairy foods,” or are accompanied by additional words or context to make this limitation to dairy-food substitutes clearly implied. But a more than significant number of the mentions of the term “plant-based products” stand alone, without any such clarifying modifiers.

More specifically, AHPA recommends and requests that any rule or policy that results from the September 28 Notice:

- Include in its title the term “plant-based products marketed to resemble dairy foods” or “plant-based products that resemble dairy foods,” or some similar phrase that makes clear at the outset the limited scope of the rule or policy;

- Include language within the rule or policy to specify that it has no bearing on plant-based foods that are not generally used as dairy food substitutes; and
- Ensure that industry may continue to use long-established common or usual names that include dairy names for foods that may be used as dairy substitutes in some capacity but also have other significant and established food uses; examples may include coconut milk (used in coffee or simply as a beverage but also used as the base for many recipes such as curries) or almond or other nut butters (for spreading on bread or toast but also used in baked goods).

In support of this recommendation and request, AHPA is providing here non-exhaustive lists of examples of plant-based ingredients that include dairy names in their common or usual names but that are not, to the best of AHPA's knowledge, generally used as or in products that are used as substitutes for dairy foods or marketed to resemble dairy foods. In each of the examples here, AHPA provides several selected (and non-exhaustive) references that document that the name presented for each is, in fact, well established as a common or usual name for the listed plant-based ingredient. The selected references for each listed ingredient generally include one or more that document long-standing use of the listed common or usual name, as well as at least one reference that documents contemporary use of the listed common or usual name.

In reviewing the examples included here in preparation of these comments, AHPA observed that for the most part use of a dairy name as an adjective or other descriptive modifier presents very little to no chance that a common or usual name that includes a dairy name could be confused as the same ingredient as the named dairy food (e.g., "butter lettuce" or "milkweed"). FDA's regulatory approach therefore should not focus on the use of a dairy name used as an adjective in a common or usual name. At the same time, use of a dairy name as a modified noun in a common or usual name, especially one that has been long-established in English, should not automatically trigger any new regulatory or policy limits related to dairy names (e.g., "coconut milk" or "jojoba butter").

Note that these comments take no position and provide no commentary on the central issue of the September 28 Notice, that is, use of dairy names on products that are, in fact, most commonly used as substitutes for dairy foods or marketed to resemble dairy foods but consist entirely of plant-based ingredients.

Dairy names are used in the common or usual names of some plants used as dietary supplements and dietary ingredients

The Food, Drug and Cosmetic Act defines dietary supplements to include “an herb or other botanical” among other allowed ingredients.³

AHPA is aware of several plants that are used as such ingredients in herbal supplements in commerce in the United States, and that include names of dairy foods as part of their common or usual names. Illustrative examples include,⁴ but are not limited to, such that these examples should not be considered to be an exhaustive list of such plants, the following:

- *Asclepias* spp. The common or usual name of this genus is “milkweed.” The common or usual names of various species within the genus are modified forms of this name, such as “swamp milkweed” (*A. incarnata*) and “pine-needle milkweed” (*A. linaria*). Selected references, including some that also document use as a food, include:
 - Hobbs CE. 1876. *C.E. Hobbs’ botanical hand-book of common local, English, botanical and pharmacopoeial names*. Page 114.
 - Muenscher WC and Rice MA. 1955. *Garden spice and wild pot-herbs*. Page 191.
 - Steinmetz EF. 1957. *Codex vegetabilis*. Numbers 152, 153, 154.
 - Fernald ML and Kinsey AC. 1958. *Edible wild plants of eastern North America*, revised edition. Page 323.
 - Harrington HD. 1967. *Edible native plants of the Rocky Mountains*. Page 113.
 - Kavasch B. 1979. *Native harvests*. Pages 47, 48.
 - American Herbal Products Association. 2000. *Herbs of commerce* 2nd edition. Pages 21, 246, 260, 283.
 - USDA Natural Resources Conservation Service; National Plant Data Team. 2019. The PLANTS Database; specific entry accessed January 5, 2019: <https://plants.sc.egov.usda.gov/core/profile?symbol=ASCLE>.

