DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2016–D–2335]

RIN 0910–AI13

Food Labeling: Nutrient Content Claims; Definition of Term ''Healthy''

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance, especially the Dietary Guidelines for Americans (Dietary Guidelines), regarding how consumers can maintain healthy dietary practices. This action, if finalized, will revise the requirements for when the term ''healthy'' can be used as an implied claim in the labeling of human food products to indicate that a food's level of nutrients may help consumers maintain healthy dietary practices by helping them achieve a total diet that conforms to dietary recommendations.

DATES: Either electronic or written comments on the proposed rule must be submitted by December 28, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by October 31, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2022. 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–2016–D–2335 for ''Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy.' '' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

Submit comments on information collection under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Food Labeling Regulations,'' OMB control number 0910–0381.

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Vincent de Jesus, Center for Food Safety and Applied Nutrition, HFS–830, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450, *vincent.dejesus@fda.hhs.gov;* or Denise See, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the information collection: Domini Bean, FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

Consumers rely on food labels when navigating the marketplace to make informed choices about the foods that are the foundation of a nutritious diet for both themselves and members of their families. FDA plays an important role in ensuring labels of food for human consumption are accurate, truthful, and not misleading, including claims that appear in product labeling to market a food. One such claim that FDA has regulated is the term ''healthy'' on product labels. Since 1994, we have recognized that when a manufacturer uses labeling that describes a product as ''healthy'' in the nutritional context, it is making an implicit claim of the level of nutrients of the product. In particular, such a label implies that the nutrient content of the food may help consumers maintain healthy dietary practices. Given that nutrition science has evolved since the 1990s when FDA first established a definition for the implied nutrient content claim ''healthy,'' the proposed rule would update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance. The proposed rule would revise the requirements for when the claim ''healthy'' can be used as an implied nutrient content claim in the labeling of human food products. In particular, because the claim indicates that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, we seek to limit the use of the claim to circumstances in which the food may help consumers achieve a healthy dietary pattern that conforms to current nutrition science and Federal dietary guidance.

B. Summary of the Major Provisions of the Proposed Rule

The proposed regulation would update the definition for the implied nutrient content claim ''healthy,'' which specifies the requirements for when the claim can be used on human food products. The claim ''healthy,'' when used in the nutritional context in food labeling, is an implied claim that the levels of the nutrients in the food are such that the food may help consumers maintain healthy dietary practices. Under the existing regulation, there are specific criteria for individual nutrients that must be met in the food for it to bear the claim, including limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts of nutrients whose consumption is encouraged, such as vitamin A, vitamin C, calcium, iron, protein, and dietary fiber. Since the time the claim was first defined in 1994, nutrition science and Federal dietary guidance have changed, making the current ''healthy'' definition outdated. Our current definition permits manufacturers to use the claim ''healthy'' on some foods that, based on the most up-to-date nutrition science and Federal dietary guidance, contain levels of nutrients that would not help consumers maintain healthy dietary practices. Further, a number of foods emphasized in current nutrition science and Federal dietary guidance as key elements of a healthy dietary pattern are not able to bear the ''healthy'' claim under the current regulation (*e.g.,* salmon due to fat levels). As a result, we believe that the definition needs to be updated so that the use of the claim will again accurately represent that the levels of the nutrients in the food may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance, as reflected in the *Dietary Guidelines for Americans, 2020–2025* (*Dietary Guidelines, 2020–2025*) (Ref. 1). The proposed framework for the updated definition of ''healthy'' uses a food group-based approach in addition to nutrients to limit (based on the understanding that each food group contributes an array of important nutrients to the diet). The proposed, updated ''healthy'' criteria would emphasize healthy dietary patterns by requiring that food products contain a certain amount of food from at least one of the food groups or subgroups recommended by the *Dietary Guidelines, 2020–2025* in order to be labeled ''healthy.'' The proposed regulation would also require a food product to be limited in certain nutrients, including saturated fat, sodium, and added sugars. The proposed rule would also add certain recordkeeping requirements for foods bearing the claim where compliance cannot be verified through information on the product label.

C. Legal Authority

We are issuing this proposed rule to update the definition of the implied nutrient content claim ''healthy'' consistent with our authority in sections 201(n), 403(a), 403(r), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(n), 343(a), 343(r), and 371(a)). We are also relying on our authority under sections 403(r), 403(a), 201(n) and 701(a) of the FD&C Act to propose certain records requirements.

D. Costs and Benefits

In the current marketplace, about 5 percent of all packaged foods are labeled as ''healthy.'' Because nutrition science has evolved over time, updating the definition of the implied nutrient content claim ''healthy'' to closely align with nutrition science underpinning the *Dietary Guidelines, 2020–2025* will better inform consumers who are selecting those products to choose a more healthful diet, which may result in lower incidence of diet-related chronic diseases, including cardiovascular disease and type 2 diabetes. Quantifiable benefits of the proposed rule are the estimated reduction over time in all-cause morbidity stemming from consumers that rely upon the ''healthy'' implied nutrient content claim selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. Quantifiable costs to manufacturers associated with updating the ''healthy'' claim are reformulating, labeling, and recordkeeping. Discounted at 3 percent over 20 years, the mean present value of costs is estimated at $276 million, or $19 million annualized. Potential costs of rebranding certain foods are discussed qualitatively. Discounted at three percent over 20 years, the mean present value of benefits is estimated at $455 million, or $31 million annualized. Net benefits are estimated at $180 million, or $12 million annualized.

II. Introduction

In 1994, FDA issued a regulation defining ''healthy'' as an implied nutrient content claim pursuant to the Nutrition Labeling and Education Act (NLEA) of 1990. Implied nutrient

content claims were defined in our regulations, in part, as claims that imply that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. At that time, nutrition science and Federal dietary guidance focused more on the individual nutrients contained in food. As a result, the criteria for ''healthy'' in the current regulation are solely based on individual nutrients. Nutrition science and Federal dietary guidance have evolved since the existing ''healthy'' regulation was issued in 1994. As the *Dietary Guidelines, 2020–2025* explains, current nutrition science focuses ''on consuming a healthy dietary pattern'' (Ref. 1). Although nearly all foods can be incorporated into a healthy dietary pattern to a greater or lesser extent, current nutrition science emphasizes nutrient-dense foods, such as fruits, vegetables, and whole grains, as key elements of a healthy dietary pattern. ''Nutrient dense'' foods and beverages are defined as foods and beverages that provide vitamins, minerals, and other health-promoting components and have little added sugars, saturated fat, and sodium (Ref. 1). These foods, which contain a variety of important nutrients, work synergistically as part of a dietary pattern to help improve health (Ref. 1). A number of these nutrient-dense foods are not able to bear the ''healthy'' claim under the current regulation (*e.g.,* salmon due to fat levels). Further, the current definition permits manufacturers to use the claim ''healthy'' on some foods that, based on the most up-to-date nutrition science and Federal dietary guidance, contain levels of nutrients that would not help consumers maintain healthy dietary practices (*e.g.,* certain ready-to-eat cereals that may be high in added sugars). Thus, we believe that the ''healthy'' claim definition needs to be updated in order to ensure that products bearing the claim are the products that may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance.

FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity as nutrition-related chronic diseases are experienced disproportionately by certain racial and ethnic minority groups and those with lower socioeconomic status. We are committed to accomplishing this, in part, by empowering consumers with more informative and accessible labeling to choose healthier diets. By making nutrition information more available to consumers in a direct, accessible, and consistent manner, consumers will be able to make informed and healthful dietary choices. A key element in achieving these goals is updating our policies for nutrition-related labeling claims to reflect current nutrition science and Federal dietary guidance, which includes aligning with the updated Nutrition Facts Label and the *Dietary Guidelines, 2020–2025* (Ref. 1), and provide information in a way that is accessible to consumers. Claims like ''healthy'' provide information to consumers that allow them to quickly identify foods that can be the foundation of a healthy dietary pattern. Thus, the goal of this rulemaking is to update the definition of ''healthy'' as an implied nutrient content claim in the labeling of human food to help ensure that consumers have access to more complete, accurate, and up-to-date information about those foods.

To provide context regarding the scope of the problem Americans face from diet-related chronic disease, chronic diseases, such as heart disease, cancer, and stroke, are among the leading causes of death and disability in the United States, and half of all American adults have one or more preventable, diet-related chronic diseases, including cardiovascular disease and type 2 diabetes (Ref. 2). Each year, more than 630,000 Americans die from heart disease and close to 600,000 die from cancer (Ref. 3). An estimated 37 percent of Americans suffer from cardiovascular disease (CVD) (Ref. 4). As of 2017, 12.2 percent of the population 18 years and older had diabetes, 33.9 percent of adults had prediabetes (Ref. 5), and 38.4 percent of the population was predicted to be diagnosed with cancer during their lifetime (Ref. 6). As noted, many of these chronic diseases are experienced at higher rates by certain racial and ethnic minority groups and those with lower socioeconomic status. For example, in 2017–2018, more than 4 in 10 American adults had high blood pressure, and that number increases to about 6 in 10 for non-Hispanic Black adults (Ref. 27). Additionally, from 2017 to 2018, the prevalence of diagnosed diabetes was highest among American Indian and Alaska Native adults compared to other race-ethnicity groups (Ref. 28). While chronic diseases result from a mix of factors, unhealthy dietary patterns throughout the lifespan increase the risk of developing chronic diseases, along with genetic, biological, behavioral, socioeconomic, and environmental factors (Ref. 1).

Further, overweight and obesity, which are associated with poor eating and physical activity behaviors, are major contributors to chronic disease in the United States (Ref. 10). Obesity raises the risk for morbidity from chronic diseases such as type 2 diabetes, coronary heart disease, and some cancers, and is also associated with increased risk of all-cause and CVD mortality (Ref. 10). More than two-thirds of U.S. adults and nearly one-third of children and youth are overweight or obese (Ref. 11). These high rates of overweight and obesity and chronic disease have persisted for more than two decades and come not only with increased health risks, but also at high economic cost. According to the Government Accountability Office, in 2018, $383.6 billion was spent to treat CVD, cancer, and diabetes, making up 25 percent of the approximately $1.5 trillion in total health care spending on conditions among U.S. adults. In particular, government payers, including Medicare and Medicaid, account for more than 50 percent of spending for treatment of CVD, cancer, and diabetes (Ref. 29).

Improved nutrition represents an opportunity to help reduce the rates of these diet-related chronic diseases. As part of our nutrition work, we are taking actions to help consumers maintain healthy dietary patterns and make food choices that contribute to such patterns. A key source that has considered the current nutrition science and established recommendations on what healthy dietary patterns look like is the Dietary Guidelines document. The Dietary Guidelines are developed jointly by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) and provide recommendations on healthy eating and the consumption of foods from various food groups, as well as the intake of specific macronutrients, such as saturated fats and added sugars, and micronutrients such as vitamins and minerals. The Dietary Guidelines are designed for policymakers and nutrition and health professionals to help all individuals and their families consume a healthy, nutritionally adequate diet (Ref. 1). The Dietary Guidelines are the foundation of Federal dietary guidance and are intended to inform policymakers when they implement Federal policies and programs related to food, nutrition, and health. The Dietary Guidelines, in addition to other consensus reports and scientific information, help FDA to shape regulations on nutrition-related claims

and other information that is permitted on a food label.

The *Dietary Guidelines, 2020–2025* explains that a healthy lifestyle—including following a healthy dietary pattern—can help people achieve and maintain good health and reduce the risk of chronic disease throughout all stages of the lifespan. The *Dietary Guidelines, 2020–2025* identifies vegetables, fruits, dairy, grains, protein foods, and oils as essential components of a healthy dietary pattern (Ref. 1). However, more than 80 percent of Americans have dietary patterns that are low in vegetables, fruits, and dairy (Ref. 1). Additionally, more than half of the population is meeting or exceeding the total grain and total protein foods recommendations but is not meeting the recommendations for the subgroups within each of these food groups (Ref. 1). In 2019, 42 percent of adolescents and 39 percent of adults said they ate fruit less than once a day, while 41 percent of adolescents and 21 percent of adults said they ate vegetables less than once a day (Ref. 13). At the same time, most Americans exceed the recommended intake limits for added sugars, saturated fats, and sodium, nutrients that should be limited in a healthy dietary pattern according to the *Dietary Guidelines, 2020–2025* (Ref. 1). Evidence shows that excess intake of these nutrients is associated with chronic disease risk; for example, diets lower in saturated fat may reduce the risk of CVD (Ref. 7), and high intakes of sodium are directly associated with elevated blood pressure, an important risk factor for CVD (Refs. 9, 10, and 17).

As consumers make their food purchases and daily food choices, food labeling provides them with valuable information about food groups, nutrients, and how a food from a particular food group fits into their daily diet. Claims on food packages such as ''healthy'' can provide quick signals to consumers about the healthfulness of a food or beverage, making it easier for busy consumers to select foods that can help build more healthful diets. To be accurate and effective, however, a claim of ''healthy'' must be based on current nutrition science and Federal dietary guidance to ensure that the foods bearing the claim in fact are useful to help consumers maintain healthy dietary practices.

We are thus proposing to update the implied nutrient content claim ''healthy,'' to make it consistent with current nutrition science and Federal dietary guidance. This update would modernize the criteria for the ''healthy'' claim to go beyond just individual nutrients to also incorporate the variety of nutrients present in a food, through the new food group requirements. This change would better reflect the overall nutrient content of the food, including nutrient density, to represent how nutrients work together and make up the food groups and subgroups that are part of a healthy dietary pattern. Aligning the concept of what it means to qualify for the ''healthy'' claim with current nutrition science and Federal dietary guidance, and its focus on nutrient density, will help ensure that the ''healthy'' claim is accurate and empowers consumers with information to make healthier decisions. Because we understand that there may be some reluctance by some food manufacturers to use the claim with the current regulatory definition, as it is not consistent with current nutrition science and Federal dietary guidance, we also expect that our proposed updated criteria for the ''healthy'' nutrient content claim may expand the availability of food labeled with the ''healthy'' claim for consumers in the marketplace due to manufacturers being more willing to use the updated claim.

