



Review of Healthy Claims

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“Healthy” Claims in Labeling

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Introduction: “Healthy” Claims in Labeling

- FDA has defined the term “healthy” as a nutrient content claim
(21 CFR § 101.65(d))
 - Specified levels for fat, saturated fat, cholesterol, sodium
 - Beneficial nutrient criterion (vitamin A, C, iron, calcium, protein, fiber)
 - Different criteria for select foods, e.g., fruits and vegetables, meals, main dishes, standardized grain products
- The regulation only applies when healthy is used in a “nutritional context”, i.e., where the claim is made in connection with an explicit or implicit statement or claim about a nutrient
 - “healthy, contains 3 grams of fat”

“Healthy” - Recent Developments

- March 2015 FDA issues Warning Letter to KIND, LLC over “healthy” claims on products containing nuts and dried fruits that are not low in saturated fat
- Dec. 2015 KIND petitions FDA to revisit the “healthy” definition and revise to achieve consistency with the Dietary Guidelines
 - Guidelines encourage consumption of nuts and recognize dried fruits count towards fruit intake
- May 2016 FDA issues closeout letter to KIND, stating the agency will not object to “healthy” if it appears as part of a corporate philosophy where it does not appear on the same display panel as nutrient content claims or nutrition information
- 2016-2018 FDA is engaged in a public process to redefine “healthy”



Commissioner Gottlieb on “Healthy”

Consumers have long been interested in finding easier ways to identify healthful foods by looking at the labels when food shopping. Claims are quick signals for consumers about what benefits a food or beverage they choose might have, and they can also encourage the food industry to reformulate products to improve their healthy qualities.

"Healthy" is one claim that the FDA believes is ready for change and we have already signaled our intention to update the criteria for this claim. The Agency is considering how to depict "healthy" on the package so that consumers can easily find it. ...

In keeping with the enhanced focus on dietary patterns and food groups rather than only single nutrients, we are also interested in exploring claims for products that offer food groups for which American diets typically fall short of recommendations. Examples include whole grains, low-fat dairy, fruits and vegetables, and healthy oils.

Key Considerations for “Healthy” Claims

1. What approach should FDA take when redefining healthy?
 - Focus on food groups/holistic approach vs. nutrients only?
 - Different criteria for different types of foods?
 - Criteria for added sugars? Total fat still relevant?
2. Use of a standardized symbol or icon?
3. When is a particular use of “healthy” a nutrient content claim subject to the FDA criteria?
 - Is the claim made in a “nutritional context”?
 - What is a nutritional context?!
4. How should other terms be treated?
 - “wholesome”
 - “nutritious”



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“Healthy” Claims – 1985 to Present



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The “Healthy” Claim Craze – 1980s

- “Healthy” claims appeared on all type of foods
- FDA had no specific criteria for the claim
- Only recourse was section 403(a)(1) of the FDCA – “false or misleading in any particular”
- Little to no regulatory action was taken

Healthy claims became a Joke

- Saturday Night Live skit told us why doughnuts were healthy:
 - “You can eat three for breakfast and reach your calorie intake for the day”



The Nutrition Labeling and Education Act

- Established pre-market rulemaking procedure for “Health” claims, i.e. “Diets low in sodium may reduce your risk of high blood pressure”
- Required pre-market approval for “nutrient content” claims, i.e. “low fat,” “High fiber”
- “Healthy” claims are not “health claims” nor express “nutrient content” claims

Legal Basis for “Healthy” Claims

- Where does “healthy” fit in?
- What is a regulatory agency to do?
- . . . Pound a square peg into a round hole

Legal Basis

- FDA regulations at ([21 CFR 101.65](#)(d)) provide the regulatory definition for use of the term “healthy” or related terms (such as “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim

“Healthy” 21 CFR 101.65(d)

The regulatory definition FDA proffered for “Healthy” claims (1994) is that “healthy” is a nutrient content claim that implies that a food contains certain levels of specified nutrients

FDA's 1994 Definition of "Healthy"

- Food must be:
 - _ "Low fat"; **mono, poly unsaturated fat excluded (2016)**
 - "Low in saturated fat";
 - ≤ 60 mg cholesterol;
 - ≤ 480 mg sodium; and
 - Contains at least 10% of DV for vitamin A, vitamin C, **D, (2016)** calcium, iron, protein, or fiber, **or potassium (2016)**
(NB: If a nutrient is added to meet 10%, addition must comply with FDA's fortification policy.)