³ 21 U.S.C. § 321(ff)(1)(C).

⁴ Note that several of the species listed here also have food uses. Such use is indicated in the cited references though these species are not listed again in the next section of these comments.

- *Juglans cenarea*. The common or usual name of this tree is “butternut.” Selected references, including some that also document use as a food, include:
 - Wood GB and Bache F. 1833. *The Dispensatory of the United States of America*. Page 372.
 - Hobbs CE. 1876. *C.E. Hobbs’ botanical hand-book of common local, English, botanical and pharmacopoeial names*. Page 125.
 - Hedrick UP. 1919. *Sturtevant’s notes on edible plants*. Page 319.
 - Steinmetz EF. 1957. *Codex vegetabilis*. Number 605 (as American butternut).
 - Fernald ML and Kinsey AC. 1958. *Edible wild plants of eastern North America*, revised edition. Page 149.
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 564.
 - American Herbal Products Association. 1992. *Herbs of commerce* 1st edition. Pages 12, 39.
 - American Herbal Products Association. 2000. *Herbs of commerce* 2nd edition. Pages 81, 179.
 - USDA Natural Resources Conservation Service; National Plant Data Team. 2019. The PLANTS Database; specific entry accessed January 5, 2019: <https://plants.sc.egov.usda.gov/core/profile?symbol=JUCL>.

- *Petasites* spp. The common or usual name of this plant is “butterbur.” The common or usual names of some species within the genus are modified forms of this name, such as “Arctic butterbur” (*P. frigidus*) and “purple butterbur” (*P. hybridus*). Selected references include:
 - Bailey LH and Bailey EZ. 1941. *Hortus second*. Page 552.
 - Kelsey HP and Dayton WA. 1942. *Standardized plant names*, second edition. Page 474.
 - Steinmetz EF. 1957. *Codex vegetabilis*. Number 815.
 - American Herbal Products Association. 2000. *Herbs of commerce* 2nd edition. Pages 109, 165, 264.
 - USDA Natural Resources Conservation Service; National Plant Data Team. 2019. The PLANTS Database; specific entry accessed January 5, 2019: <https://plants.sc.egov.usda.gov/core/profile?symbol=PETAS>.

- *Silybum marianum*. The common or usual name of this plant is “milk thistle.” Selected references, including some that also document use as a food, include:

- Jepson WL. 1925. *A manual of the flowering plants of California*. Page 1161.
- Steinmetz EF. 1957. *Codex vegetabilis*. Number 1064.
- Clarke CB. 1977. *Edible and useful plants of California*. Pages 220-222.
- Couplan F. 1998. *The encyclopedia of edible plants of North America*. Page 447.
- American Herbal Products Association. 1992. *Herbs of commerce* 1st edition. Pages 46, 65.
- American Herbal Products Association. 2000. *Herbs of commerce* 2nd edition. Pages 135, 246.
- USDA Natural Resources Conservation Service; National Plant Data Team. 2019. The PLANTS Database; specific entry accessed January 5, 2019: <https://plants.sc.egov.usda.gov/core/profile?symbol=SILYB>.

Dairy names are used in the common or usual names of some plants used as conventional foods and their ingredients

AHPA is also aware of several plants that are used as conventional foods or as ingredients in such foods in commerce in the United States, and that include names of dairy foods as part of their common or usual names. Illustrative examples include, but are not limited to, such that these examples should not be considered to be an exhaustive list of such plants, the following:

- *Arachis hypogaea*. The common or usual name of the ground seeds of this plant when used as food is “peanut butter.”⁵ Selected references include:
 - Wiley HW. 1907. *Foods and their adulteration*. Page 412.
 - Davis A. 1954. *Let’s eat right to keep fit*. Pages 32, 42, 43, 101.
 - Pillsbury A. 1954. *1954 Grand National recipe book*. Page 78.
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 564.