III—Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
CVD	Cardiovascular Disease.
Dietary Guidelines	Dietary Guidelines for Americans.
DV	Daily Value.
DRV	Daily Reference Value.
c-eq	Cup Equivalent.
DRI	Daily Reference Intake.
DGAC	Dietary Guidelines Advisory Committee.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FGE	Food Group Equivalent.
HHS	U.S. Department of Health and Human Services.
G	Gram.
IOM	Institute of Medicine.
OMB	Office of Management and Budget.
National Academies	National Academies of Sciences, Engineering, and Medicine.
NFL Final Rule	Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule.
NLEA	Nutrition Labeling and Education Act.
oz-eq	Ounce Equivalent.
Mg	Milligram.
Oz	Ounce.
PRA	Paperwork Reduction Act.
RDI	Reference Daily Intake.
RACC	Reference Amount Customarily Consumed.
RFI	Request for Information.
PHO	Partially Hydrogenated Oil.
USDA	U.S. Department of Agriculture.
Dietary Guidelines, 2020–2025	*Dietary Guidelines for Americans, 2020–2025.*
2020 DGAC Report	Scientific Report of the 2020 Dietary Guidelines Advisory Committee.

IV. Background

A. Regulatory History

In the **Federal Register** of May 10, 1994, we published a final rule entitled ''Food Labeling: Nutrient Content Claims, Definition of Term: Healthy'' amending § 101.65(d) to define the term ''healthy'' as an implied nutrient content claim under section 403(r) of the FD&C Act (59 FR 24232). The definition in § 101.65(d) establishes parameters for use of the implied nutrient content claim ''healthy'' or related terms (such as ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') on the label or in the labeling of a food that is useful in creating a diet that is consistent with dietary recommendations, if the food meets certain nutrient conditions. Under the existing regulation, these conditions include specific criteria for nutrients that must be met in the food for it to bear such claims. These criteria include limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts (10 percent of Daily Value (DV)) of nutrients whose consumption is encouraged, such as vitamin A, vitamin C, calcium, iron, protein, and dietary fiber. Under the regulation, foods must meet all limits and contain the minimum amount of at least one nutrient to encourage to bear the ''healthy'' claim. The required nutrient criteria vary for certain food groups (*e.g.,* there are different criteria for seafood, game meat, and raw fruits and vegetables) (§ 101.65(d)(2)). The current claim is also linked to use with an explicit or implicit claim or statement about a nutrient (*e.g.,* ''healthy, contains 3 grams of fat'').

B. Need To Update ''*Healthy*''

The existing definition in § 101.65(d) is linked to certain requirements in the Nutrition Facts label at 21 CFR 101.9 and serving size regulations at 21 CFR 101.12 that were in effect in 1994 when the final rule to define the nutrient content claim ''healthy'' was published. For example, the existing ''healthy'' regulation requires that a product provide a specified percentage of the RDI or Daily Reference Value (DRV) for nutrients that were of ''sufficient public health significance to warrant their inclusion on the nutrition label'' (59 FR 24232). Since that time, FDA has issued final rules updating the Nutrition Facts label and serving size information for packaged foods to reflect new scientific information. This includes the final rules ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742, ''NFL Final Rule'') and ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (81 FR 34000, ''Serving Size Final Rule''), which were published on May 27, 2016. These rules included changes to the nutrients that must be declared on the Nutrition Facts label. For example, the Nutrition Facts label must now include a declaration of the amount of added sugars in a serving of a product, based on our conclusion that evidence on dietary patterns and health outcomes supports a mandatory declaration of added sugars (81 FR 33742 at 33799). The updates also included changes to the DV of certain individual nutrients to reflect changes in recommended intake levels based on current nutrition science. The Nutrition Facts label declaration requirements and DVs for individual nutrients significantly inform the regulations for nutrient content claims such as ''healthy,'' including the updated criteria outlined in this proposed rule. The NFL Final Rule and the Serving Size Final Rule reflect the nutrition science in the 2015–2020 *Dietary Guidelines,* other consensus reports, national survey intake data, and research regarding consumer use and understanding of the label.

The Dietary Guidelines are published every five years to reflect current nutrition science. Although some of its specific recommendations have evolved as scientific knowledge has grown, many of its foundational recommendations have remained consistent over time (*e.g.,* recommending increased consumption of fruits, vegetables, and whole grains, and diets low in saturated fat and sodium). Advancements in nutrition science have provided a greater understanding of, and focus on, the importance of healthy dietary patterns, and how dietary components act synergistically to affect health. The *Dietary Guidelines, 2020–2025* has a particular focus on the importance of dietary patterns as a whole, with recommendations to help Americans make choices from across and within all food groups within calorie needs to add up to an overall healthy dietary pattern (Ref. 1). The *Dietary Guidelines, 2020–2025* also emphasizes ''shifts,'' or replacement of less healthy food choices with nutrient-dense foods, as a method for consumers to achieve a healthy dietary pattern. The body of scientific evidence discussed in the *Dietary Guidelines, 2020–2025,* and the recommendations based on that nutrition science, inform this proposed rule.

As stated above, a key element in helping to reduce the burden of nutrition-related chronic diseases and advance health equity is updating FDA's policies for nutrition-related labeling claims to ensure that they reflect current nutrition science and Federal dietary guidance, and provide information in ways that are useful and easier to understand for consumers. Because the implied nutrient content claim ''healthy,'' as codified at § 101.65(d)(2), is linked to the nutrition labeling regulations and dietary guidance that were in effect at the time of its issuance in 1994, we propose to update the criteria for ''healthy'' to ensure they are harmonized with current regulations, nutrition science, and Federal dietary guidance.

The framework underlying the existing ''healthy'' claim is, in some respects, inconsistent with current nutrition science and Federal dietary guidance. For example, the *Dietary Guidelines, 2020–2025,* which reflects current nutrition science, is centered on the importance of dietary patterns; their recommendations focus on the combination of nutrient-dense foods and beverages that people should consume to meet nutritional needs within calorie limits (Ref. 1), rather than focusing on individual nutrients. Nutrient density is important, among other reasons, because consumption of nutrient-dense foods provides beneficial nutrients, with little added sugars, saturated fat, or sodium. In contrast, the existing criteria for ''healthy'' only include requirements for individual nutrients. Under the solely individual nutrient-based framework, foods that are encouraged by the *Dietary Guidelines, 2020–2025* for inclusion in a healthy dietary pattern are sometimes not able to meet the nutrient criteria under § 101.65(d) for use of the claim ''healthy.'' For example, although consumption of certain oils, such as olive and canola oil, in place of sources of saturated fat, is supported by current nutrition science and emphasized by Federal dietary guidance (such as the *Dietary Guidelines, 2020–2025*) as part of a healthy dietary pattern, these oils are currently ineligible to bear the ''healthy'' claim, in part, because they do not contain 10 percent of the DV for vitamin A, vitamin C, protein, dietary fiber, calcium, or iron as specified by the existing rule. Thus, the existing ''healthy'' claim has become inconsistent with the longstanding

purpose of this type of implied claim to indicate that the nutrient levels in a food may help consumers maintain healthy dietary practices.

To the extent that current nutrition science and Federal dietary guidance (such as the *Dietary Guidelines, 2020–2025*) do still focus on individual nutrients (*e.g.,* recommending limits on saturated fat, sodium, and added sugars; identifying certain underconsumed nutrients), there have been some developments in scientific understanding related to intake of such nutrients. For example, Federal dietary guidance has shifted from recommending diets low in total fat (Ref. 12) to emphasizing increased intakes of monounsaturated and polyunsaturated fats and decreased intakes of saturated fat (Ref. 1). Additionally, current nutrition science, as reflected in the *Dietary Guidelines, 2020–2025,* recommends limiting consumption of foods higher in added sugars, which provide excess calories to the diet without contributing significant amounts of essential nutrients. In contrast, the existing ''healthy'' criteria include limits on total fat and do not include limits for added sugars, which makes the criteria inconsistent with current nutrition science and Federal dietary guidance.

Finally, as noted above, the existing definition for healthy includes a nutrient contribution criterion focused on nutrients that had sufficient public health significance to warrant their inclusion on the nutrition label and that had been highlighted by leading health authorities as being important to the public health (59 FR 24232 at 24243). At the time the existing ''healthy'' regulation was finalized in 1994, the nutrients included in the nutrient contribution requirement were vitamin A, vitamin C, protein, iron, calcium, and dietary fiber. Nutrient intakes have shifted over time, and vitamins A and C are no longer considered nutrients of public health significance because deficiency of these nutrients in the U.S. population is rare and not currently of substantial public health concern. In our recent updates to the Nutrition Facts label, we required declaration of vitamin D and potassium, but no longer required declaration of vitamins A and C (81 FR 33742 at 33744). These updates are consistent with the *Dietary Guidelines, 2020–2025,* which includes calcium, potassium, dietary fiber, and vitamin D as nutrients of public health concern, in addition to iron, for certain population groups (Ref. 1). Thus, in addition to a shift in focus from consumption of individual nutrients to healthy dietary patterns as the primary way to achieve nutritional adequacy, there have been some changes in Federal dietary guidance regarding individual nutrients since the original ''healthy'' rule was issued.

Noting the changes to the Nutrition Facts label, current nutrition science, and the *Dietary Guidelines, 2020–2025,* a variety of stakeholders, including from academia, industry, and consumers, have requested that we update the implied nutrient content claim ''healthy.'' Some stakeholders have provided specific recommendations on how they believe we should approach such an update. For example, in a citizen petition dated December 1, 2015 (Docket No. FDA–2015–P–4564) (''Kind Citizen Petition''), KIND LLC requested that we make certain changes to existing nutrition claim regulations, including a number of changes specifically related to the nutrient content claim ''healthy.''

C. Actions Taken To Update ''Healthy''

Because the framework for many of our nutrition labeling regulations is linked to elements in the Nutrition Facts label and serving size regulations, we have already taken several steps toward harmonizing the ''healthy'' nutrient content claim with our updated regulations and current nutrition science. In the **Federal Register** of September 28, 2016 (81 FR 66527), we published a notice of availability of a final guidance entitled ''Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry.'' The guidance describes our intent to reevaluate the existing criteria for ''healthy'' in light of the changes to the Nutrition Facts label and serving size regulations, as well as the changes in nutrition science as reflected in the Dietary Guidelines. The guidance also advises manufacturers of our intention to exercise enforcement discretion with respect to some of the existing criteria for the nutrient content claim ''healthy'' until we amend § 101.65(d)(2). The guidance is available at: *https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf.*

Specifically, the guidance advises food manufacturers of our intent to exercise enforcement discretion with respect to the implied nutrient content claim ''healthy'' for foods that have a fat profile of predominantly monounsaturated and polyunsaturated fats, but do not meet the regulatory definition of ''low fat,'' and on foods that contain at least 10 percent of the DV per reference amount customarily consumed (RACC)[1] of potassium or vitamin D. This guidance reflects the changes in science and the Dietary Guidelines as described above related to intake of dietary fat and the changes in the nutrients of public health concern since the ''healthy'' definition was originally issued.

In September 2016, we also announced the establishment of a docket (Docket No. FDA–2016–D–2335) to receive information and comments (request for information or RFI) on the use of the term ''healthy'' in the labeling of human food products (81 FR 66562, September 28, 2016). In the RFI, we invited interested persons to comment on the Kind Citizen Petition; the use of the term ''healthy'' as a nutrient content claim in the labeling of human food products; and when, if ever, the use of the term ''healthy'' may be false or misleading. We also sought input on 12 specific questions and asked interested parties to provide supporting data, consumer research, and other information to support their comments and answers to our questions. Along with the RFI, we held a public meeting on March 9, 2017, entitled ''Use of the Term 'Healthy' in the Labeling of Human Food Products'' (Ref. 13). The purpose of the public meeting was to give interested persons an opportunity to discuss the use of the term ''healthy'' in the labeling of human food.

Overall, the comments to the docket (nearly 1,200) and at the public meeting supported updating the criteria for the ''healthy'' nutrient content claim to reflect current nutrition science and the Dietary Guidelines. Most health organizations, industry representatives, and consumers supported an enforceable, specific definition that would help guide consumers toward healthier options. There was broad support for limiting certain nutrients, especially added sugars, in foods labeled ''healthy,'' and in allowing whole, nutrient-dense foods and foods high in monounsaturated and polyunsaturated fats to meet the definition. Comments to the docket provided specific recommendations for nutrient criteria, whole food servings, and flexibility for different food categories. While there was some variation in the specific criteria proposed in comments, virtually all of the proposed frameworks included a combination of nutrient criteria and food group requirements.

Some comments from consumers, and a few comments from industry and

[1] Our regulations at § 101.12(b) establish RACCs for specified product categories that manufacturers can use to determine the required label serving size.

health organizations, expressed hesitation at the notion of a ''healthy'' nutrient content claim. Their primary concerns were that ''healthy'' could be too simplistic, could deter consumers from looking further into a product's nutritional content, could lead to excessive consumption of ''healthy'' products, or could mean different things to different consumers (*e.g.,* some consumers may not understand ''healthy'' in a nutritional context, but, rather, as referring to other aspects of the product, such as its production method (*e.g.,* organic)). FDA notes that the claim is not new and has been used on food product labels for decades, but we welcome additional comments on these issues in the context of this proposed rule.

We carefully considered comments received in response to the RFI and are addressing many aspects of the concerns noted within those comments in this proposed rule. We view the ''healthy'' claim as an opportunity to signal and provide information to consumers on which food products, because of their nutrient content, can be most helpful in maintaining healthy dietary practices, based on current nutrition science and Federal dietary guidance. The availability of a revised, updated ''healthy'' claim may also result in some members of the food industry developing and/or reformulating food products to better match current nutrition science recommendations and use the claim. Given the widespread support for updating ''healthy'' along with the need to align the claim with current nutrition science, we are proposing updated criteria for the claim.

D. Table of Past Publications Referenced in This Proposed Rule

Title	Publication date	Citation
Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms Final Rule.	January 6, 1993	58 FR 2302
Food Labeling: Nutrient Content Claims, Definition of Term: Healthy Final Rule	May 10, 1994	59 FR 24232
Food Labeling: Revision of the Nutrition and Supplement Facts Labels Final Rule	May 27, 2016	81 FR 33742
Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments Final Rule.	May 27, 2016	81 FR 34000
Notice of Availability for a Final Guidance ''Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry''.	September 28, 2016	81 FR 66527
Request for Information on the Use of the Term ''Healthy'' in the Labeling of Human Food Products.	September 28, 2016	81 FR 66562

V. Legal Authority

We are issuing this proposed rule to update the definition of the implied nutrient content claim ''healthy'' consistent with our authority in sections 201(n), 403(a), 403(r), and 701(a) of the FD&C Act. These sections authorize FDA to adopt regulations that prohibit labeling that is: (1) false and misleading in that it fails to reveal facts that are material in light of the representations that are made with respect to consequences that may result from consuming the food or (2) uses terms to characterize the level of any nutrient in a food that has not been defined by regulation by FDA.

