Olsson Frank Weeda
Terman Matz PC

2000 Pennsylvania Avenue NW
Suite 4003
Washington, DC 20006
www.ofwlaw.com

Phone: (202)789-1212 • Fax (202)234-3550

**Tish Pahl – Principal**
tpahl@ofwlaw.com

**Mason Weeda – Principal**
mweeda@ofwlaw.com

**Kyla Kaplan – Associate**
kkaplan@ofwlaw.com

**MEMORANDUM**

December 24, 2024

**BY ELECTRONIC MAIL**

FROM: Olsson Frank Weeda Terman Matz PC

RE: Final Rule: "Healthy" Nutrient Content Claims

---

On December 19, 2024, the U.S. Food and Drug Administration (FDA or the agency) issued the long-awaited pre-published version of the final rule, *Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'* (Final Rule or Healthy Rule).

FDA first defined the voluntary nutrient content claim (NCC) for the term "healthy" in 1994 (1994 Rule) following the enactment of the Nutrition Labeling and Education Act (NLEA). The 1994 Rule, 21 C.F.R. § 101.65(d), sets forth the requirements for when "healthy" can be used in the labeling of human food products. FDA proposed amending the 1994 Rule on September 28, 2022, *Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"* (Proposed Rule). OFW Law prepared a memorandum on the Proposed Rule (here).

FDA issued a News Release and additional resources, including fact sheets and infographics, available here. The Final Rule is expected to be published officially in the *Federal Register* on December 27, 2024. It will be effective and published in the *Code of Federal Regulations* 60 days after publication, on or about February 25, 2025. ***However, the compliance date for the Final Rule is February 25, 2028.*** Food labeled after February 25, 2028, must comply with the Final Rule, however, manufacturers may voluntarily comply with the Final Rule prior to this compliance

date. Thus, manufacturers could either comply with the new requirements or continue to use the original definition of "healthy"[1] until the compliance date.

Below, we address how the Final Rule differs from the original 1994 Rule and the Proposed Rule and summarize in chart form the Final Rule's complex criteria for when a food is eligible to make a "healthy"[2] claim. We briefly discuss the potential impacts of the Final Rule. We conclude with a discussion of how the Final Rule is not fully aligned with some stated positions of the incoming Trump Administration and explain what further steps new leadership could take to change, revoke, or delay the Final Rule.

**Contents**

1. Changes To The 1994 Rule ..... 2
2. Changes From The Proposed Rule ..... 4
3. Requirements To Make A "Healthy" Claim ..... 4
4. Impacts of the Final Rule ..... 7
5. The Trump Administration and the Final Rule ..... **Error! Bookmark not defined.**

## *1. Changes To The 1994 Rule*

The Final Rule represents a significant departure from the 1994 Rule. Consistent with consensus nutrition science and the 2020-2025 Dietary Guidelines for Americans (2020 DGA), FDA abandons the nutrient focus of the 1994 Rule. The Final Rule focuses on the contributions of specific food groups to a healthy diet. Similar to the 1994 Rule, the Final Rule prohibits a "healthy" claim if the food exceeds levels of certain nutrients but removes *Total Fat* and *Dietary Cholesterol* and adds *Added Sugars* as disqualifying nutrients. An FDA fact sheet describes how the Final Rule differs from the 1994 Rule. To summarize:

[1] FDA established an enforcement discretion policy that permits manufacturers to deviate from the "healthy" criteria in the 1994 Rule for products that (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

[2] The Final Rule covers use of the term "healthy" and the derivative terms, "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness." Healthy Rule at 101.65(d)(3). The Final Rule does address or define other terms, such as "nutritious," "wholesome," and "good for you" though it notes that when these terms appear on labels or labeling, they may be subject to regulation under the general misbranding provision of section 403(a) of the Federal Food, Drug & Cosmetic Act.