⁵ The listing here is representative of various nut “butters” widely marketed in the United States, including for example almond butter, cashew butter and sunflower (or sunflower seed) butter. Note that FDA itself referred to “almond butter,” “cashew butter,” and “hazelnut butter” in Table 2L of a document issued as Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry; accessed January 21, 2019 at <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517402.pdf>.

- USDA ARS. Nutrient Data Laboratory. 2019. USDA Food Composition Databases; specific entry accessed January 21, 2019:
https://ndb.nal.usda.gov/ndb/search/list?SYNCHRONIZER_TOKEN=341ea07e-5020-4ff1-88a7-36a0bf9f8991&SYNCHRONIZER_URI=%2Fndb%2Fsearch%2Fadvanced&q=&qp=peanut+butter&q=&qn=&ing=&ing=on&ds=BF&manu=&new=0&max=25&qlookup=afi%3A%28+%2B%22peanut+butter%22++%29&qt=standard&field=afi; reported 3,640 branded food products labeled as “peanut butter” or with “peanut butter” as a declared ingredient.
- NOTE: 21 C.F.R. § 164.150 provides a description of “peanut butter” as a standardized food.

- *Cocos nucifera*. The edible portion of the fruit of this plant is used to make food ingredients with common or usual names of “coconut butter,” “coconut cream,” and “coconut milk.” Selected references include:
 - Bentley R. 1877. *A manual of botany*, 5th edition. Page 712 (milk and butter).
 - Wiley HW. 1907. *Foods and their adulteration*. Page 411 (coconut butter).
 - Anon. 1946. *Trader Vic’s book of food & drink*. Page 149 (coconut cream).
 - Anon. (Staff of *The Journal of Living*). 1948. *The economy cookbook*. Page 117 (coconut milk).
 - Kennedy N. 1950. *The Ford treasury of favorite recipes from famous eating places*. Pages 206 (coconut milk), 243 (cream of coconut).
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 566 (coconut cream and coconut milk); page 567 (coconut butter).
 - USDA ARS. Nutrient Data Laboratory. 2019. USDA Food Composition Databases; several entries accessed January 21, 2019, reported 21 branded food products labeled as “coconut cream” from 11 named manufacturers; 232 branded food products labeled as “coconut milk” or as a food with “coconut milk” and other ingredients from 74 named manufacturers; and 13 branded food products labeled as “coconut butter” from seven named manufacturers; note this search did not include food ingredients in the search parameters so it only returned products with these terms in the product name.

- *Cucurbita maxima* (various cultivars). One of the common or usual names for this variety of winter squash is “buttercup squash.” Selected references include:
 - Clark DE (executive editor). 1967 (1976). *Sunset western garden book*, third edition, fourteenth printing (updated). Page 421.
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 328.
 - Anon. (Staff of *Organic Gardening* magazine). 1978. *The encyclopedia of organic gardening*, new revised edition. Page 1073.
 - Fossum C (managing editor). 1979. *Pillsbury Kitchens’ family cookbook*. Page 615.
 - A Google search for the term “buttercup squash recipes” returned “about 2,100,000 results;” search conducted January 21, 2019:
<https://www.google.com/search?q=buttercup+squash+recipes&oq=buttercup+squash+recipes&aqs=chrome..69i57j0l5.10111j0j9&sourceid=chrome&ie=UTF-8>.

- *Cucurbita moschata* (various cultivars). One of the common or usual names for this variety of winter squash is “butternut squash.” Selected references include:
 - Clark DE (executive editor). 1967 (1976). *Sunset western garden book*, third edition, fourteenth printing (updated). Page 421.
 - Nichols NB. 1972. *Farm Journal’s country cookbook*, revised, enlarged edition. Page 169.
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 328.
 - Anon. (Staff of *Organic Gardening* magazine). 1978. *The encyclopedia of organic gardening*, new revised edition. Page 1073.
 - Fossum C (managing editor). 1979. *Pillsbury Kitchens’ family cookbook*. Page 615.
 - USDA ARS. Nutrient Data Laboratory. 2019. USDA Food Composition Databases; specific entry accessed January 21, 2019:
https://ndb.nal.usda.gov/ndb/search/list?format=&count=&max=25&sort=man_s&fgcd=&manu=&qlookup=af%3A%28+%2B%22butternut+squash%22++%29&ds=BF&qt=standard&qp=&qa=&qn=&q=&ing=&order=asc;
reported 155 branded food products labeled as “butternut squash” or as a food with “butternut squash” and other ingredients; note this search did not include food ingredients in the search parameters so it only returned products with this term in the product name.