What Foods Should Qualify as Healthy

- Meanwhile, other foods generally recognized as part of a healthy dietary pattern (U.S. Dietary Guidelines 2015-2020) were excluded by FDA's 1994 definition.

- Examples:



Other FOODS THAT DO NOT QUALIFY AS “Healthy”

- Plain yogurt — unhealthy, too high in saturated fat.
- At 5 grams of saturated fat per serving, yogurt's not in a great spot for being considered healthy.
- However, plain yogurt is relatively low in sugar and it's packed with protein and calcium

Challenging the Status Quo

- A FDA 2015 complaint against Kind Bars ending up starting a huge policy change process
- Kind bars — which contain almonds and other nuts — pushed back against an FDA complaint about its use of the phrase "healthy and tasty."
- After reviewing the situation, FDA said it was comfortable with the company using the phrase under certain modified conditions.

Redefining “Healthy”

- The Kind Bar debate pushed FDA to further study the issue on an industry-wide basis
- FDA issues new Guidance for Industry document in 2016 that excluded certain healthful fats from the calculation of the maximum of Total Fat that limited use of the claim

FDA – September 2016

- “Because the science supporting public health recommendations for intake of various nutrients has evolved, as reflected in the updated Nutrition Facts Label, FDA intends to exercise enforcement discretion with respect to some of the criteria for bearing the implied nutrient content claim “healthy.”

FDA September 2016

- In particular, FDA intends to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim “healthy” meet the low fat requirement provided that: (1) The amounts of mono- and polyunsaturated fats are declared on the label; and (2) the amounts declared constitute the majority of the fat content.

Legal Basis: FDA Exercise of Enforcement Discretion

- Similarly, we intend to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim “healthy” contain at least 10 percent of the DV per RACC of vitamin A, vitamin C, calcium, iron, protein, or fiber, if the food instead contains at least 10 percent of the DV per RACC of potassium or vitamin D.

FDA's Current Definition of a "Healthy" Food – Updates in Red

- Food must be:
 - “Low fat”; **mono, poly unsaturated fat excluded (2016)**
 - “Low in saturated fat”;
 - ≤60 mg cholesterol;
 - ≤480 mg sodium; and
 - Contains at least 10% of DV for vitamin A, vitamin C, **D, (2016)** calcium, iron, protein, or fiber, **or potassium (2016)**
(NB: If a nutrient is added to meet 10%, addition must comply with FDA's fortification policy.)

What's Still Missing

- Added Sugars ?
- Cholesterol limit ?
- Other healthful qualities of a food
- Emphasis on meal patterns

FDA Responds with Public Meeting (2016) and Requests Comments (2017)

- FDA explains: Back in the 1990s, the agency used the best nutritional science available at that time to define what “healthy” meant.
- And so, over the past two decades, food packages could be labeled as healthy if they met certain criteria for the content of fat, saturated fat, sodium and cholesterol and contained certain minimum amounts of nutrients like vitamins and minerals.

FDA Reconsiders Its Traditional Position

- FDA now states, “But nutrition science has evolved. Whereas in the past we placed greater emphasis on total fat, we now know that not all fats are alike, and some are better for health than others.
- And while the focus on ensuring that people are getting the right amounts of different nutrients still matters, other things matter as well, such as food groups or the combinations of different foods and beverages in the diet.”