Congress passed the Nutrition Labeling and Education Act (NLEA) of 1990 (Pub. L. 101–535), with three basic objectives: (1) to make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary of HHS, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods (58 FR 2302, January 6, 1993). The NLEA created section 403(r)(1)(A) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (q)(2) to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA's authorizing regulations (section 403(r)(1)(A) & (r)(2)(A) of the FD&C Act). Such claims are referred to as ''nutrient content claims.''

Nutrient content claims can either be claims that expressly characterize the level of a nutrient (express claims, such as ''low fat'') or claims that by implication characterize the level of any nutrient (implied claims, like the ''healthy'' claim). Nutrient content claims are typically based per RACC. This allows nutrient content claims on foods to be considered consistently across products and product sizes. In rulemaking to implement section 403(r)(1)(A) and 403(r)(2) of the FD&C Act shortly after the enactment of the NLEA, we determined that a claim that states that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is a claim that characterizes the levels of nutrients in a food (''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms,'' 58 FR 2302 at 2374–75, January 6, 1993). That rulemaking resulted in regulations defining ''implied nutrient content claims,'' in part, as claims that imply that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. As the preamble explained, ''[t]he claims are essentially saying that the levels of nutrients in the food are such that the food will contribute to good health'' (58 FR 2302 at 2375).

FDA issued another implementing regulation in 1994, in which we defined ''healthy'' when the term is used as an implied nutrient content claim (59 FR 24232, May 10, 1994). We explained in the preamble to the 1994 final rule that the statute requires that FDA define terms by regulation before they are used as nutritional claims in food labeling; more specifically, under the terms of section 403(r)(1)(A) and 403(r)(2) of the FD&C Act, a nutrient content claim would misbrand a food unless it is made in accordance with a definition of the Secretary (and, by delegation, FDA) or with one of the other provisions in section 403(r)(2) of the FD&C Act (59 FR 24232 at 24234). The preamble explained that FDA had already determined that, when used in the nutritional labeling context, the term ''healthy'' is making an implied claim about the levels of the nutrients in the food; that is, that these levels are such that the food would be useful in achieving a total diet that conforms to current dietary recommendations (56 FR 60421 at 60423, November 27, 1991). Accordingly, FDA was establishing a

definition for ''healthy'' when it is used in a nutritional context.

In this rulemaking, we are proposing to update the definition of ''healthy'' when used as an implied nutrient content claim based on developments in current nutrition science and Federal dietary guidance, as we did with the rulemaking updating the Nutrition Facts label. Our proposed, updated criteria for ''healthy'' incorporate both food group and nutrient-to-limit requirements. These changes are intended to ensure that foods bearing the implied nutrient content claim ''healthy'' are foods that may help consumers maintain healthy dietary practices, based on current nutrition science and Federal dietary guidance. The fundamental purpose of this rulemaking furthers the congressional objectives underlying the NLEA of providing nutrition information to consumers to help in selecting foods that can lead to healthier diets and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims.

The proposed revised definition of ''healthy'' is consistent with the statutory language, particularly in light of the way current nutrition science and Federal dietary guidance, such as the Dietary Guidelines, have evolved and built upon previous editions. The Dietary Guidelines reflect the consensus scientific understanding that nutrients are not consumed in isolation and focus their recommendations on consuming a variety of nutrient-dense foods, across all food groups, as part of a healthy dietary pattern. The statutory language describes nutrient content claims as claims in the label or labeling of a food that ''expressly or by implication'' ''characterize the level of any nutrient in a food'' (section 403(r)(1)(A) of the FD&C Act). The claim ''healthy'' on its face is an implied claim because it suggests that the food, because of its nutrient content, may help consumers maintain healthy dietary practices. In the 1994 definition of the claim, levels for nine different individual nutrients were discussed: fat, saturated fat, cholesterol, vitamin A, vitamin C, calcium, iron, protein, and fiber (21 CFR 101.65(d)(2)(i)). As discussed elsewhere in this document, in recent years the Dietary Guidelines have shifted to recommending healthy dietary patterns and the consumption of food groups in certain quantities to achieve adequate nutrient intake, based on the understanding that each food group contributes an array of important nutrients to the diet (*Dietary Guidelines, 2020–2025*). Specifically, the *Dietary Guidelines, 2020–2025* states that because foods provide an array of nutrients and other components that have health benefits, nutritional needs should be met primarily through a variety of nutrient-dense foods. Additionally, the *Dietary Guidelines, 2020–2025* recommends increasing intakes of food groups to move intakes of underconsumed dietary components closer to recommendations.

Accordingly, the new proposed definition includes food groups that provide a number of different nutrients and is thus characterizing the overall nutrient content of the food, rather than focusing on one individual nutrient in isolation, as with an express nutrient content claim. Each food group that is included in the food group requirement for the proposed updated definition of the ''healthy'' claim represents the inclusion of multiple important nutrients. Therefore, the use of food groups better accounts for how all these nutrients contribute to, and may work synergistically to create, a healthy dietary pattern and improve health outcomes. By requiring products to contain a certain amount of a food group, the proposed rule will help ensure foods bearing the ''healthy'' claim contain a variety of important beneficial nutrients and, therefore, help Americans meet recommended nutrient intakes and maintain healthy dietary patterns. Consistent with Congress's objectives to provide appropriate nutritional information to consumers, and based on current nutrition science and Federal dietary guidance, the statutory phrase ''characterize the level of any nutrient in a food'' encompasses both limits on certain individual nutrients and food group criteria that more broadly incorporate a variety of nutrients from nutrient dense foods which may also have a synergistic effect.

In addition to section 403(r)(2) of the FD&C Act, we are issuing this proposed rule under section 701(a) of the FD&C Act, which states that we may issue regulations for the efficient enforcement of the FD&C Act and has been interpreted to apply in order to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Sup. 1179, 1183 (D. Del. 1980)).

We are also relying on our authority under sections 403(r), 403(a), 201(n) and 701(a) of the FD&C Act, to propose records requirements designed to ensure that the use of the ''healthy'' claim is accurate, truthful and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where FDA has found such records to be necessary (*National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The recordkeeping we propose to require applies only to foods voluntarily bearing the ''healthy'' claim for which an adequate analytical method to determine food group equivalents is not available or the amount cannot be discerned from the label alone. The records would allow us to verify that the product meets the requirements to bear the claim and that use of the nutrient content claim ''healthy'' is truthful and not misleading. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act (see discussion in section VI.B.4 ''Records Requirements'' for more information).

The authority granted to FDA under sections 701(a), 403(r), 403(a)(1) and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without access to such records, FDA would not know whether the food meets the proposed requirements to bear the ''healthy'' claim consistent with section 403(r) of the FD&C Act, and whether the use of the claim is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether a food that is voluntarily bearing a ''healthy'' nutrient content claim is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be kept under proposed § 101.65(d)(4) (21 CFR 101.65(d)(4)). Failure to make and keep records and provide the records to FDA, as described in proposed § 101.65(d)(4), would result in the food bearing the ''healthy'' claim being misbranded under sections 403(r) and 403(a)(1) of the FD&C Act.

VI. Proposed Action

We propose to update the ''healthy'' nutrient content claim to align its criteria with our updates to the Nutrition Facts label and with current nutrition science and Federal dietary guidance, especially the *Dietary Guidelines, 2020–2025.* We also took several additional factors into

consideration while developing the proposed, updated criteria for ''healthy.'' We intend for the updated ''healthy'' criteria to help identify and encourage consumption of nutrient-dense foods to meet current nutrition science and Federal dietary guidance, especially the intake recommendations of the individual food groups as discussed in the *Dietary Guidelines, 2020–2025.* We also intend for the ''healthy'' criteria to be appropriately flexible to allow for industry innovation, thereby increasing the availability of foods in the marketplace that will help consumers meet dietary recommendations. Finally, we based the proposed criteria on well-established and longstanding foundations of dietary guidance, including food group recommendations and nutrients to limit.

A. Overview of Approach

The *Dietary Guidelines, 2020–2025* recommends following a healthy dietary pattern at every life stage with a focus on meeting food group needs with nutrient-dense foods and beverages, and staying within calorie limits. Specifically, the *Dietary Guidelines, 2020–2025* states that because foods provide an array of nutrients and other components that have health benefits, nutritional needs should be met primarily through a variety of nutrient dense foods. Additionally, the *Dietary Guidelines, 2020–2025* recommends increasing intakes of food groups to move intakes of underconsumed dietary components closer to recommendations. Consistent with current nutrition science and Federal dietary guidance, our proposed, updated criteria for ''healthy'' use an approach based on both food groups and nutrients to limit, rather than focusing solely on individual nutrients. The updated ''healthy'' criteria emphasize the food groups and subgroups identified in the *Dietary Guidelines, 2020–2025* as part of a healthy dietary pattern: vegetables, fruits, grains, dairy, and protein foods, as well as oils. Under the proposed, updated criteria, food products would need to contain a certain amount of food (a ''food group equivalent'') from at least one of these recommended food groups or subgroups (*e.g.,* ½ cup of fruit or ¾ cup of dairy) to be labeled ''healthy.'' The proposed incorporation of food group criteria is consistent with the current nutrition science articulated in the *Dietary Guidelines, 2020–2025* and its focus on dietary patterns as a whole and is appropriate for this implied nutrient content claim because claims that imply a food product contains a certain amount of a food group would characterize the level of a variety of nutrients important to help consumers maintain healthy dietary practices.

In addition to the food group criteria, we are proposing that foods must continue to adhere to certain criteria regarding nutrients to limit to be labeled ''healthy.'' Specifically, we propose maintaining sodium and saturated fat as nutrients to limit (which are already included in the current criteria), along with adding a limit on added sugars, consistent with the rationale for the new Nutrition Facts label requirement for added sugars declaration. These criteria are also consistent with the *Dietary Guidelines, 2020–2025* recommendations to limit intake of sodium, saturated fat, and added sugars, and, based on current nutrition science, would strengthen the public health benefits of foods bearing the ''healthy'' claim. The specific food group criteria and the nutrients to limit are discussed in further detail in sections VI.A.1 and VI.A.2 (''Food Groups'' and ''Nutrients to Limit'').

Because of the proposed food group approach, we propose that the ''healthy'' criteria no longer include minimum amounts of nutrients to encourage (*i.e.,* nutrients that are underconsumed and whose low intake in the general population or in individual subpopulations raise public health concern). The *Dietary Guidelines, 2020–2025* recommendations to consume various food groups and subgroups in certain quantities are intended to ensure overall nutritional adequacy and consumption in a manner to help consumers maintain healthy dietary practices. FDA is concerned that including criteria for nutrients to encourage could spur fortification to allow foods that are low in saturated fat, sodium, and added sugars to qualify for the ''healthy'' claim, despite these foods not contributing to a meaningful amount of a food group (*e.g.,* white bread fortified with calcium). FDA does not support indiscriminate fortification of foods but, rather, encourages the rational addition of nutrients to foods, as discussed further in our fortification policy guidance (Ref. 30). We request comment on whether nutrients to encourage should be included in addition to the food group criteria.

As described below, there are some foods that we propose to include in the updated criteria for ''healthy'' including raw, whole fruits and vegetables, and water, that under the proposed updated criteria, will not need to meet requirements for food group equivalents and nutrients to limit. These foods are included in categories of food that can automatically use the ''healthy'' claim because of their nutrient content and positive contribution to an overall healthy diet. This is not the case for these foods under the current rule; rather the individual fruit or vegetable must meet the criteria for the nutrients to limit (total fat, saturated fat, sodium, cholesterol) in order to bear the ''healthy'' claim. These exceptions will be discussed in further detail in section VI.B.3 (''Covered Products'').

1. Food Groups

Current nutrition science and Federal dietary guidance specifically emphasize the importance of following a healthy dietary pattern across the lifespan (Ref. 1). As described earlier, the *Dietary Guidelines, 2020–2025* notes that foods and beverages are not consumed in isolation, but rather in various combinations over time—a ''dietary pattern.'' Components of a dietary pattern may have interactive, synergistic, and potentially cumulative relationships, such that the dietary pattern may be more predictive of overall health status and disease risk than individual foods or nutrients (Ref. 1). The principal message of the *Dietary Guidelines, 2020–2025* is to follow a healthy dietary pattern that focuses on meeting food group needs with nutrient-dense foods and beverages and stays within calorie limits. The recommendations include an emphasis on meeting nutritional needs ''primarily from foods and beverages—specifically, nutrient-dense foods and beverages'' (Ref. 1), as opposed to dietary supplements. While FDA's definition includes dietary supplements as foods, they may not always be included in what the nutrition science literature refers to as ''foods.'' This recommendation also reflects the view that good nutrition does not come from intake of individual nutrients (as dietary supplements often provide) but rather from foods with their mix of various nutrients working together in combination. The *Dietary Guidelines,* 2020–2025 goes on to describe that ''[e]ating an appropriate mix of foods from the food groups and subgroups—within an appropriate calorie level—is important to promote health at each life stage. Each of the food groups and their subgroups provides an array of nutrients, and the amounts recommended reflect eating patterns that have been associated with positive health outcomes'' (Ref. 1, page 31). This focus on food groups is consistent with longstanding Federal nutrition education and messaging structured around food groups, such as those associated with MyPlate and the former MyPyramid Food Guidance System and Food Guide Pyramid (Ref. 14).

The *Dietary Guidelines, 2020–2025* further explains that a healthy dietary pattern includes:

- Vegetables of all types—dark green; red and orange; beans, peas, and lentils; starchy; and other vegetables;
- Fruits, especially whole fruit;
- Grains, at least half of which are whole grain;
- Dairy, including fat-free or low-fat milk, yogurt, and cheese, and/or lactose-free versions and fortified soy beverages and soy yogurt alternatives;
- Protein foods, including lean meats, poultry, and eggs; seafood; beans, peas, and lentils; and nuts, seeds, and soy products;
- Oils, including vegetable oils and oils in food, such as seafood and nuts.

In the *Dietary Guidelines, 2020–2025* and previous iterations, foods fit into groups based on how they are consumed, and their nutrient content, even if this is different from their botanical classification. For example, a bell pepper is considered a vegetable in the *Dietary Guidelines, 2020–2025* even though it is botanically a fruit. Additionally, foods from the same source may be categorized differently depending on how they are consumed. For example, soybean oil is classified as an oil, but tofu made from soybeans is classified as a protein food in the *Dietary Guidelines, 2020–2025.* In considering which foods contribute to meeting the individual food group requirements, we are adopting the categorizations used in the *Dietary Guidelines, 2020–2025* to determine the appropriate food group for the food. For example, in the previously mentioned bell pepper example, the presence of bell pepper ingredients would contribute to satisfying the vegetable food group requirements, rather than the requirements for fruit ingredients.