| 1994 Rule "Healthy" Claim | Final Rule "Healthy" Claim |
|---|---|
| A food may not make a "healthy" claim if it exceeds limits on:<br>• Saturated Fat<br>• Sodium<br>• Total Fat<br>• Dietary Cholesterol | A food may not make a "healthy" claim if it exceeds limits on:<br>• Saturated fat<br>• Sodium<br>• Added Sugars |
| To be able to make a "healthy" claim, a food must have a minimum amount of beneficial individual nutrients:<br>• Vitamin A,<br>• Vitamin C,<br>• Calcium,<br>• Iron,<br>• Protein, or<br>• Fiber | To be able to make a "healthy" claim, a food must have a minimum amount of recommended food groups and/or sub-groups that contain an array of nutrients:<br>• Vegetables,<br>• Fruits,<br>• Dairy,<br>• Protein Foods,<br>• Whole Grains |

Additionally, FDA has other efforts underway pertaining to "healthy," including continuing development of a "healthy" symbol that may be used to indicate if a food meets the "healthy" criteria.

In the fact sheet, FDA gives examples of foods that will no longer be able to make a "healthy" claim – *e.g.*, due to added sugars or not meeting food group equivalent requirements – and new foods that would be able to make a "healthy" claim under the Final Rule:

| Examples of foods that qualified for a "healthy" claim under the 1994 Rule | Examples of foods that qualify for a "healthy" claim under the Final Rule (assuming saturated fat, sodium, and added sugars limits are not exceeded) |
|---|---|
| • Yogurt that is high in added sugars<br>• Fortified breakfast cereal that is high in added sugars<br>• Fortified white bread with no whole grains<br>• Fruit snacks that are high in added sugars<br>• Snack bars that are high in added sugars<br>• Fortified fruit punch (not 100% juice) | • Fresh whole fruits and vegetables<br>• Frozen, chopped, dried, or canned fruits and vegetables<br>• Salmon<br>• Trail mix with nuts and dried fruit<br>• Plain low-fat or fat-free yogurt<br>• Eggs<br>• Water<br>• 100% olive oil |

### *2. Changes From The Proposed Rule*

The Final Rule is consistent with the Proposed Rule's focus on qualifying foods, rather than nutrients, and the identification of disqualifying levels of saturated fat, sodium, and added sugars. The Final Rule does, however, also include several key changes from the Proposed Rule.

- Application criteria:
  - Foods with a Reference Amount Customarily Consumed (RACC) of 50 g or less or 3 Tbsp or less on a per 50 g basis are permitted to make a "healthy" claim.
- Expanded categories:
  - Raw, whole fruits and vegetables, and foods comprised of Dietary Guidelines-encouraged foods with no added ingredients except water, automatically qualify to make a "healthy" claim.
  - All water, tea, and coffee with less than 5 calories per RACC and per labeled serving are permitted to make a "healthy" claim.
- Food Group Equivalent (FGE) criteria changes:
  - Dairy FGE reduced to 2/3 cup equivalent from 3/4 cup equivalent.
  - More flexible proportions for combination foods.
  - Vegetable and fruit powders may be considered in FGE calculations.
- Nutrient limit criteria adjustments:
  - Sodium limit for mixed products increased to ≤ 15% of the DV per RACC.
  - Added sugar limit for whole grain products increased to ≤ 10% of the DV.
  - Added sugar limit of ≤ 2% of the DV for individual fruits, vegetables, and protein foods.
  - Excludes inherent saturated fat in seafood from the saturated fat limit.
  - Streamlines nutrient limits for combination foods.

### *3. Requirements To Make A "Healthy" Claim*

FDA helpfully summarized in chart format the requirements for various foods to make a Healthy claim including what foods may make a claim and what the limits are on added sugars, sodium, and saturated fat as a percentage of the Daily Value (DV) that would disqualify the food.

- For an individual food that has a RACC greater than 50 grams (g) or greater than 3 tablespoons (Tbsp), or an individual food that has a RACC of 50 g or less or 3 Tbsp or less and meets the following conditions per 50 g (Healthy Rule at 21 C.F.R. § 101.65(d)(3)(ii)(A) and (B)):