FDA Research Results 2017

- FDA research shows that claims on labels have a significant impact on consumer perceptions, beliefs and behaviors.
- Preliminary work on “healthy” claims indicate that they may likely have similar effects on consumers and may influence consumer choices.

March 2018 – 2nd FDA Public Meeting

Comments Varied Widely

- *Kind Snacks*, which has petitioned FDA to change its “healthy” definition, proposed, in part, that foods be defined as healthy if they contain a “meaningful amount” of foods that comprise a healthy diet and that don’t contain low- or no-calorie sweeteners or synthetic colors
- ConAgra Foods presented a framework for defining “healthy” by ranking foods based on their nutritional makeup, an approach that permits greater flexibility.

Public Comments - 2018

- The Center for Science in the Public Interest said that a “healthy label” shouldn’t be a marketing tool that helps marginally better processed foods compete with fruits, vegetables and other “truly” healthy foods.
- The Academy of Nutrition and Dietetics, after talking to its members, said it could not come up with a good definition for “healthy” that FDA should adopt.

Public Comments

- Participants also urged FDA to consider the goal of redefining “healthy” before deciding the criteria.
- Is the term primarily an educational tool? If so, then FDA must be transparent about what the term means because people view the word healthy differently depending on their perspectives and values.
- Alternatively, is the definition intended to be a guideline for industry in making claims about their products, or, is it a way to spur product reformulation towards healthier foods?

Next Steps on Redefining Healthy

- Commissioner Gottlieb states in 2018 that redefining the term is a top priority of the agency's new Nutrition Innovation Strategy: "'Healthy' is one claim that the FDA believes is ready for change and we have already signaled our intention to update the criteria for this claim."
<https://www.fda.gov/food/labelingnutrition/ucm602651.htm>
- "In keeping with the enhanced focus on dietary patterns and food groups rather than only single nutrients, we are also interested in exploring claims for products that offer food groups for which American diets typically fall short of recommendations. Examples include whole grains, low-fat dairy, fruits and vegetables, and healthy oils." *Id.*

What's Down the Road

- The Agency is also considering how to depict "healthy" on the package so that consumers can easily find it." *Id.*
- Commissioner Gottlieb said he is even considering putting in place a standard icon or symbol for the word "healthy" that's featured on food items,
<https://www.politico.com/story/2018/03/29/trumps-fda-salt-reduction-491256>

Meanwhile . . .

- The more things change, the more they stay the same
- 2018 web search for “healthy” donuts
- Reveals dozens of examples of questionable claims

“Healthy” Donuts - 2018

- [Healthy Flourless Cinnamon Bun Breakfast Doughnuts](#)
- <https://thebigmansworld.com/.../healthy-flourless-cinnamon-bun-breakfast...> [Cached](#)
- May 6, 2016 - Easy and delicious baked (not fried!) *doughnuts* which tastes like a classic cinnamon bun but in *doughnut* form AND specifically designed for ...

- [Healthy Baked Doughnut Recipes - Health](#)
- <https://www.health.com › Nutrition> [Cached](#)
- Sep 7, 2013 - *Healthy doughnuts* do exist. Try baking, instead of frying, to cut out the fat and calories. These healthy recipes make great, guilt-free treats

- [Lemon Poppy Seed Healthy Baked Donuts - Jar Of Lemons](#)
- <https://www.jaroflemons.com/lemon-poppy-seed-healthy-baked-donuts/> [Cached](#)

“Healthy” Donuts 2018

- May 28, 2018 - Sweet, fluffy Lemon Poppy Seed *Healthy* Baked *Donuts* drizzled with a melt-in-your-mouth glaze that are perfect for an indulgent (and ...
- [Healthy Baked Doughnuts | Bondi Harvest TV Show - Bondi Harvest](#)
- [https://bondiharvest.com/.../healthy-baked-doughnuts-bondi-harvest-tv-sh...Cached](https://bondiharvest.com/.../healthy-baked-doughnuts-bondi-harvest-tv-sh...)
- [healthy donuts – Blogilates](#)
- [https://www.blogilates.com/tag/healthy-donuts/Cached](https://www.blogilates.com/tag/healthy-donuts/)

Are “Healthy” Donuts Still in Our Future?