- *Lactuca sativa* (various cultivars). Numerous of the cultivars of lettuce are known by the common or usual name “butter lettuce,” “butterhead lettuce,” or “buttercrunch lettuce.” Selected references include:
 - Blot P. 1863. *What to eat, and how to cook it*. Pages 184 and 200 (butter lettuce)
 - Clark DE (executive editor). 1967 (1976). *Sunset western garden book*, third edition, fourteenth printing (updated). Page 320 (butterhead and buttercrunch).
 - Riotte L. 1975 printing. *Planetary planting*. Page 90 (buttercrunch lettuce).
 - Anon. (Staff of *Organic Gardening* magazine). 1978. *The encyclopedia of organic gardening*, new revised edition. Page 672 (butterhead).
 - Markle GM, Baron JJ and Schneider BA. 1998. *Food and feed crops of the United States*, second edition, revised. Page 152 (butterhead lettuce).
 - USDA ARS. Nutrient Data Laboratory. 2019. USDA Food Composition Databases; specific entry accessed January 23, 2019: https://ndb.nal.usda.gov/ndb/search/list?format=&count=&max=25&sort=man_s&fgcd=&manu=&qlookup=butter+AND+lettuce&ds=BF&qt=&qp=&qa=&qn=&q=&ing=&order=desc; reported 12 branded food products labeled as “butter lettuce” from 11 named manufacturers; note this search did not include food ingredients in the search parameters so it only returned products with this term in the product name.

- *Phaseolus lunatus*. One of the common or usual names for the seeds of this plant when used as food is “butter bean.” Selected references include:
 - Lyons AB. 1900. *Plant names scientific and popular*. Page 284.
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 289.
 - Wiersema JH and León B. 1999. *World economic plants*. Page 375.
 - USDA ARS. Nutrient Data Laboratory. 2019. USDA Food Composition Databases; specific entry accessed January 21, 2019: https://ndb.nal.usda.gov/ndb/search/list?SYNCHRONIZER_TOKEN=dfb2900d-8e04-4f92-a55d-26a359e50031&SYNCHRONIZER_URI=%2Fndb%2Fsearch%2Fadvanced&q=&qp=butter+beans&qa=&qn=&ing=&ds=BF&manu=&new=0&max=25&qlookup=af%3A%28+%2B%22butter+beans%22++%29&qt=stand&rd; reported 42 branded food products labeled as “butter beans” from

26 named manufacturers; note this search did not include food ingredients in the search parameters so it only returned products with this term in the product name.

- *Theobroma cacao*. A common preparation derived from the seeds of this plant is known by the common or usual name of “cocoa butter.” Selected references include:
 - Bentley R. 1877. *A manual of botany*, 5th edition. Page 482.
 - Wiley HW. 1907. *Foods and their adulteration*. Page 410 (as “cacao butter”).
 - Steinmetz EF. 1957. *Codex vegetabilis*. Number 1136 (as “cacao-butter”).
 - Rombauer IS and Becker MR. 1975 printing. *Joy of cooking*. Page 565.
 - USDA ARS. Nutrient Data Laboratory. 2019. USDA Food Composition Databases; specific entry accessed January 21, 2019: https://ndb.nal.usda.gov/ndb/search/list?SYNCHRONIZER_TOKEN=49ac49ad-7e97-405e-b6d6-d5a0ea267a6d&SYNCHRONIZER_URI=%2Fndb%2Fsearch%2Fadvanced&q=&qp=cocoa+butter&qa=&qn=&ing=&ing=on&ds=BF&manu=&new=0&max=25&qlookup=afi%3A%28+%2B%22cocoa+butter%22++%29&qt=standard&field=afi; reported 15,178 branded food products with “cocoa butter” as a declared ingredient.