Evidence relied on in the *Dietary Guidelines, 2020–2025* shows that a healthy dietary pattern, as outlined above, is associated with beneficial outcomes for all-cause mortality, cardiovascular disease, overweight and obesity, type 2 diabetes, bone health, and certain types of cancer) (Ref. 1). Specifically, evidence shows that common characteristics of dietary patterns associated with positive health outcomes include relatively higher intake of vegetables, fruits, legumes, whole grains, low- or non-fat dairy, lean meats and poultry, seafood, nuts, and unsaturated vegetable oils, and relatively lower consumption of red and processed meats, sugar-sweetened foods and beverages, and refined grains (Ref. 1).

The existing criteria for ''healthy'' at § 101.65(d)(2) include minimum content thresholds for a limited number of nutrients for which consumption is encouraged. These nutrient criteria were originally included to identify foods that are particularly helpful to consumers in maintaining healthy dietary practices and achieving dietary recommendations. Instead of including a limited set of nutrients for which consumption is encouraged in the definition as surrogates for recommended food groups and subgroups, we propose to directly incorporate food groups as criteria in the definition of the claim ''healthy.'' We tentatively conclude that using food groups to encourage as the criteria for ''healthy,'' rather than a limited set of nutrients, would better identify foods with the nutrient content that may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance. This approach is consistent with the *Dietary Guidelines, 2020–2025* focus on overall dietary patterns to ensure that a range of nutrients are consumed at appropriate levels, rather than on nutrients in isolation. We solicit comment on this tentative conclusion.

Our proposed criteria for updating ''healthy'' emphasize healthy dietary patterns by requiring that food products contain a certain amount of food from a recommended food group to bear the claim ''healthy.'' In this rule, the phrase ''food group'' refers to the groups of foods recommended in the *Dietary Guidelines, 2020–2025,* which include vegetables, fruits, dairy, grains, protein foods, as well as oils (Ref. 1). The *Dietary Guidelines, 2020–2025* does not categorize oils as a ''food group,'' but they emphasize that oils are one of the six core elements of a healthy dietary pattern, along with vegetables, fruits, grains, dairy, and protein foods, and recommend daily intake objectives for oils, similar to the food groups. Therefore, we will include oils as a food group for purposes of this rule. However, because of their specific role in healthy dietary patterns, the proposed criteria for oils differ from the criteria for other food groups, as discussed in further detail in section VI.B.3 (''Covered Products''). In this rule, the phrase ''food group equivalent'' refers to the amount of a food group that must be contained in a food product for it to bear the ''healthy'' claim. In this rule, the phrase ''food group equivalent'' refers to the amount of a food group that must be contained in a food product for it to bear the ''healthy'' claim.

We used the ''Healthy U.S.-Style Dietary Pattern,'' as described in table A3–2 in the *Dietary Guidelines, 2020–2025* (Ref. 1), using the 2000-calorie level pattern as the reference, to determine the food group equivalent amounts. We are basing our food group equivalent recommendations on amounts recommended at the 2,000 calorie level because 2,000 calories is often used for general nutrition advice and this reference amount is already used for other purposes in nutrition labeling. The 2000-calorie level pattern establishes specific daily food group and subgroup amounts in cup-equivalents (c-eq), ounce-equivalents (oz-eq), or grams (g), depending on the type of food. Cup- and ounce-equivalents identify the amounts of foods from each food group with similar nutritional content. For example, while the structural forms of whole wheat bread and brown rice are very different, the *Dietary Guidelines, 2020–2025* considers one medium (1 oz) slice of whole wheat bread to be nutritionally similar to one half cup of cooked brown rice, and both represent an oz-eq of whole grains. The 2000-calorie level dietary pattern establishes daily amounts for each food group as follows:

- 2½ c-eq of vegetables (comprising recommendations for vegetable subgroups);
- 2 c-eq of fruits;
- 6 oz-eq of grains, of which at least 3 oz-eq should be whole grains;
- 3 c-eq of dairy;
- 5½ oz-eq of protein foods (comprising recommendations for protein food subgroups, such as seafood); and
- 27 g of oils.

In past rulemakings, we have assumed that the typical American dietary pattern is three meals and one snack per day, *i.e.,* four eating occasions, not including beverage-only eating occasions (see final rules on general requirements for health claims and nutrient content claims in food labeling, 58 FR 2478 at 2495 and 58 FR 2302 at 2379 to 2380). In other words, we assume that individuals generally have four opportunities in a day to meet the recommended daily food group amounts in the Healthy U.S.-Style Dietary Pattern, and thereby satisfy their nutritional needs. Consistent with this assumption, and with our approach in past rulemakings, our proposed food group equivalents are based on four eating occasions per day. To determine the amount of a food group required for an individual food to bear the ''healthy'' claim, we divided the recommended daily food group amounts by four eating occasions. For example, because the recommended daily amount of fruit in the 2000-calorie level pattern is 2 c-eq, we determined that the food group equivalent for fruit would be ½ c-eq

(*i.e.,* 2 c-eq divided by four). This would mean that a ''fruit product'' would need to contain ½ c-eq of fruit per RACC (in addition to other requirements) to meet the proposed criteria for ''healthy.'' While this calculation provided a baseline amount for the food group equivalent requirements, we adjusted the baseline amount for certain food groups and subgroups, as warranted, based on considerations as described in section VI.B.3 (''Covered Products''). This calculation also informs the food group criteria for combination foods (foods that contain a meaningful amount of more than one food group) as will be discussed in section VI.B.3 (''Covered Products''). We seek comment on this proposed calculation—based on four eating occasions per day—for the food group equivalent requirement.

2. Nutrients to Limit

While our proposed updates to the ''healthy'' regulation reflect the importance of the overall nutrient content of foods that build dietary patterns rather than individual nutrients in isolation, we do propose keeping certain nutrients to limit as criteria for bearing the claim ''healthy.'' This is because current nutrition science and Federal dietary guidance continue to recommend limiting certain nutrients as a key component in emphasizing healthy overall dietary patterns. In the NFL Final Rule, we found that nutrition science supports limiting intake of saturated fat, sodium, and added sugars. Similarly, the *Dietary Guidelines, 2020–2025* includes recommendations to choose nutrient-dense foods across and within food groups while limiting foods and beverages higher in added sugars, saturated fat, and sodium (Ref. 1). Moreover, under the *Dietary Guidelines, 2020–2025,* ''nutrient dense'' food and beverages are defined as foods and beverages that provide vitamins, minerals, and other health-promoting components and have little added sugars, saturated fat, and sodium. Vegetables, fruits, whole grains, seafood, eggs, beans, peas, and lentils, unsalted nuts and seeds, fat-free and low-fat dairy products-, and lean meats and poultry—when prepared with no or little added sugars, saturated fat, and sodium—are identified as nutrient-dense foods (Ref. 1). Thus, in addition to the food group criteria for ''healthy,'' we are proposing updates to criteria for nutrients to limit for saturated fat, sodium, and are proposing to add criteria for added sugars. The proposed nutrients to limit criteria help ensure that foods bearing the ''healthy'' claim do not contain excess saturated fat, sodium, or added sugars, which can increase calories and/or the risk of chronic disease and therefore diminish the potential beneficial public health impact of the ''healthy'' claim.

In setting the criteria for nutrients to limit, we are proposing baseline values for each nutrient and have adjusted the values, as warranted. Different food groups and subgroups each contain foods that provide a variety of nutrients, including important nutrients that are underconsumed and some naturally contain higher amounts of nutrients that should be limited. For example, dairy foods provide vitamin D and calcium; however, they also may contain saturated fat. In contrast, fruits and vegetables contain minimal or no saturated fat. Using the same saturated fat criteria across all food groups could exclude foods that provide important nutrients and that are recommended by the Dietary Guidelines, such as low-fat milk and low-fat cheese. However, increasing the saturated fat limit across all food groups could encourage the unnecessary addition of saturated fat for foods in food groups such as vegetables, which are generally not sources of saturated fat. Therefore, based on current nutrition science and Federal dietary guidance, adjustments to the baseline amount for different food groups allow a variety of foods across recommended food groups to meet the proposed, updated definition without encouraging unnecessary addition of saturated fat, sodium, and added sugars. The adjustments made to the baseline amount for different food groups and subgroups are further described in section VI.B.3.b (''Individual foods'').

The baseline values are percentages of the DV for each nutrient to help ensure flexibility and longevity of the ''healthy'' criteria if the DVs shift in the future. DVs are reference amounts of nutrients to consume or not to exceed each day. Historically, the DVs established in regulation by FDA have been based on the nutritional needs of adults and children 4 years of age and older. However, the recent revisions to the regulations for the Nutrition Facts label have established DVs specific to infants up to 12 months of age and to children 1 to 3 years of age (§ 101.9(c)(9)). As discussed earlier, we are proposing that use of the nutrient content claim ''healthy'' remains limited to adults and children 2 years of age and older. Therefore, the claim ''healthy'' could appear on foods directed to children 2 to 3 years of age and on foods directed to adults and children 4 years of age and older. When determining eligibility for use of the claim ''healthy,'' specifically whether a food meets the ''percent DV'' criteria for saturated fat, sodium, and added sugars, the ''percent DV'' criteria will be based on the set of DVs appropriate for that food. For the majority of foods, the DVs established for adults and children 4 years of age and older will be the basis of the nutrient criteria for the claim that are discussed in the following sections. However, for the subset of foods specifically directed to children 2 to 3 years of age (*e.g.,* fruit pouches, toddler snack puffs), the basis of the ''percent DV'' nutrient criteria are the specific set of DVs established for that age range in § 101.9(c)(9).

a. Saturated Fat

The current ''healthy'' nutrient content claim regulation includes limits on saturated fat for all food categories (§ 101.65(d)(2)(i)(A)–(F)). Dietary recommendations have long recognized the well-established relationship between consumption of saturated fat and its effect on blood cholesterol levels (Refs. 16 and 17). Evidence shows that replacement of saturated fats with unsaturated fats, especially polyunsaturated fats, reduces blood total cholesterol and low-density lipoprotein cholesterol (LDL-cholesterol) concentrations and, therefore, the risk of CVD (Ref. 16). Evidence shows that replacing saturated fats with polyunsaturated fats is associated with a reduced risk of CVD mortality and/or coronary heart disease (CHD) (Ref. 16). Saturated fat is required to be declared on food labels by section 403(q)(1)(D) of the FD&C Act, and we reaffirmed in the NFL Final Rule that saturated fat declaration is necessary to assist consumers in maintaining healthy dietary practices (81 FR 33742 at 33786).

The DVs for nutrients are established either as RDIs or as DRVs. The DRV for saturated fat is 20 grams (for children 1 to 3 years old, the DRV is 10 grams), which is approximately 10 percent of calories based on a 2,000-calorie reference intake level (§ 101.9(c)(9)). In the preamble to the proposed NFL rule (79 FR 11879 at 11895, March 3, 2014, Docket No. FDA–2012–N–1210), we discussed how consensus reports (*e.g.,* Institute of Medicine (IOM) Dietary Reference Intakes (DRI) and 2002 report from the National Cholesterol Education Program of the National Institutes of Health's National Heart, Lung, and Blood Institute) continue to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. We reaffirmed in the NFL Final Rule that the 20-gram DRV is consistent with scientific evidence (81 FR 33742 at 33786). Additionally, the Dietary Guidelines have consistently

recommended limiting calories from saturated fats. The *Dietary Guidelines, 2020–2025* states that intake of saturated fat should be limited to less than 10 percent of calories per day by replacing them with unsaturated fats, particularly polyunsaturated fats. Accordingly, we propose limiting saturated fat in foods bearing the implied nutrient content claim ''healthy,'' to ensure that such foods do not contribute to a dietary pattern that contains excess saturated fat. Many of the comments on the RFI supported including a limit on saturated fat in foods bearing the ''healthy'' claim.

For saturated fat, we are proposing a baseline limit of 5 percent of the DV per RACC (≤1 g for adults and children 4 years of age and older). This level is consistent with the low saturated fat nutrient content claim (21 CFR 101.62(c)(2)), and with the saturated fat criteria for most of the individual foods in the current definition for ''healthy.'' We are also proposing to adjust the baseline limit for saturated fat, as warranted, based on specific nutrient considerations associated with the different food groups and subgroups and the Dietary Guideline consumption recommendations for different food groups. As discussed in section V.B.3.b (''Individual foods''), we are proposing the baseline limit for saturated fat (5 percent of the DV per RACC) for fruit products; vegetable products; grain products; bean, pea, and soy products; and nut and seed products (excluding saturated fat derived from nuts and seeds, as discussed in section VI.B.3.b (''Individual foods''). We are proposing the following adjustments to the baseline limit for saturated fat, as described further in the discussion of individual foods below, for certain categories of foods that are core elements of healthful dietary patterns associated with reducing chronic disease risk (*e.g.,* low-fat dairy products): 10 percent of the DV for dairy products; 10 percent of the DV for game meats, seafood, and eggs; and 20 percent of total fat for oils and oil-based spreads and dressings.

We are also considering alternatives to the proposed limits on saturated fat. We are considering an approach using a ratio of saturated fat to total fat, such as a ratio based on current DVs for saturated fat and total fat, which are based on 10 percent and 35 percent of daily calorie intake, respectively. The intent of this approach would be to apply a single ratio across all food groups, thereby reducing the variation in the currently proposed limits, while still allowing some flexibility for foods that provide monounsaturated and polyunsaturated fats. We seek comment on the use of a limit for saturated fat based on the ratio of saturated fat to total fat, including any data supporting this approach.

b. Sodium

The current ''healthy'' nutrient content regulation includes limits on sodium content for all food categories (§ 101.65(d)(2)(ii)). Dietary recommendations have long emphasized reductions in sodium intake because average population-level intake continually exceeds recommended levels. As we stated in the NFL Final Rule, evidence continues to support the association between increased sodium consumption and blood pressure (81 FR 33742 at 33875). For example, the National Academy of Medicine (formerly IOM), of the National Academies of Sciences, Engineering, and Medicine (National Academies), 2005 DRI Electrolytes Report noted a direct relationship between sodium intake and increased blood pressure (Ref. 9) and the 2013 National Academies report entitled ''Sodium Intake in Populations: Assessment of the Evidence'' (Ref. 8) concluded that a strong body of evidence has been documented in adults that blood pressure decreases as sodium intake decreases. The Scientific Report of the 2020 Dietary Guidelines Advisory Committee Report (2020 DGAC Report) states that sodium intake is directly related to blood pressure across the lifespan and that elevated blood pressure contributes to the risk of CVD and stroke, which are both leading causes of morbidity and mortality in the United States (Ref. 15).