Questions ?

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Healthy Claims - Litigation

- Wide Diversity of Claims Under “Healthy” Rubric
 - High in fat products
 - *Transfat* (PHO)
 - Coconut oil
 - “Low in Sodium” claims
 - Chemical preservatives
 - Evaporated Cane Juice (ECJ)
 - Excess “Added Sugars”



The Great War on Fat

- *Kaufer v. KIND*, MDL 2645, 1:15-cv-06344 (S.D.N.Y. 2017)
 - Bars marketed as “healthy,” “no trans fat,” “non-GMO,” “all natural”
 - Allegedly higher in saturated fat than permitted by regulations for “healthy” claims
 - MDL proceedings stayed pending “natural” regulatory definition



Fat Wars – *Kind* Cont'd

- Underlying Regulatory Basis For These Claims
 - Express or Implied Nutrient Content Claims. [21 C.F.R. 101.65(d)(1)]
 - “Healthy,” “health,” “healthful,” “healthfully.” [21 C.F.R. 101.65(d)(2)]
 - FDA: “wholesome,” “nutritious” *may* mean “healthy.” 59 Fed. Reg. 24236 (May 10, 1994).
 - “Disqualifying Levels” (21 C.F.R. §§ 101.14 and 101.65)
 - Fats
 - Saturated Fat
 - Sodium
 - Cholesterol
 - The amount of these nutrients limits claims that can be made



Fat Wars – Kind Cont'd

21 CFR Ch. I (4-1-14 Edition)

present in a certain amount (e.g., "high in oat bran") are implied nutrient content claims and must comply with paragraph (a) of this section.

(2) The phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as in the labeling of [food]" are implied nutrient content claims and must comply with paragraph (a) of this section.

(3) A food is a "good source" of a nutrient if the amount of the nutrient in the food is "good enough" to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz glass of orange juice.").

(4) Claims may be made that a food contains or is made with a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either "low" in or a "good source" of the nutrient, or is associated with the nutrient or type of preparation. If a more specific level is claimed (e.g., "high in..."), that level of the nutrient must be present in the food. For example, a claim that a food contains a certain amount of a nutrient is a claim that it is a good source of that nutrient; a claim that a food is made with a particular nutrient is a claim that it is low in saturated fat; and a claim that a food contains no oil is a claim that it is fat free.

(5) **General nutritional claims.** (i) This paragraph covers labeling claims that are implied nutrient content claims because they:

- (A) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and
- (B) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., "healthy," "contains 3 grams of fat," "healthy").

(ii) You may use the term "healthy" or related terms (e.g., "health," "healthful," "healthfully," "healthiness," "healthier," "healthiness") as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is useful with dietary recommendations.

Food and Drug Administration, HHS

§ 101.65

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients:

If the food is...	The fat level must be...	The saturated fat level must be...	The cholesterol level must be...	The food must contain...
(A) A raw fruit or vegetable	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(f) or less	N/A
(B) A single-ingredient or a mixture of frozen or canned fruits and vegetables	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(f) or less	N/A
(C) An enriched cereal-grain product that conforms to a standard of identity in part 136, 137 or 139 of this chapter.	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(f) or less	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 grams total fat per RFA and per 100 g	Less than 2 g saturated fat per RFA and per 100 g	Less than 95 mg cholesterol per RFA and per 100 g	At least 10 percent of the RDI or the DFR* per RFA of one or more of vitamins A, vitamin C, calcium, iron, protein, or fiber
(E) A meat product as defined in § 101.138 or a main dish product as defined in § 101.139(a)	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	60 mg or less cholesterol per LSP	At least 10 percent of the RDI or the DFR* per RFA of one or more of vitamins A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this table	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(f) or less	At least 10 percent of the RDI or the DFR* per RFA of one or more of vitamins A, vitamin C, calcium, iron, protein or fiber