| To bear a claim subject to this rule, if the food is… | It must contain at least... | The added sugars content must be no greater than… (50 g DV) | The sodium content must be no greater than… (2300 mg DV) | The saturated fat content must be no greater than… (20 g DV) |
|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| A vegetable product | | 1/2 cup equivalent vegetable | 2% DV | 10% DV | 5% DV |
| A fruit product | | 1/2 cup equivalent fruit | 2% DV | 10% DV | 5% DV |
| A grain product | | 3/4 oz equivalent whole grain | 10% DV | 10% DV | 5% DV |
| A dairy product | | 2/3 cup equivalent dairy | 5% DV | 10% DV | 10% DV |
| Protein Foods | Game meats | 1 1/2 oz equivalent | 2% DV | 10% DV | 10% DV |
| | Seafood | 1 oz equivalent | 2% DV | 10% DV | 5% DV, excluding saturated fat inherent in seafood |
| | Egg | 1 oz equivalent | 2% DV | 10% DV | 10% DV |
| | Beans, peas, and lentils | 1 oz equivalent | 2% DV | 10% DV | 5% DV |
| | Nuts, seeds, and soy products | 1 oz equivalent | 2% DV | 10% DV | 5% DV, excluding saturated fat inherent in nuts, seeds, and soybeans |
| Oils | 100% Oil | | 0% DV | 0% DV | 20% of total fat |
| | Oil-based spreads whose fats come solely from oil | | 0% DV | 10% DV | 20% of total fat |
| | Oil-based dressing containing at least 30% oil and oils meet the requirements in § 101.65(d)(3)(ii)(A) or (B)(6)(*i*) | | 2% DV | 10% DV | 20% of total fat |

- A mixed product that meets the following conditions per RACC (Healthy Rule at 21 C.F.R. § 101.65(d)(3)(iii)):

| To bear a claim subject to this rule, if the mixed product contains at least… | The added sugars content must be no greater than… (50 g DV) | The sodium content must be no greater than… (2300 mg DV) | Excluding saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than… (20 g DV) |
|---|---|---|---|
| One total FGE with no less than 1/4 FGE from at least two food groups | 10% DV | 15% DV | 10% DV |

- A main dish product as defined 21 C.F.R. §101.13(m)) that meets the following conditions per labeled serving: (Healthy Rule at 21 C.F.R. § 101.65(d)(3)(iv)):

| To bear a claim subject to this rule, if the main dish product contains at least… | The added sugars content must be no greater than… (50 g DV) | The sodium content must be no greater than… (2300 mg DV) | Excluding saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than… (20 g DV) |
|---|---|---|---|
| Two total FGEs with no less than 1/2 FGE from at least two food groups | 15% DV | 20% DV | 15% DV |

- A meal product as defined in 21 C.F.R. § 101.13(l) that meets the following conditions per labeled serving: (Healthy Rule at 21 C.F.R. § 101.65(d)(3)(v)):

| To bear a claim subject to this rule, if the main dish product contains at least… | The added sugars content must be no greater than… (50 g DV) | The sodium content must be no greater than… (2300 mg DV) | Excluding saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than… (20 g DV) |
|---|---|---|---|
| Three total FGEs with no less than 1/2 FGE from at least three food groups | 20% DV | 30% DV | 20% DV |

The following **automatically qualify** under the "healthy" definition:

- Individual foods and mixed products comprised of one or more of the following with no other added ingredients except for water: **vegetable; fruit; whole grains; fat-free and low-fat dairy; lean meat, seafood, eggs, beans, peas, lentils, nuts and seeds**. Healthy Rule at 21 C.F.R. § 101.65(d)(3)(i).

- **Water, tea, and coffee** with less than 5 calories per RACC and per labeled serving. Healthy Rule at 21 C.F.R. § 101.65(d)(3)(vi).

Importantly, the Final Rule includes recordkeeping requirements. A manufacturer of a food that bears a "healthy" claim must make and keep written records to verify the food meets the FGE requirements. The records must be maintained for two years after the introduction or delivery of the food into interstate commerce. These records must be provided to FDA upon request, during an inspection. This requirement does not apply to foods where the label provides sufficient information to verify that the food meets the Final Rule's requirements or where the food automatically qualifies as described above (*i.e.*, water, tea, coffee, fruits, vegetables, etc.)

### *4. Impacts of the Final Rule*

An update to reflect current nutritional science and the 2020 DGA was long overdue. Overall, the adoption of the "food group equivalent" approach, with focused limitations on saturated fats, added sugars, and sodium, is a giant step forward in terms of consistency with today's nutrition science.