Reducing sodium intake has also been a consistent recommendation in the Dietary Guidelines; the *Dietary Guidelines, 2020–2025* carries forward the National Academies' recommendation to limit sodium to less than 2,300 milligrams (mg) per day—and even less for children younger than age 14 (Refs. 1 and 17). According to the *Dietary Guidelines, 2020–2025,* healthy dietary patterns limit sodium to the Chronic Disease Risk Reduction (CDRR) levels defined by the National Academies—1,200 mg/day for ages 1 through 3; 1,500 mg/day for ages 4 through 8; 1,800 mg/day for ages 9 through 13; and 2,300 mg/day for all other age groups. However, average intakes of sodium are high across the U.S. population compared to the CDRR levels. Average intakes for those ages 1 and older is 3,393 mg/day, with a range of about 2,000 to 5,000 mg/day (Ref. 1). In 2019, the National Academies set the CDRR levels for sodium based on evidence of the beneficial effect of reducing sodium intake on blood pressure and risk of CVD and hypertension (Ref. 17). This most recent evaluation of the evidence reaffirms the 2,300 mg/day recommended daily limit for those 14 years and older. To reduce sodium intake to the recommended limits, the *Dietary Guidelines, 2020–2025* recommends implementing multiple strategies, including making food choices in all food groups with less sodium (Ref. 1). We propose to include a limit on the amount of sodium in foods bearing the nutrient content claim ''healthy'' to help individuals identify foods that are consistent with dietary recommendations for sodium. Many comments on the RFI supported a sodium limit on foods bearing the claim ''healthy.''

The DRV for sodium is 2,300 mg (for children 1 to 3 years old, the DRV is 1,500 mg). We are proposing a baseline sodium limit of ≤10 percent of the DV (currently, 230 mg for adults and children 4 years of age and older) per RACC for individual foods. This proposed, updated sodium limit is lower than the limit in the existing criteria for ''healthy'' (480 mg, or about 20 percent of current DV) (§ 101.65(d)(2)(ii)). We expect that it is feasible to lower the sodium level requirement for ''healthy'' due to reductions in sodium in certain foods and food categories in response to consumer support for policies to limit sodium content in manufactured foods (Refs. 18 and 19) and to technological progress since the existing definition of ''healthy'' was issued in 1994. Additionally, in October 2021, FDA published short-term (2.5 year) voluntary sodium reduction targets for the food industry (Ref. 31). These targets are anticipated to support gradual sodium reduction in the food supply and increase available options that are lower in sodium. When selecting the proposed, updated limit for the ''healthy'' claim, we considered the many functions of sodium in food, including taste, texture, microbial safety, and stability. For example, while a baseline limit for sodium of ≤5 percent of the DV would be consistent with the proposed saturated fat and added sugar baseline limits and the low sodium nutrient content claim, we are concerned that a limit of ≤5 percent of the DV for sodium is not practical at this time. We are proposing to adjust the baseline values for sodium as warranted, based on specific considerations of the different food groups and subgroups, as described below. We seek comment on this approach.

c. Added Sugars

In the NFL Final Rule, we required the declaration of the amount of added sugars in a serving of a product after we concluded that evidence on dietary patterns and health outcomes supports a mandatory declaration of added sugars (81 FR 33742 at 33799). We determined that declaration of the amount and percent DV of added sugars in a serving of a product is necessary to assist consumers to maintain healthy dietary practices and determine how a serving of a product fits into the context of their total daily diet (81 FR 33742 at 33804). This conclusion was based on scientific evidence showing that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a decreased risk of CVD (Ref. 7). This is consistent with a key recommendation of the *Dietary Guidelines, 2020–2025* to limit foods and beverages higher in added sugars (Ref. 1). To achieve this recommendation, the *Dietary Guidelines, 2020–2025* recommends that individuals 2 years of age and older consume less than 10 percent of calories per day from added sugars.

Current consumption data indicate that most Americans are consuming more than 10 percent of calories from added sugars (Ref. 16). According to the 2020 DGAC Report, current intake of added sugars remains high at 267 calories, or 12.7 percent of total calories per day among the total population ages 1 year old and older (Ref. 16). Evidence shows that consumption of excess calories from added sugars can lead to a less nutrient-dense diet. When sugars are added to foods and beverages, the sugars add calories without contributing essential nutrients. Foods with added sugars displace other nutrient-dense foods in the diet, and as the amount of added sugars increase in the diet, it becomes more difficult to also eat foods with sufficient dietary fiber and essential vitamins and minerals and stay within calorie limits. Thus, a diet low in added sugars helps individuals achieve a healthy dietary pattern through nutrient-dense choices within calorie limits (Ref. 1). Many of the comments on the RFI and public meeting support limiting the amount of added sugars permitted in foods bearing the claim ''healthy.''

Consistent with our rationale in the NFL Final Rule and with the *Dietary Guidelines, 2020–2025,* we find that it is critical that foods bearing the implied nutrient content claim ''healthy'' do not contribute to a dietary pattern that contains added sugars over the recommended levels. We therefore propose including a limit on the amount of added sugars in foods bearing the nutrient content claim ''healthy'' to help consumers choose foods that will contribute to a healthy dietary pattern that is lower in added sugars, consistent with current nutrition science and Federal dietary guidance. The DRV for added sugars is 50 g (for children 1 to 3 years old, the DRV is 13 g). For individual foods, we are proposing a baseline value for added sugars of ≤5 percent of the DV per RACC (≤2½ g for adults and children 4 years of age and older). While there is no low added sugars nutrient content claim, the proposed ≤5 percent DV level is consistent with our approach of using a low in saturated fat claim, which the *Dietary Guidelines, 2020–2025* also recommends limiting to less than 10 percent of calories per day starting at age 2. We are also proposing to adjust the baseline values for added sugars as warranted, based on specific considerations of the different food groups and subgroups, as described in the discussion of individual food groups below. We seek comment on this approach.

We note that high-intensity (low- and no-calorie) sweeteners are not considered added sugars by FDA. Additionally, the *Dietary Guidelines, 2020–2025* does not consider high-intensity sweeteners to be added sugars and do not make any recommendations for those 2 years of age and older on the intake of high-intensity sweeteners. Therefore, high-intensity sweeteners are not a factor in this proposed rule. The *Dietary Guidelines, 2020–2025* did note that ''replacing added sugars with low- and no-calorie sweeteners may reduce calorie intake in the short-term and aid in weight management, yet questions remain about their effectiveness as a long-term weight management strategy.'' FDA reviews high-intensity sweeteners for use in foods based on available scientific evidence. There is reasonable certainty of no harm under the intended conditions of use of high-intensity sweeteners because the estimated daily intake is not expected to exceed the acceptable daily intake for each sweetener.

d. Nutrients Not Included

(1) Total Fat

In contrast to the existing criteria at § 101.65(d), we propose removing the limit for total fat in the updated criteria for ''healthy.'' Federal dietary guidance, based on current nutrition science, has shifted away from recommending diets low in total fat—which includes saturated fat, *trans* fat, and unsaturated fat—to focus instead on the types of fat in the diet due to their different effects on health outcomes. The *Dietary Guidelines, 2020–2025,* for example, includes no key recommendation for intake of total fat, and emphasize replacing intake of saturated fats with unsaturated fats, particularly polyunsaturated fats (Ref. 1). The shift away from emphasizing total fat is also reflected in the NFL Final Rule (81 FR 33742). For example, the declaration of ''Calories from fat'' is no longer required on the Nutrition Facts label because current nutrition science supports a view that the type of fat is more relevant than overall total fat intake in risk of chronic diseases. Reflecting this shift in science, our guidance for industry on the use of the term ''healthy,'' published in 2016, advises food manufacturers of our intent to exercise enforcement discretion for products labeled ''healthy'' that are not low in total fat, but have a fat profile makeup of predominantly monounsaturated and polyunsaturated fat (Ref. 19). Therefore, while we propose maintaining a limit on saturated fat, we are not proposing to include total fat as part of the criteria for the ''healthy'' nutrient content claim.

(2) Trans Fat

In 2015, we released a final determination that partially hydrogenated oils (PHOs) which are the primary dietary source of industrially produced *trans* fat, are no longer generally recognized as safe for use in food (80 FR 34650, June 17, 2015) to eliminate the majority of uses of PHOs. The compliance date for this determination was June 18, 2018, for most foods, with extended compliance dates in 2020 and 2021 for certain uses of PHOs (83 FR 23358, May 21, 2018). As a result of this determination, what was previously the primary dietary source of *trans* fat has been largely removed from the food supply.

We recognize that there are other sources of *trans* fat in the food supply, including refined edible oils and naturally occurring sources in products from ruminant animals (*e.g.,* meat and dairy). The *Dietary Guidelines, 2020–2025* does not make any recommendations regarding intake of *trans* fat but notes that the National Academies recommends that *trans* fat consumption be as low as possible without compromising the nutritional adequacy of the diet. However, because foods that contain declarable levels of *trans* fat from sources other than PHOs typically contain saturated fat as well, we expect that the proposed saturated fat limits will disqualify most foods containing declarable levels of naturally

occurring *trans* fat from meeting the ''healthy'' criteria (Ref. 20). Therefore, we are not proposing to include a limit for *trans* fat in the updated ''healthy'' criteria because we do not think such a limit is necessary due to the limits we are proposing for saturated fat in this rule and due to our other regulatory actions to remove PHOs from the marketplace. We seek comment on our proposed approach to *trans* fat, including any data demonstrating that the saturated fat limit will not adequately disqualify foods containing *trans* fat from meeting the proposed ''healthy'' definition.

(3) Dietary Cholesterol

The *Dietary Guidelines, 2020–2025* does not make any recommendations regarding intake of dietary cholesterol but discuss dietary cholesterol in conjunction with *trans* fat and note that the National Academies recommends that dietary cholesterol consumption be as low as possible without compromising the nutritional adequacy of the diet. The *Dietary Guidelines, 2020–2025* also notes that the USDA Dietary Patterns are limited in dietary cholesterol (Ref. 1). Additionally, the 2020 DGAC Report states that ''[b]ecause dietary cholesterol is found only in animal-source foods that are typically also sources of saturated fat, the independent effects on blood lipids and CVD are difficult to assess. Although, we recognize the importance of limiting dietary cholesterol, we tentatively conclude that it is unnecessary to include a limit for dietary cholesterol for the ''healthy'' claim because, as with *trans* fat, dietary cholesterol is already sufficiently limited by the proposed limits for saturated fat.

Dietary cholesterol and saturated fats are found in similar foods, *i.e.,* foods that are higher in dietary cholesterol, such as fatty meats and full-fat cheese, which are generally also higher in saturated fats (Ref. 16). As a result, a dietary pattern low in saturated fat is typically also low in dietary cholesterol. We therefore expect that the proposed saturated fat value of 5 percent DV per RACC (or the adjusted baseline limit for certain foods) will disqualify most foods that contain more than 60 mg of dietary cholesterol, the current limit under § 101.65, from meeting the proposed ''healthy'' criteria.

There are a few exceptions, including foods such as eggs and some shellfish, that contain ≤5 percent DV of saturated fat per RACC and are not low in dietary cholesterol (Ref. 20). However, eggs and seafood (which includes fish and shellfish) are specifically highlighted in the *Dietary Guidelines, 2020–2025* as being nutrient-dense foods, supplying nutrients such as choline, vitamin D, and essential fatty acids (Refs. 1 and 17). The *Dietary Guidelines, 2020–2025* also found that almost 90 percent of Americans do not meet the recommendations for consumption of seafood, and specifically recommend shifts within the protein foods group to increase seafood intake.

Because eggs and seafood are nutrient-dense foods, provide important nutrients, and are specifically recommended by the *Dietary Guidelines, 2020–2025* for inclusion in a healthy dietary pattern, we consider that it is appropriate for these foods to meet the updated ''healthy'' criteria. For these reasons, we are not proposing to include a limit on dietary cholesterol as part of the updated criteria for ''healthy.'' We seek comments on our proposed approach to dietary cholesterol, including any data showing that the proposed saturated fat limit does not adequately limit dietary cholesterol, or any data indicating that foods containing lower saturated fat levels and higher cholesterol levels (*i.e.,* seafood and eggs) should not bear the ''healthy'' nutrient content claim.

3. Infants and Children Under Two Years of Age

In developing updates to the criteria for ''healthy,'' we have also considered whether the proposed definition should be extended to cover foods targeted to those age groups. Defined nutrient content claims currently apply to foods intended for adults and children 2 years of age and older. With the exception of claims on the percent of the Reference Daily Intake (RDI) for vitamins and minerals, nutrient content claims currently cannot be made on foods intended specifically for use by infants and children less than 2 years of age (*e.g.,* jarred baby foods, fruit pouches, toddler snack puffs) unless the claim is explicitly provided for in the regulations for each individual claim (21 CFR 101.13(b)(3)). Thus, as with most other nutrient content claims, the current definition for the nutrient content claim ''healthy'' does not include provisions for foods intended specifically for use by infants and children less than 2 years of age.

Our tentative conclusion is to continue to limit the use of the claim to foods directed to adults and children 2 years of age and older. As described in section IV.C. (''Need to Update 'Healthy' ''), we relied primarily on the science articulated in the *Dietary Guidelines, 2020–2025* in developing the specific criteria on which to base the definition of ''healthy.'' Historically, the Dietary Guidelines have been directed to adults and children 2 years of age and older. The *Dietary Guidelines, 2020–2025* highlights the importance of encouraging healthy dietary patterns at every life stage, and have included new recommendations for healthy dietary patterns for infants and children younger than 2 years of age in this lifespan approach. Infants and children younger than 2 years of age have specific nutritional needs that apply to their particular life stages and their dietary recommendations are different from the recommendations for other age groups. In our last update to the Nutrition Facts label (81 FR 33742), we established Daily Values (DVs) specifically for infants 7 through 12 months and children 1 through 3 years of age. The science underlying the recommended intake levels of individual nutrients demonstrates the specific nutritional needs of infants and children in this life stage. Evaluating the specific nutritional needs of this population can help us in determining whether it is appropriate to extend use of the claim ''healthy'' to foods directed at infants and children younger than 2 years of age. We intend to consider the scientific information discussed in the *Dietary Guidelines, 2020–2025,* as well as information from other sources, as we evaluate whether specific criteria can be developed for foods targeted to infants and children in those age groups for use in the definition of ''healthy.'' Because we are continuing to evaluate the information on the nutritional needs of this life stage, at this time, we are not proposing that the updated definition of ''healthy'' apply to foods targeted to infants and children under 2 years of age.