* May include ingredients whose addition does not change the nutrient profile of the food or vegetable.
 RFA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(h)).
 LSP means Reference Daily Intake (§ 101.12(c)(1)(v)).
 DFR means Daily Reference Value (§ 101.9(c)(1)).
 LFS means Labeled Serving, i.e., the serving size that is specified in the nutrition information on the product label (§ 101.9(b)).

(ii) The food meets the following conditions for sodium:

If the food is...	The sodium level must be...
(A) A food with a RFA that is greater than 30 g or 2 tablespoons (tablespoon)	480 mg or less sodium per RFA and per LS
(B) A food with a RFA that is less than or equal to 30 g or 2 tbsp.	480 mg or less sodium per 50 g*

If the food is...	The sodium level must be...
(C) A meat product as defined in § 101.138 or a main dish product as defined in § 101.139(a)	600 mg or less sodium per LS

* For dehydrated food that is typically reconstituted with water or a liquid that contains insignificant amounts per RFA of all nutrients (as defined in § 101.9(f)(1)), the 50 g refers to the "prepared" form of the product.

(iii) The food complies with the definition and declaration requirements in this part 101 for any specific nutrient content claim on the label or in labeling, and

(iv) If you add a nutrient to the food specified in paragraphs (d)(2)(i)(D),

Fat Wars – *Kind* Cont'd

- “Healthy” or nutrient content claim plus elevated fat/saturated fat/sodium/cholesterol levels
 - “useful in creating a diet that is consistent with dietary recommendations.” [21 C.F.R. § 101.65(d)(2)]
 - How can a plaintiff plead this with specificity?
- Question: Does the reasonable consumer believe Froot Loops are “healthy” but Kind bars are not?
- “Type of fat consumed was more relevant in reducing the risk of CHD.” 79 Fed. Reg. 11891 (Mar. 3, 2014).
- Claims shifted away from healthy via amended complaint

Fat Wars – Other Cases

- *Hunter v. Nature's Way Products*, Case No. 16-cv-4957 (S.D. Cal. 2016) (coconut oil);
- *Brower v. Campbell Soup Company*, Case No. 16-cv-1005 (S.D. Cal. 2016) (PHO) (preempted);
- *Gomez v. Jelly Belly Candy Co.*, Case No. 5:17-cv-00575 (C.D. Cal. 2017) (ECJ, Healthy);
- *Shin v. Campbell Soup Company*, Case No. 2:17-cv-01082 (C.D. Cal. 2017) (Healthy, Less Sodium, Fat Free)
- *Sowizrol v. The Coca-Cola Company*, Case No. 4:14-cv.03774 (N.D. Cal. 2014) (Natural, Healthy, has chemical preservatives);
- **Turner v. Jamba Inc.*, Case No. 3:18-cv-05168 (N.D. Cal. 2018) (healthy, filler juices, high in sugar).

Sugar Wars

- Plaintiffs' Counsel - Jack W. Fitzgerald and Joseph Paul
- *Hadley v. Kellogg Sales Company*, Case No. 16-cv-04955 (N.D. Cal. 2016) (Judge Koh);
- *Krommenhock v. Post Foods, LLC*, Case No. 16-cv-04958 (N.D. Cal. 2016) (Judge Orrick);
- *Truxel v. General Mills*, Case No. 4:16-cv-04957 (N.D. Cal. 2016) (Judge White);
- *McMorrow v. Mondelēz International, Inc.*, Case No. 3:17-cv-2327 (S.D. Cal. 2017) (Judge Benitez);