The 1994 Rule's focus on specific nutrients rather than foods is a good example of the challenge of a federal regulation to keep up with advances in science. Moreover, the 1994 Rule's attention to total fats, and cholesterol, and lack of attention to iron, and potassium became so obsolete and problematic that FDA issued a 2016 enforcement discretion policy to permit "healthy" claims for certain foods that include mono and polysaturated fats, and potassium and vitamin D at certain levels. Although the Final Rule represents an enormous improvement over the prior criteria and requirements for a "healthy" claim, it is possible that the basis for "healthy" criteria could change rapidly, particularly with the upcoming publication of the 2025-2030 DGA.

As of today, FDA has not yet published the full regulatory impact analysis for the Final Rule, though a summary is available in the preamble. The agency is touting the new claim as a "powerful tool for change" that "may help foster a healthier food supply" and reduce the incidence of diet-related chronic disease in the U.S. population. However, the "healthy" claim currently sees minimal use in the marketplace – the Final Rule states that the "healthy" claim is currently only used on 5 percent of products on the market. The Final Rule also states that a mere 0 to 0.4 percent of American consumers who try to follow the government's dietary guidelines would look for the 'healthy' claim to make meaningful food purchasing decisions.

In sum, though the Final Rule represents a significant departure from the 1994 Rule, its actual impacts may be negligible because the term is used so little in food marketing or by consumers in making purchasing decisions.

### *5. The Trump Administration and the Final Rule*

When the Trump Administration takes office on January 20, 2025, the "Make America Healthy Again" (MAHA) movement is poised to shape food policy. The President-elect intends to nominate Robert F. Kennedy Jr. and Dr. Marty Makary as Secretary of Health and Human Services

(HHS) and FDA Commissioner, respectively. Both are prominent advocates for the MAHA agenda which, in some respects, conflicts with the Final Rule.

Mr. Kennedy and Dr. Makary have persistently criticized scientific institutions like the FDA and the food industry. They have expressed strong opposition to food and color additives, "ultra-processed" or "processed" foods, and seed oils, with Dr. Makary notably stating that "[w]e have poisoned our food supply" and linking ultra-processed foods to chronic diseases. Mr. Kennedy has expressed similar concerns and criticized the marketing of seed oils as "healthy, while placing doubt on the correlation between intake of saturated fat and coronary heart disease.

Given these positions, the incoming HHS and FDA might support certain aspects of the Final Rule, such as healthy claims for minimally processed fruits, vegetables, beans, and peas. On the other hand, they may oppose other parts of the Final Rule, such as permissible claims for seed oils and its limitations upon saturated fat. Assuming the incoming Administration opposes the Final Rule in whole or in part, it has several options for amending, repealing, or nullifying the Final Rule (and any other regulation). We review those options below.

- ***New Rulemaking Process***

Because the Healthy Rule is final,[3] HHS and FDA would have to use the same burdensome process to amend or repeal the Final Rule that FDA used to issue the Final Rule. Under the Administration Procedure Act (APA), repealing or amending the Healthy Rule would require initiation of a new rulemaking process.[4] The requirement for new rulemaking applies even though the Healthy Rule is not effective until on or about February 25, 2025 – over a month after the inauguration of the Trump Administration. While the Trump Administration could attempt to suspend the Final Rule, courts have reviewed suspensions as akin to repealing or amending a rule, and the same notice and comment requirements are required.[5]

To suspend, amend, or repeal the Final Rule, FDA would, therefore, have to issue a Notice of Proposed Rulemaking in the *Federal Register*, allow an opportunity for comment, and then respond to those comments. The agency must provide a reasoned explanation for any changes to the Final Rule and address why the factual findings and/or policy considerations underlying the Final Rule are no longer valid. This rulemaking process is time-consuming; as we saw with the Final Rule it can take years.

---

[3] Regardless of its compliance date or effective date (for the Final Rule, February 25, 2028 and 60 days from publication in the *Federal Register*) , a rule is deemed final when the Office of the Federal Register (OFR) makes it available for public inspection. *Humane Society of the U.S. v. U.S.D.A.*, No. 20-5291 (D.C. Cir. July 22, 2022). The Healthy Rule was available for public inspection on December 19, 2024.