B. Description of the Proposed Regulation

1. Terms Subject to Definition

''Healthy'' is a broad term that can have connotations beyond the nutritional properties of a food. This proposed rule would define ''healthy'' as a nutrient content claim only when it is used in a nutritional context; in other words, the proposed criteria would only apply when ''healthy'' is used on a label or in labeling and other information, such as other claims, images, or vignettes, about the nutrition content of the food is also present somewhere on the labeling. For example, if the word ''healthy'' is used above a picture of vegetables or alongside another nutrient claim such as ''0g of fat,'' that would clearly place it in the nutritional context. If, however,

the word ''healthy'' was used on a label to say ''our manufacturing processes support a healthy planet'' with an adjacent picture of the earth, that would not be in the nutritional context. Under proposed § 101.65(d)(1), this regulation would cover labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices because of its nutrient content, where there is also implied or explicit information about the nutrition content of the food (other than required disclosures, such as the Nutrition Facts Label) elsewhere on the label or in labeling.

We determined in the 1994 rule that the term ''healthy'' constitutes an implied nutrient content claim only when it appears on the label or labeling of a food in a nutritional context (59 FR 24232 at 24234 to 24235). We first determined that the term ''healthy'' does not *inherently* imply the absence or presence of a nutrient in a particular amount, or that the nutrient content of the food would be helpful to consumers in structuring a diet that conforms to the Dietary Guidelines. Rather, such inferences are likely to be drawn only if the term ''healthy'' is accompanied by additional language or graphic material or is otherwise presented in a context that explicitly or implicitly suggests that the food has a particular nutrient content. Based on this reasoning, we concluded that the nutritional context is a critical factor as to whether ''healthy'' is used as an implied nutrient content claim.

We reaffirm our position in the 1994 rule that ''healthy'' is only an implied nutrient content claim when used in a nutritional context, as described above. However, we propose some minor revisions to § 101.65(d)(1)(ii) defining implied nutrient content claims. Under the existing regulation, labeling claims are implied nutrient content claims when they are made in connection with an explicit or implicit claim or statement about a nutrient (such as ''healthy, contains 3 grams of fat'').

While we want to ensure that the regulation only reaches claims that are made in a nutritional context, based on our years of experience with the current claim, we think the existing language may be too narrow and not reach all information about nutritional context. Further, because this proposed rule would expand the criteria for ''healthy'' to incorporate food group requirements in addition to individual nutrients to limit, we want to ensure that the regulation encompasses the full range of nutrition information covered by the rule. Based on these considerations, we propose revising the existing text to broaden the description of what a nutritional context entails. We seek comment on the definition of nutritional context provided here.

Specifically, we propose revising § 101.65(d)(1)(i) and (ii) to appear as § 101.65(d)(1). Proposed § 101.65(d)(1), as revised, would no longer require that an implied nutrient content claim be used ''in connection with an explicit or implicit claim or statement about a nutrient.'' Instead, we propose in § 101.65(d)(1) that ''healthy'' constitutes a nutrient content claim where the term ''healthy'' is used to characterize the food itself and ''where *there is also* implied or explicit information about the nutrition content of the food.'' This clarifies that the information on the label that places use of the claim ''healthy'' into a nutritional context would not necessarily be immediately adjacent to the implied nutrient content claim, as in the ''healthy, contains 3 grams of fat'' example. Instead, we propose to make clear that any information on the label or labeling that puts the term ''healthy'' into a nutritional context would make ''healthy'' an implied nutrient content claim when it is used to characterize the food. For example, where ''healthy'' appears on the front of a cereal product that is described elsewhere on the label or labeling as high in dietary fiber (*e.g.,* on the back of the package, or on a website), the ''healthy'' claim would constitute a nutrient content claim under § 101.65(d). There may also be instances where the use of a graphic on the label of a food bearing ''healthy'' would place the term in a nutritional context; for example, if the label on a can of beans labeled ''healthy'' also used the MyPlate symbol (which graphically puts the food groups together in the context of an overall dietary pattern, as a translation of the *Dietary Guidelines*) or other front of pack labeling (such as the ''Facts Up Front'' labeling program) to imply that the product meets nutritional needs (Ref. 32). In addition, some brands include ''healthy'' or related words in their brand name, which could be considered an implied nutrient content claim if any other information on the label or labeling puts the term ''healthy'' into a nutritional context—for example, if a food product included ''healthy'' within the brand name also used the ''low sodium'' nutrient content claim. FDA considers food labels and labeling as a whole and will consider the context of statements made in labels and labeling to determine whether a product bears a ''healthy'' implied nutrient content claim.

We also propose revising the codified text in § 101.65(d)(1) to no longer require that the accompanying material be a ''claim or statement about a *nutrient*.'' It would instead require that it be ''information about the *nutrition content of the food*.'' This text is still intended to ensure that the regulation only applies where a ''healthy'' claim is used in a nutritional context. However, it would not limit the accompanying material on the labeling to phrases declaring presence/level of a specific nutrient (as in the ''healthy, contains 3 grams of fat'' example), but include any material stating or implying that the nutrient content of the food would be helpful to consumers in structuring a diet that is supported by current dietary recommendations. For example, if a cereal package bore the claim ''healthy'' as a descriptor of the cereal, and its labeling elsewhere stated, ''Provides all of your child's essential vitamins and minerals,'' this would constitute an implied nutrient content claim, because in that context, the ''healthy'' claim suggests that the nutrient content of the food would be helpful in structuring a diet that conforms to current dietary recommendations. Information about the nutrition content of the food need not make explicit references to nutrients but can refer to nutrients by implication. For example, if the label on a food product characterizes food using the term ''healthy'' and elsewhere stated that the product is ''made with whole grain ingredients,'' or ''made with real fruits and vegetables,'' or ''contains a variety of nuts,'' this would put ''healthy'' in a nutritional context because the labeling implies that the food should contain nutrients commonly associated with and contributed by those food components.

We therefore propose that the updated § 101.65(d)(1) state that it covers labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices due to its nutrient content, where there is also implied or explicit information about the nutrition content of the food. Additionally, because the language in § 101.13(b)(2)(ii) parallels the definition of ''healthy'' in § 101.65, we are also proposing to update the language in § 101.13(b)(2)(ii) to provide that an implied nutrient content claim suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food (*e.g.,* healthy).

Under the proposed regulation, ''healthy,'' when used outside of a nutritional context, would not be an implied nutrient content claim. However, even outside of the nutritional context, we have the authority under the misbranding provisions at section 403(a) of the FD&C Act, to ensure that ''healthy'' is not used in a misleading manner. The proposed regulation also does not address use of the term ''healthy'' when used as part of an implied health claim (*e.g.,* ''heart healthy'') instead of a nutrient content claim. See 21 CFR 101.14 for information on the use of express and implied health claims.

2. Food Group Equivalents

As explained in section VI.A (''Overview of Approach''), a food group equivalent is the amount of a food from a particular food group that must be contained in a food product for it to bear the ''healthy'' claim. Proposed § 101.65(d)(2) would define a ''food group equivalent'' as equal to the following:

- A food group equivalent of a vegetable would be equal to one ½ c-eq vegetables.
- A food group equivalent of a fruit would be equal to one ½ c-eq fruit.
- A food group equivalent of grain would be ¾ oz-eq whole grain.
- A food group equivalent of dairy would be equal to ¾ c-eq dairy.
- A food group equivalent of protein would:
  - For game meats, such as deer, rabbit, quail, and wild geese, be 1 ½ oz-eq; and
  - For seafood; eggs; beans, peas, and soy products; and nuts and seeds, be 1 oz-eq.

We have divided the protein foods group into these subgroups, which are distinct from the *Dietary Guidelines, 2020–2025* subgroups, as explained further in section V.B.3.b (''Individual foods'').

We are not proposing a food group equivalent for oils, because, as explained in section V.B.3.b (''Individual foods''), we are only proposing that certain oil-based foods meet the criteria for healthy, and oil used in other foods does not contribute to eligibility for bearing the ''healthy'' claim.

These food group equivalents are indicated in table 1.

TABLE 1—FOOD GROUP EQUIVALENTS

Food group and/or subgroup	Food group equivalent
Vegetables	½ cup equivalent vegetable.
Fruits	½ cup equivalent fruit.
Grains	¾ ounce (oz) equivalent whole grain.
Dairy	¾ cup equivalent dairy.
Protein Foods	Game meats.
	1½ oz equivalent.
	Seafood.
	1 oz equivalent.
	Egg.
	1 oz equivalent.
	Beans, peas, and soy products.
	1 oz equivalent.
	Nuts and seeds.
	1 oz equivalent.

As noted in section VI.A (''Overview of Approach''), the c-eq and oz-eq amounts are based on the amounts discussed in the *Dietary Guidelines, 2020–2025.* For vegetables and fruits, a 1 c-eq is: 1 cup raw or cooked vegetable or fruit, 1 cup 100 percent vegetable or fruit juice, 2 cups leafy salad greens, or ½ cup dried fruit or vegetable. For grains, a 1 oz-eq is: ½ cup cooked whole grain rice, whole grain pasta, or cereal; 1 oz dry whole grain pasta or rice; 1 medium (1 oz) slice whole grain bread, tortilla, or flatbread; 1 oz of ready-to-eat whole grain cereal. For dairy, a 1 c-eq is: 1 cup fat-free or low-fat milk, yogurt or lactose-free versions, or fortified soy beverage or yogurt alternatives; 1½ oz natural cheese or 1 oz processed cheese. For protein foods, a 1 oz-eq is: 1 oz game meat or seafood; 1 egg; ¼ cup cooked beans or tofu; 1 tbsp nut or seed butter; ½ oz nuts or seeds (Refs. 1 and 22).

This means, for example, that a ½ cup portion of fresh or frozen green beans and a 1 cup portion of raw spinach would both constitute ½ c-eq vegetables. A ½ cup portion of fresh or frozen fruit, ½ cup portion of 100 percent orange juice, and a ¼ cup portion of raisins (a dried fruit) would all be equal to a ½ c-eq of fruit. A slice of whole wheat bread and a ½ cup portion of cooked brown rice would both be equal to a 1 oz-eq whole grains. A 6-ounce portion of yogurt would be equivalent to ¾ c-eq dairy. An ounce portion of walnuts and 2 tablespoons of peanut butter would be equal to 2 oz-eq of protein foods. A ½ cup portion of black beans would be equal to 2 oz-eq of protein foods (Refs. 1 and 22). Examples of foods and their amounts that meet the food group equivalent requirements are included in a table in the proposed codified language for § 101.65(d)(2).

3. Covered Products

Under proposed § 101.65(3), you may use the term ''healthy'' or related terms (*e.g.,* ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') as an implied nutrient content claim if the food meets the requirements laid out in proposed § 101.65(d)(3)(i)–(vi). These terms are unchanged from the existing regulation at § 101.65(d); see the 1994 ''healthy'' final rule for a more detailed discussion of how these terms were selected (59 FR 24232 at 24235). However, we seek comments on whether there are any other terms synonymous with ''healthy'' that we should consider as we finalize this rulemaking.

Foods that may bear the nutrient content claim ''healthy'' under the proposed updated criteria are broken out into several categories: (1) raw, whole fruits and vegetables; (2) individual food products; (3) combination foods, which encompasses mixed products, main dish products, and meal products; and (4) plain water. The specific requirements for these foods are described in more detail in the following sections.

TABLE 2—ELIGIBLE PRODUCTS FOR ''HEALTHY'' NUTRIENT CONTENT CLAIM

Eligible products for ''healthy'' nutrient content claim	
Product	Criteria for bearing ''healthy'' claim
Raw, whole fruits and vegetables	No additional criteria; all raw, whole fruits and vegetables may bear the claim.
Individual food products	At least 1 food group equivalent per RACC from 1 food group, and Nutrients to limit.
Mixed products	At least ½ food group equivalent each from at least 2 different food groups, and Nutrients to limit.
Main dish as defined at 21 CFR 101.13(m)	At least 1 food group equivalent each from at least 2 different food groups, and Nutrients to limit.
Meal as defined at 21 CFR 101.13(l)	At least 1 food group equivalent each from at least 3 different food groups, and Nutrients to limit.
Water	Plain water and plain, carbonated water may bear the claim.

a. Raw, Whole Fruits and Vegetables

A key objective of the updated criteria is to ensure conformity with current nutrition science and Federal dietary guidance by, among other things, ensuring that the nutrient dense foods recommended by the *Dietary Guidelines, 2020–2025* are eligible to bear the ''healthy'' claim. Precluding such foods from bearing the ''healthy'' claim could undermine an important element of the claim, as the purpose of the healthy claim is to identify foods that, because of their nutrient content, may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance. Healthy dietary patterns described by the *Dietary Guidelines, 2020–2025* include vegetables from all vegetable subgroups (dark green, red and orange, beans, peas, and lentils, starchy, and other) and fruits, especially whole fruits. Vegetables contribute many nutrients to the diet including dietary fiber, potassium, vitamin A, vitamin C, vitamin K, copper, magnesium, vitamin E, vitamin B6, folate, iron, manganese, thiamin, niacin, and choline, while fruits are important contributors of dietary fiber, potassium, and vitamin C. The Dietary Guidelines have consistently emphasized consumption of fruits and vegetables (Ref. 15), and diets high in fruits and vegetables have been associated with specific health benefits, including lower occurrence of coronary heart disease and some cancers (Ref. 16 and 59 FR 24232 at 24244). Despite their importance to a healthy dietary pattern, average intake of vegetables and fruits is below recommended levels among nearly all age-sex groups (Ref. 1).