Sugar Wars

- *Hadley v. Kellogg Sales Company*, Case No. 16-cv-04955 (N.D. Cal. 2016) (Judge Koh);
- Cereal products with 18% to 40% of total calories per serving from added sugars
- Excessive added sugars
- Claims:
 - “healthy”; “nutritious”; “wholesome”;
 - “HEART HEALTHY”;
 - “whole grain”; “fiber”;
 - “lightly sweetened”;
 - “No high fructose corn syrup”



Sugar Wars - Hadley

- Complaint references:
 - American Heart Association standard for added sugars = 5% of total calories
 - FDA “Daily Value” = 10% of total calories
 - No allegation how consuming products caused a plaintiff to exceed these limits
 - Scientific studies linking excessive added sugars to disease
- Serving of products can fall below AHA 5% upper limit
 - AHA recommendation only
 - Sliding scale depending on each individual person’s caloric needs
- What is the definition of *excessive* added sugars?
- Court: added sugars “contributed” to excessive added sugars??



Sugar Wars - Hadley

- Motion To Dismiss (*Hadley II*):

- Lack of Specificity
- Preemption
- Puffery

- Motion Results

- Contribution Theory - Enough to say that the product is high sugar
 - “eating Defendant’s product would require the individual to eat lower sugar foods throughout the rest of the day to maintain a daily percentage of added sugar intake that is below the two thresholds for added sugar”
 - “Plaintiff provides scientific studies that link added sugar to cardiovascular disease, metabolic syndrome, and diabetes”
 - (“30% increased risk in cardiovascular disease when consuming between 10% and 24.9% of daily calories as added sugar”)



Sugar Wars - Hadley

- Motion Results (Hadley II)
 - NLEA [21 U.S.C. § 343-1]: FDCA preemption if state laws “not identical to”
 - No FDA “disqualifying level” for sugar
 - Therefore, “health” or “implied nutrient content claims” re sugar preempted
 - Limited utility:
 - Health claim = “any claim . . . That expressly or by implication . . . Characterized the relationship of any substance to a disease or health-related condition.” 21 CFR § 101.14(a)(1);
 - “Heart healthy” not preempted because not in compliance with regulations
 - “Foods high in fiber help support good health” is preempted
 - “Health claim” here is different than “healthy” claim
 - Puffery
 - “Unbelievably nutritious” is non-actionable puffery
 - “Start with a healthy breakfast,” “wholesome,” “nutritious” are not puffery
 - Conclusion: No “silver bullet” given diversity in allegations

Sugar Wars - Hadley

- Preemption Arguments Not Really Briefed
 - NLEA
 - Conflict/Obstruction
 - 21 U.S.C. §§ 343(q)(1)(D) + 21 U.S.C. §§ 343(q)(2)(A) and (B)
 - Food label must provide “the total amount of . . . sugars . . . contained in each serving size”
 - Which are “necessary to assist consumers in maintaining healthy dietary practices.”
 - Final Rule Preamble re 10% Daily Value [81 Fed. Reg. 33759 (May 27, 2016)]:
 - “The declaration of added sugars is also reasonably related to the government’s interest in providing information needed to assist consumers in maintaining healthy dietary practices by providing them with information about added sugars content in a serving of food to construct diets containing more nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars to less than 10% of calories.”
 - This is not about the regulatory definition of “health claim” or “healthy”

Sugar Wars - Hadley

- Class Action Certified! (Aug. 17, 2018)
 - Products were high in added sugars, 18% to 40% of total calories
 - Reasonable consumer test satisfied the predominance requirement
- Troubling/Troubled Decision
 - The test is whether statements were false for all consumers
 - Individual consumers' calorie consumption needs vary widely
 - The question is how much sugar does the product contribute to the daily intake of calories
 - Jelly beans are almost 100% sugar
 - Statements could be true or false depending on the consumer and from consumer to consumer
 - How to measure “excessive” added sugar on a class-wide basis