[4] *See* 5 U.S.C. § 551(5) ("rule making" means agency process for formulating, ***amending, or repealing*** a rule)(emphasis added); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015) (explaining that the definition of "rule making" in the APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance").

[5] *See, e.g.*, *NRDC v. NHTSA* , 894 F.3d 95, 111–12 (2d Cir. 2018); *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2019); *Air Alliance Houston v. Envtl. Prot. Agency*, 906 F.3d 1049, 1067 (D.C. Cir. 2018).

Further, any repeal or amendment of the Final Rule is an agency action subject to judicial review under the APA. FDA's action may be set aside if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42 (1983) (*State Farm*), "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *State Farm*, 463 U.S. at 43. FDA would be required to "examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." An agency repeal of a rule may be arbitrary and capricious and therefore unlawful if, among other things, the agency "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency."

The "arbitrary and capricious" standard is highly deferential to agency actions and a reviewing court should not substitute its own judgment for that of the agency. However, given the detailed scientific rationale provided in and supporting the Final Rule, FDA could face significant challenges in providing the requisite "reasoned analysis" and "a rational connection between the facts found" and the decision to repeal or amend the Final Rule. We note that the 2030 DGA will be finalized by Kennedy's HHS, alongside USDA, which could be used to support FDA's action. However, FDA would have difficulty in providing a rationale if the 2030 DGA is inconsistent with evidence that formed basis of the DGA Advisory Committee recommendations.

- ***Congressional Action***

**Amend the law.** With Republicans controlling both chambers of Congress, several options are available for action on agency rules, including the Final Rule. As FDA, and other federal agencies, may only exercise such authority as Congress has delegated, Congress, by statute, repeal or amend rules or order agencies to do so.

**Congressional Review Act (CRA).** The CRA allows Congress to review and potentially overturn new federal regulations within 60 legislative days of their submission to Congress. With the Final Rule set to be published in the *Federal Register* on December 27, 2024, Congress would be able to use this fast-track procedure to disapprove the Final Rule. This approach would not only nullify the Final Rule but also prevent the agency from issuing a "substantially similar" rule without Congressional authorization.

The Healthy Rule, however, may not be an especially likely candidate for CRA action. While it is unknown what opposition the rule might have in the Republican caucus, a "healthy" claim is voluntary and the Final Rule may not be viewed as imposing the burdens and controversies that typically animate a CRA resolution.

**Appropriations Process.** The Republican-controlled Congress could include riders in appropriations bills that would prohibit the use of funds to implement or enforce this Final Rule. This would be an option because the incoming Congress will need to reintroduce all appropriations bills as they expire at the end of the year. While this does not formally repeal the Final Rule, it

would effectively prevent its implementation and enforcement. This method would require the incoming Congress to take Congressional action and would need to be renewed each fiscal year.

- ***Enforcement Discretion***

FDA could exercise enforcement discretion and elect to not enforce the Final Rule. An agency's outright refusal to enforce a rule can be challenged in court as tantamount to repeal of a rule without following APA notice and comment rulemaking requirements. However, given that the Final Rule currently is enforceable only as to products labeled after February 25, 2028, such an action is speculative and three years in the future.

- ***Litigation Strategy***

If the Final Rule is challenged in court, the new Administration may choose not to defend it. Additionally, they may seek a voluntary remand to reconsider the Final Rule or settle the case in a way that modifies or nullifies the Final Rule. While we are not aware of any legal challenges to the Final Rule at this time, if someone were to challenge the Final Rule, this option may be available.

* * *

In sum, there are numerous ways the Final Rule could be amended, repealed, or otherwise nullified. How the new Administration and Congress might respond, if at all, may depend upon timing, competing (and more urgent) priorities, and whether any legal challenges are mounted. We believe that any attempt by FDA to repeal or amend the Final Rule would be scrutinized by stakeholders and could face legal challenges, especially from those who do not believe that the agency has met its legal burden to justify the changes.

* * *

We hope you find this summary of a lengthy document useful. Please let us know if we can assist you in complying with the Final Rule.