While we are proposing food group equivalent and nutrient-to-limit requirements for most foods, we are not proposing to subject raw, whole fruits and vegetables to the criteria. For the purpose of this rule, ''raw, whole'' means whole fruits and vegetables that have not been processed, such as whole apples, bananas, or carrots. Raw, whole fruits and vegetables automatically qualify for use of the claim, regardless if they meet the criteria required of other foods. As discussed in the *Dietary Guidelines 2020–2025,* most of the U.S. population (around 80 percent) does not meet the dietary intake recommendation for fruits and an even larger percentage (around 90%) do not meet the intake recommendation for vegetables. Excluding some raw, whole fruits and vegetables from qualifying for the proposed, updated ''healthy'' definition is not supported by scientific evidence or current dietary guidance. Therefore, we tentatively conclude that raw, whole fruits and vegetables do not need to contain a certain amount of fruit or vegetable to contribute to a healthy dietary pattern—for example, a strawberry should be able to bear the ''healthy'' claim even though one strawberry does not constitute a ½ c-eq of fruit. Moreover, raw, whole fruits and vegetables are often sold without packaging or labels. While these products typically do not carry label claims, they may appear on other materials in the stores and elsewhere that may constitute labeling. We therefore tentatively conclude that raw, whole vegetables and fruits should be able to meet the ''healthy'' criteria without meeting a food group equivalent threshold. We seek comment on our tentative conclusions.

We also tentatively conclude that it would be inappropriate to apply nutrient-to-limit criteria to raw, whole vegetables and fruits. For example, sodium and added sugars are not a concern for raw, whole fruits and vegetables because they contain no added ingredients. Furthermore, including a limit for saturated fat would actually *disqualify* certain vegetables, such as whole avocados, which are vegetables containing beneficial nutrients and are sources of unsaturated fat, from meeting the updated ''healthy'' criteria.

For these reasons, we are proposing a narrow exception to the requirements for food group equivalents and nutrients to limit for raw, whole fruits and vegetables. We propose allowing all raw, whole fruits and vegetables to bear the implied nutrient content claim ''healthy,'' without any additional requirements for food group equivalents or nutrients to limit.

We do not propose to include processed fruits and vegetables, such as canned, frozen, dried, or pureed fruits and vegetables, within this exemption, though many may still meet the criteria to bear ''healthy.'' For purposes of this claim, fruits and vegetables that have been cut and packaged for sale, such as cantaloupe pieces cut and packaged for sale in a supermarket are considered processed. We note that fruits and vegetables that have been solely cut and packaged for sale would generally qualify for use of the claim under the criteria for individual foods, as raw fruits and vegetables do not exceed the nutrient criteria and would meet the food group equivalent requirement. For example, plain frozen fruit or vegetables would not exceed the nutrient-to-limit criteria and would meet the food group equivalent requirement. It is possible, though, that there are a few forms of fruit and vegetable products that may have RACCs that are smaller than the size of the required food group equivalent requirement. For example, frozen avocado pieces, specifically, may have a RACC that does not meet the FGE amount criteria of ½ c fruit. We request comment on whether there are any other fruit or vegetable products for which the RACC size may have an impact in terms of qualifying for the claim and we request comment on ways we could address how those products, including frozen avocados, could qualify for the claim. Many processed fruits and vegetables are packaged and sold in a form that makes it appropriate to apply

the food group equivalent requirement to these kinds of food to ensure the product contains a meaningful amount of the fruit and/or vegetable. For example, it is appropriate to require that canned fruit products contain a certain amount of fruit per serving in order to bear the ''healthy'' claim because they contain additional ingredients (*e.g.,* sugar solution) which may impact whether the product has enough fruit per serving to meet the food group equivalent requirement. Furthermore, processed vegetables and fruits may contain other ingredients, such as added sugars or sodium, that can affect their nutrient content; thus, it is necessary to include nutrient-to-limit criteria for such foods. For any type of processed fruits and vegetables where the fruits and vegetables remain primarily unchanged, such as plain frozen fruits and vegetables, those products would generally qualify for use of the claim under the criteria for individual foods, as they do not exceed the nutrient criteria and would meet the food group equivalent requirement. As described in section V.B.3.b (''Individual foods''), we are proposing that individual fruit and vegetable products (including processed fruits and vegetables, but which excludes raw, whole fruits or vegetables) may bear the nutrient content claim ''healthy'' only when they meet certain additional food group equivalent and nutrient-to-limit requirements.

b. Individual Foods

Individual foods are foods that are comprised entirely or almost entirely of one food group (excluding raw, whole fruits and vegetables, as explained above). Foods that contain a meaningful amount (at least half a food group equivalent) of more than one food group would be considered a combination food and are discussed in section VI.B.3.c (''Combination foods''). In many cases, an individual food will be comprised of only one food group; for example, individual foods include oatmeal (which is comprised of only whole grain), dried fruit (fruit), or low-fat plain yogurt (dairy). In some cases, individual foods include ingredients from multiple food groups, but one food group would still predominate, and the product may only contain a minimal amount of another food group; for example, cinnamon raisin oatmeal (primarily whole grain) and yogurt with granola topping (primarily dairy) would both be individual foods. To bear the nutrient content claim ''healthy,'' individual foods would have to meet the criteria outlined in § 101.65(d)(3)(iii), which includes requirements for food group equivalents and for nutrients to limit.

For the purposes of this rule, individual foods have been separated into the six food groups described in the *Dietary Guidelines, 2020–2025:* vegetables, fruits, grains, dairy, proteins (including all subgroups), as well as oils. As in the *Dietary Guidelines, 2020–2025,* individual foods fit into food groups based on how they are consumed, even if this is different from their botanical classification. We are proposing that individual products would need to contain a specified minimum food group equivalent per RACC (*e.g.,* ½ cup of fruit, ¾ cup of dairy) to be labeled ''healthy.'' Individual products would also need to adhere to criteria for nutrients to limit per RACC for saturated fat, sodium, and added sugars. The food group equivalents and the nutrients-to-limit benchmarks are adjusted for each food group. The specific food group equivalent criteria, along with the criteria for nutrients to limit, are discussed further in the following sections.

(1) Vegetable Products

As discussed previously, healthy dietary patterns include vegetables from all vegetable subgroups: dark green, red and orange, beans, peas, and lentils, starchy, and other. The nutrient content of beans, peas, and lentils is similar to foods in both the protein foods group and in the vegetable group and may be counted under either food group. Vegetables contribute many nutrients to the diet including dietary fiber, potassium, and iron, among others, and nutrient contributions can vary across the subgroups (Ref. 21). The *Dietary Guidelines, 2020–2025* notes that each of the food groups and their subgroups provides an array of nutrients and that eating an appropriate mix of foods from the food groups and subgroups is important to promote health at each life stage (Ref. 1). Therefore, consumption of a variety of vegetables from all vegetable subgroups in nutrient-dense forms is encouraged. The vegetables food group can include fresh, frozen, canned, and dried forms of vegetables, as well as 100% vegetable juice. FDA considers concentrated vegetable purees and vegetable pastes to be vegetables for the purpose of calculating food group equivalents since these products are essentially whole vegetables that have been processed to change the physical form of the vegetable to remove moisture. We tentatively do not consider vegetable powders to be vegetables for the purpose of calculating food group equivalents. These products could be produced or used in a way that modifies the whole vegetable to an extent that removes some essential characteristics that are beneficial when consuming the whole vegetable, which could impact nutrient content. However, we recognize that food manufacturers continue to innovate in this space. We welcome comment on whether we should consider certain vegetable powders to be vegetables for the purpose of calculating food group equivalents. In particular, we are interested in any comments or data regarding whether vegetable powders have similar or different nutrient content, or similar or different roles in a healthy dietary pattern, compared to whole vegetables.

The recommended amount of vegetables in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 2½ c-eq of vegetables per day. As described in section VI.B.3.b (''Individual foods''), for most food groups and subgroups, we determined the ''food group equivalent'' by dividing the daily recommended amount by four (for four eating occasions per day). For vegetables, we revised the amount derived from the baseline calculation slightly (from ¾ c-eq down to ½ c-eq) for two reasons. First, vegetables are significantly underconsumed according to the *Dietary Guidelines, 2020–2025.* Second, we found that a ½ c-eq aligned better with the RACCs for most vegetable products as set out in FDA's NFL final rule. Thus, we are proposing that to bear the nutrient content claim ''healthy,'' a vegetable product must contain at least ½ c-eq vegetables per RACC.

We are proposing that the added sugars content for vegetable products must be no greater than 0 percent DV per RACC. This is lower than some other food groups because vegetable products generally do not contain added sugars. We are proposing that vegetable products be subject to the baseline values for sodium and saturated fat; *i.e.,* the sodium content must be no greater than 10 percent DV per RACC and the saturated fat content must be no greater than 5 percent DV per RACC, as many vegetable products in the food supply contain some sodium and added fats for taste, processing, and preservation. We are seeking comment on this proposal.

TABLE 3—VEGETABLE PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Vegetable product	½ cup-equivalent	0% DV	10% DV	5% DV

(2) Fruit Products

Healthy dietary patterns include fruits, especially whole fruits. Fruits contribute many nutrients to the diet, including dietary fiber, potassium, and vitamin C (Ref. 21). Fruits can be consumed in fresh, frozen, canned, and dried forms. FDA considers concentrated fruit purees and fruit pastes to be fruit for the purpose of calculating food group equivalents since these products are essentially whole fruits that have been processed to change the physical form of the fruit to remove moisture. The fruits food group also includes 100 percent fruit juice. We tentatively do not consider fruit powders to be fruits for the purpose of calculating food group equivalents. These products could be produced or used in a way that modifies the whole fruit to an extent that removes some essential characteristics that are beneficial when consuming the whole fruit, which could impact nutrient content. However, we recognize that food manufacturers continue to innovate in this space. We welcome comment on whether we should consider certain fruit powders to be fruits for the purpose of calculating food group equivalents. In particular, we are interested in any comments or data regarding whether fruit powders have similar or different nutrient content, or similar or different roles in a healthy dietary pattern, compared to whole fruits.

The recommended amount of fruits in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 2 c-eq per day. Applying the baseline calculation discussed in section VI.B.3.b (''Individual foods''), we propose that an individual fruit product must contain at least ½ c-eq of fruit per RACC to bear the ''healthy'' claim. We are seeking comment on this proposal.

As with vegetable products, we are proposing to lower the baseline added sugars limit to 0 percent DV per RACC for fruit products. While small amounts of added sugars can be part of a healthy dietary pattern—the *Dietary Guidelines, 2020–2025* recommendations allow for a certain allotment of added sugars per day—we do not want the ''healthy'' claim to encourage addition of added sugars in otherwise nutrient-dense fruit products, which are generally already naturally sweet. Moreover, while we recognize that some fruit juices and canned fruits contain added sugars, the *Dietary Guidelines, 2020–2025* specifically recommends that juices should be 100 percent juice, without added sugars, and that individuals should choose canned fruits that are canned with 100 percent juice or options lowest in added sugars. Thus, to qualify for the ''healthy'' claim, we propose to allow no added sugars in fruit products (which includes products with 100 percent fruit juice). For the fruit category, we find that there are no special circumstances that require deviation from the baseline levels for sodium and saturated fat, so we are proposing the baseline value for sodium of 10 percent DV per RACC and 5 percent DV saturated fat per RACC for fruit products.

TABLE 4—FRUIT PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Fruit product	½ cup-equivalent	0% DV	10% DV	5% DV

(3) Grain Products

Healthy dietary patterns include whole grains and limit the intake of refined grains. Whole grains contain the entire kernel, including the endosperm, bran, and germ. Refined grains differ from whole grains in that the grains have been processed to remove the bran and germ, which removes important nutrients. Whole grains provide nutrients such as dietary fiber, iron, zinc, manganese, folate, magnesium, copper, thiamin, niacin, vitamin B6, phosphorus, selenium, riboflavin, and vitamin A (Ref. 21). Whole grains can be consumed as single foods (*e.g.,* brown rice, oats), or as products that include grains as an ingredient (*e.g.,* breads, cereals, crackers, and pasta).

The recommended amount of grains in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 6 oz-eq per day. At least half of this amount should be whole grains (*i.e.,* at least 3 oz-eq). Whole grains, when prepared with little or no added sugars, sodium, and saturated fat, are typically more nutrient-dense foods and the *Dietary Guidelines, 2020–2025* indicates that whole grains are underconsumed while refined grains are overconsumed. Thus, we propose that grain products must contain whole grains to bear the ''healthy'' claim. Applying the baseline calculation for food group equivalent as explained in section VI.A (''Overview of Approach''), we are proposing that a whole grain equivalent is ¾ oz-eq. This means that to bear the ''healthy'' claim, an individual grain product must contain at least ¾ oz-eq whole grains per RACC. We seek comment on this approach.

For the grains category, we find that there are no special circumstances that require deviation from the baseline levels, so we are proposing the baseline value for all of the nutrients to limit: the added sugars content must be no greater than 5 percent DV per RACC, the sodium content must be no greater than 10 percent DV per RACC, and the saturated fat content must be no greater than 5 percent DV per RACC.

TABLE 5—GRAIN PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Grain product	¾ ounce-equivalent wholegrain	5% DV	10% DV	5% DV

(4) Dairy Products

Dairy in healthy dietary patterns includes fat-free (skim) and low-fat (1 percent) milk, yogurt, cheese, and fortified soy beverages or soy yogurt alternatives. Nutrients provided by foods in the dairy food group include calcium, phosphorus, vitamin A, vitamin D, riboflavin, vitamin B12, protein, potassium, zinc, choline, magnesium, and selenium (Ref. 21). The *Dietary Guidelines, 2020–2025* states that about 90 percent of the U.S. population does not meet dairy recommendations and most individuals would benefit by increasing intake of dairy in fat-free or low-fat forms, whether from milk, yogurt, and cheese, lactose-free versions, or from fortified soy beverages or soy yogurt alternatives. Fat-free and low-fat dairy products provide the same nutrients but less saturated fat (and thus, fewer calories) than higher fat options, such as 2 percent and whole milk and regular cheese.

The *Dietary Guidelines, 2020–2025* includes fortified soy beverages and soy yogurt alternatives in the dairy group because they have similar nutrient compositions and use in meals (Refs. 1, 22). Other products and beverages made from plants (*e.g.,* almond, rice, coconut, oat, and hemp products) are not included in the dairy group because their overall nutritional content is not similar to dairy milk, yogurt, and fortified soy beverages and soy yogurt alternatives (*e.g.,* lower levels of calcium, vitamin D, and other nutrients). However, it is possible that these types of products may eventually be formulated or fortified to have nutritional profiles that are more similar to the nutritional profile of the dairy food group. Although FDA does not generally support fortification as a method to qualify for a ''healthy'' claim, fortification of soy beverage and yogurt alternatives and other plant-based beverage and yogurt alternatives are a special circumstance. As discussed earlier in this rule, around 90 percent of the U.S. population does not meet the dairy recommendations even though dairy is a core element of a healthy dietary pattern. The *Dietary Guidelines, 2020–2025* highlights the importance of increasing overall intake of dairy foods while acknowledging that some individuals are in need of alternative dairy options. For example, lactose-free and low-lactose options are suggested for those with issues in digesting traditional dairy products. For individuals with restrictions on consumption of traditional dairy foods (*e.g.,* medical restrictions or religious preferences), fortified soy beverages and soy yogurt alternatives are included in the dairy group. Including fortified plant-based dairy alternatives among the food options in the dairy group can assist consumers in increasing their dairy intake and meeting the dairy intake recommendations. Therefore, to support the availability of non-dairy choices for individuals who are lactose intolerant or allergic to dairy or choose not to consume dairy, plant-based milk alternatives and plant-based yogurt alternatives whose overall nutritional content is similar to dairy (*e.g.,* provide similar amounts of protein, calcium, potassium, magnesium, vitamin D, and vitamin A) (Ref. 21) and are used as alternatives to milk and yogurt would be evaluated against the dairy criteria for the purposes of the ''healthy'' nutrient content claim.