Dairy names are used in the common or usual names of some plants used as cosmetic ingredients

AHPA is also aware of several plants that are used as ingredients in cosmetics in commerce in the United States, and that include names of dairy foods as part of their common or usual names. Illustrative examples include, but are not limited to, such that these examples should not be considered to be an exhaustive list of such plants, coconut butter (*Cocos nucifera*; already addressed above), cocoa butter (*Theobroma cacao*; already addressed above), as well as the following examples:

- *Simmondsia chinensis*. A common preparation derived from the seeds of this plant is known by the common or usual name of “jojoba butter.” Selected references include:

- Leung AY and Foster S. 1996. *Encyclopedia of common natural ingredients used in food, drugs and cosmetics*, second edition. Page 322.
 - CIR Expert Panel. 2008. Final Report of the Cosmetic Ingredient Expert Panel: Safety Assessment of Simmondsia Chinensis (Jojoba) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Wax, Hydrogenated Jojoba Oil, Hydrolyzed Jojoba Esters, Isomerized Jojoba Oil, Jojoba Esters, Simmondsia Chinensis (Jojoba) Butter, Jojoba Alcohol, and Synthetic Jojoba Oil. 36 pages; cited as “Simmondsia Chinensis (Jojoba) butter” throughout.
 - A Google search for the term “jojoba butter’ cosmetic brands” returned “about 25,100 results;” search conducted January 27, 2019:
https://www.google.com/search?ei=gP9NXIm4G9i_0PEPkKaRuAQ&q=%22jojoba+butter%22+cosmetic+brands&oq=%22jojoba+butter%22+cosmetic+brands&gs_l=psy-ab.3...15346.17974..18912...0.0..0.100.624.6j1.....0....1..gws-wiz.YTgH5-FZ5wg.
- *Vitellaria paradoxa* subsp. *paradoxa* (syn. *Butyrospermum parkii*). A common preparation derived from the seeds of this plant is known by the common or usual name of “shea butter.” Selected references, including some that also document use as a food, include:
- Hedrick UP. 1919. *Sturtevant’s notes on edible plants*. Page 123 (as *Butyrospermum parkii*).
 - Irvine FR. 1948. The Indigenous Food Plants of West African Peoples, in *Journal of the New York Botanical Garden*, Vol. 49, No. 586. Page 231 (as *Butyrospermum parkii*).
 - Menninger EA. 1977. *Edible nuts of the world*. Page 31 (as *Butyrospermum parkii*).
 - A Google search for the term “shea butter’ cosmetic brands” returned “about 13,700,000 results;” search conducted January 27, 2019:
https://www.google.com/search?ei=qf1NXKLhLJas0PEPjbejwAs&q=%22shea+butter%22+cosmetic+brands&oq=%22shea+butter%22+cosmetic+brands&gs_l=psy-ab.3..35i302i39.8679.9290..10007...0.0..0.81.160.2.....0....1..gws-wiz.....0i71.DcDkES_fvJA.

Concluding statement

AHPA's recommendation and request as presented in these comments is simply that FDA ensure that any rule or guidance that results from the September 28 Notice makes completely clear that the Agency's "approach to the labeling of plant-based products" applies only to any plant-based product and ingredient therein that is used as a substitute for or marketed to resemble a dairy product.. More specific suggestions on how to ensure the clarity of any eventual rule or policy on this subject are included above.

In support of this recommendation and request, AHPA has presented in these comments examples, specifically identified as non-exhaustive, of plant-based foods used in dietary supplements, in conventional foods, and in cosmetic products, that include dairy names such as "milk," "cream" and "butter" in their common or usual names. AHPA has provided selected references that document the use of the cited dairy name in each listed plant-based product, which references should also be understood to be not exhaustive as other references may also exist. The selected references for each listed plant-based product include at least one historical reference and one contemporary reference to indicate continuous use of the cited dairy name for each listed example.

AHPA appreciates the opportunity to present comments on this matter and welcomes any questions that may arise from AHPA's comments.

Respectfully submitted,



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