The recommended amount of dairy in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 3 c-eq per day. Based on our baseline calculations, we are proposing that a food group equivalent of dairy equal ¾ c-eq. This means that an individual dairy food must contain at least ¾ c-eq of dairy per RACC to bear the ''healthy'' nutrient content claim.

We are proposing to increase the saturated fat limit for dairy products from the baseline level. Under the baseline saturated fat limit of 5 percent DV, low-fat dairy (*e.g.,* 1 percent milk) would not meet the criteria for bearing the ''healthy'' claim (Ref. 20). Forms of dairy that are more nutrient dense (*i.e.,* fat-free and low-fat dairy products) provide important nutrients with less saturated fat than 2 percent or whole-fat dairy. As stated above, the *Dietary Guidelines, 2020–2025* therefore recommends increasing intake of dairy products in fat-free and low-fat forms, to replace intake of 2 percent or whole dairy. We are proposing to revise the saturated fat limit for dairy to ≤10 percent DV of saturated fat per RACC to allow low-fat dairy to bear the ''healthy'' claim provided the other proposed criteria are met.

We are also proposing that dairy products (*e.g.,* sweetened yogurt and cheese) must meet the baseline limit for added sugars of 5 percent DV per RACC and for sodium of 10 percent DV per RACC. We find that there are no special circumstances that require deviation from the baseline levels for added sugars and sodium. Additionally, the sodium level of 10 percent is appropriate because many dairy products, especially cheeses, can be expected to contain some sodium due to processing and preservation methods. We seek comment on this approach.

TABLE 6—DAIRY PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Dairy product	¾ cup-equivalent	5% DV	10% DV	10% DV

(5) Protein Food Products

Healthy dietary patterns include a variety of protein foods in nutrient-dense forms, including protein foods from both plant and animal sources. Plant sources of proteins can include nuts, seeds, beans, peas, and lentils, and soy products. The nutrient content of beans, peas, and lentils is similar to foods in both the protein foods group and in the vegetable group and may be counted under either category. Animal sources can include seafood, meat, poultry, and eggs. Along with protein, foods in this group contribute important nutrients such as niacin, vitamin B12, vitamin B6, riboflavin, selenium,

choline, phosphorus, zinc, copper, vitamin D, and vitamin E and iron (Ref. 21). Additionally, seafood can provide polyunsaturated omega-3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid). While Americans' overall intakes of protein foods are close to the recommended amounts, many Americans do not meet the intake recommendations for specific protein subgroups. Therefore, the *Dietary Guidelines, 2020–2025* recommends shifts within the protein group to add variety to the intake of protein foods (Ref.1).

Since specific considerations for different foods within the protein foods group may vary, we are proposing to divide protein foods into the following subgroups: (1) game meats; (2) seafood; (3) eggs; (4) beans, peas, lentils, and soy products; and (5) nuts and seeds. These subgroups are slightly different from the subgroups in the *Dietary Guidelines, 2020–2025* because they are based on what we determined as the specific needs for variation in food group equivalents and the nutrients to limit, as discussed below. In addition, our subgroups do not include the animal sources of protein whose labeling is regulated by USDA's Food Safety and Inspection Service (*e.g.,* meat and poultry products, egg products, and catfish).

The recommendation for protein foods in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 5½ ounce-equivalents per day. As with all of the food groups, we calculated the food group equivalent using the method described in section VI.B.3.b (''Individual foods''). One fourth of 5½ oz equivalents is 1⅜ oz equivalents and based on standard rounding rules, we propose that the food group equivalent criteria for game meat is at least 1½ oz equivalent. We propose rounding down to 1 oz-eq for all other protein subgroups. For beans, peas, lentils, soy products, and seafood, we propose rounding down to increase the number of products containing these subgroups that would be eligible to bear the claim, and therefore encourage consumption of them. This is consistent with the Dietary Guidelines, 2020–2025 strategy to increase variety of choices made by replacing some meats, poultry, and egg intake with seafood, beans, peas, and lentils, nuts, seeds, and soy products. Game meat, which is part of the traditional diets of certain populations, falls within the meat, poultry, and egg protein subgroup in the Dietary Guidelines. However, we acknowledge that intake levels of game meat may not be at similar levels as other meat, poultry and egg products. We also propose rounding down to at least 1 oz-eq for eggs as this is equal to one egg, a common serving size. We welcome comments on the values set for the food group equivalents for the protein subgroups.

For all of the protein food subgroups, we propose that the food contain no more than 0 percent DV of added sugars per RACC because most protein food products generally do not contain added sugars. We are also proposing that all protein products must meet the baseline limit for sodium of 10 percent DV per RACC as many protein products in the food supply contain some sodium for taste, processing, and/or preservation.

Because protein foods are a diverse group of foods containing varying amounts of saturated fat, we are proposing different saturated fat limits for some subgroups. For game meats, seafood, and eggs, we are proposing to increase the limit for saturated fat to 10 percent DV because using the baseline saturated fat limit would prevent these foods from being able to bear the ''healthy'' claim even though they contain important nutrients that may help consumers maintain healthy dietary practices. The *Dietary Guidelines, 2020–2025* recommends shifting to nutrient-dense options when selecting protein foods, specifically lean and low-fat options. We propose a ≤10 percent DV saturated fat limit for game meat, which is similar to the <2 g per RACC saturated fat limit for the ''extra lean'' nutrient content claim for seafood or game meat products (§ 101.62(e)(4)) as is used in the current criteria for ''healthy.'' Seafood provides important nutrients, such as beneficial fatty acids (*e.g.,* eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)). The *Dietary Guidelines, 2020–2025* encourages consumption of seafood but note that almost 90 percent of Americans do not meet that recommendation and that protein foods are generally consumed in forms with higher amounts of saturated fat or sodium. Thus, the *Dietary Guidelines, 2020–2025* recommends replacing processed or high-fat meats with seafood to help lower intake of saturated fat and sodium (Ref. 1). We propose a ≤10 percent DV saturated fat limit for seafood consistent with § 101.62(e)(4) and because seafood contains beneficial nutrients that make it part of a healthy dietary pattern.

We are also proposing an adjustment for eggs. As mentioned previously, the *Dietary Guidelines, 2020–2025* recommends increasing variety in protein food choices in order to meet the recommendations for specific protein subgroups. Eggs are considered a nutrient dense protein food option, particularly compared with some protein foods that typically have high levels of saturated fat and sodium (*e.g.,* sausages). While about three-quarters of Americans meet the recommendation for the meat, poultry, and eggs subgroup, eggs provide choline and vitamin D, two nutrients with notably low intakes (Ref. 1). As noted above, using the baseline limit of 5 percent DV of saturated fat per RACC would prevent eggs from being able to bear the ''healthy'' claim, so we are also proposing to raise the saturated fat limit for eggs to ≤10 percent DV per RACC. Beans, peas, and lentils and soy products are inherently low in saturated fat; therefore, we are proposing the baseline value for saturated fat of ≤5 percent DV per RACC for these foods.

We are also proposing that the saturated fat content of nuts and seeds does not contribute toward the overall saturated fat limit for nut and seed products, which would be the baseline value of ≤5 percent DV per RACC. Unsalted nuts and seeds are considered nutrient dense protein foods due to their nutrient content (*e.g.,* they provide important nutrients such as unsaturated fatty acids and vitamin E). While nuts and seeds contain saturated fat, they have a fat profile makeup of predominantly monounsaturated and polyunsaturated fats. Numerous studies have demonstrated that replacing other sources of saturated fat in the diet with nuts has beneficial effects on cardiovascular disease risk, including nuts with higher saturated fat content (Refs. 22 and 33). Based on the scientific evidence, FDA has qualified health claims characterizing the relationship between the consumption of nuts and a reduced risk of coronary heart disease, including a qualified health claim for macadamia nuts which are relatively higher in saturated fat than other nuts. More than half of Americans do not meet the recommendation for nuts, seeds, and soy products, and the *Dietary Guidelines, 2020–2025* recommends consuming nuts without differentiating among types and the saturated fat content of nuts is variable. The *Dietary Guidelines, 2020–2025* also recommends reducing saturated fat by substituting certain ingredients with sources of unsaturated fats, including using nuts and seeds in a dish instead of cheese (Ref. 1). If nuts' and seeds' saturated fat content contributed to the overall baseline saturated fat value of ≤5 percent DV per RACC, then most nuts and seeds would be prevented from meeting the ''healthy'' definition (Ref. 20). Even increasing the allowable level

of saturated fat to levels twice as much (10 percent DV) would prevent some nuts and seeds, such as macadamia nuts, from being eligible for the ''healthy'' claim, despite the science supporting their beneficial impact on cardiovascular health. As mentioned above, the saturated fat content of nut and seed varieties vary. However, excluding specific types of nuts and seeds from being eligible for the claim would be inconsistent with the scientific evidence demonstrating a beneficial effect of nut consumption on health outcomes, which is the basis for current dietary recommendations that nuts and seeds are part of a healthy dietary pattern. We therefore propose that, for nut and seed products, the saturated fat from the nuts and seeds do not contribute toward the overall saturated fat limit. For example, a peanut butter product may contain peanuts and vegetable oil. In this example, both the peanuts and vegetable oil contain saturated fats. However, the saturated fat from the peanuts would not contribute to the saturated fat limit of ≤5 percent DV per RACC; only the saturated fat from the vegetable oil would contribute to the limit. Therefore, if the saturated fat from the vegetable oil is ≤5 percent DV of the RACC, then the peanut butter would meet the saturated fat limit. Additionally, if a product only contained nuts, such as a jar of raw, unsalted peanuts, the product would not be subject to a saturated fat limit in order to bear the ''healthy'' claim.

We seek comment on whether nuts with relatively higher amounts of saturated fat should be eligible for the ''healthy'' claim.

TABLE 7—PROTEIN PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Game meat	1½ oz equivalent	0% DV	10% DV	10% DV.
Seafood	1 oz equivalent	0% DV	10% DV	10% DV.
Egg	1 oz equivalent	0% DV	10% DV	10% DV.
Beans, peas, and soy products	1 oz equivalent	0% DV	10% DV	5% DV.
Nuts and seeds	1 oz equivalent	0% DV	10% DV	5% DV (excluding saturated fat derived from nuts and seeds).

(6) Oils

While oils are not technically a food group in the *Dietary Guidelines, 2020–2025,* the *Dietary Guidelines, 2020–2025* emphasizes oils as part of a healthy dietary pattern because they are a common characteristic of dietary patterns associated with positive health outcomes and provide essential fatty acids (Ref. 1). As part of its focus on shifts—that is, choosing nutrient-dense foods and beverages in place of less healthy choices, rather than increasing intake overall—the *Dietary Guidelines, 2020–2025* recommends cooking with vegetable oil in place of fats high in saturated fat (such as butter, shortening, lard, and coconut oil) as a strategy to shift intake.

We propose including 100 percent oils, oil-based spreads, and oil-based dressings in the definition of ''healthy'' where they meet certain specified requirements. While the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level recommends 27 g (about 5 teaspoons) per day of oils, we are not proposing that oil products contain a certain *quantity* of oil in order to be labeled healthy. This is because the *Dietary Guidelines, 2020–2025* does not recommend high consumption of oil, but instead that oils be used instead of fats high in saturated fats while staying within daily calorie limits. The proposed requirements for oils, oil-based spreads, and oil-based dressings are discussed in further detail in this section.

Under proposed § 101.65(d)(2)(iii)(F)(*1*), for 100 percent oils to bear the ''healthy'' claim, they would have to contain only oil, which means they would contain no sodium or added sugars. For the 100 percent oil subcategory, we are proposing a limit of saturated fat of ≤20 percent of total fat. The *Dietary Guidelines, 2020–2025* emphasizes oils, such as canola, corn, olive, and sunflower oils, as part of a healthy dietary pattern because of their fatty acid profile. However, the *Dietary Guidelines, 2020–2025* specifically does not include the fat from some tropical plants, such as coconut oil, palm kernel oil, and palm oil, in the category of oils because they contain a higher percentage of saturated fats than other oils. We propose the 20 percent limit on saturated fat to ensure that only oils with a fat profile of predominantly monounsaturated and polyunsaturated fats, as recommended by the *Dietary Guidelines, 2020–2025,* meet the criteria for ''healthy.'' The proposed 20 percent limit is consistent with the percentage used by the National Academies to describe dietary fats low in saturated fatty acids (Ref. 7). This 20 percent saturated fat limit is also consistent with the saturated fat requirement for determining the type of foods that are eligible to bear the claim on the ''Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease'' (Docket No. FDA–2007–Q–0291). Thus, we propose a 20 percent limit on saturated fat in oils to bear the nutrient content claim ''healthy.''

We also propose allowing oil-based spreads, such as tub margarine, to bear the claim ''healthy'' when they meet certain requirements. Use of spreads made with vegetable oils can help shift intake away from other fats high in saturated fat. The *Dietary Guidelines, 2020–2025* recommends cooking and purchasing products made with oils higher in polyunsaturated and monounsaturated fats rather than using butter, shortening, or coconut or palm oils (Ref. 1). Thus, we propose allowing oil-based spreads to qualify only when their fat content comes solely from oils and where the product's overall saturated fat content is no more than 20 percent of total fat. For such spreads, we are proposing a limit for added sugars of 0 percent DV per RACC, as these products are not expected to contain added sugars. We are also proposing to lower the sodium limit to 5 percent DV per RACC for spreads, due to their small RACCs. This approach is reasonable given that many of these products already contain less than 5 percent DV of sodium per RACC (Ref. 20). We seek comment on the proposed criteria for oil-based spreads, particularly on whether the proposed saturated fat criteria would adequately ensure that spreads that are part of a healthy dietary pattern (because they are lower in saturated fat and higher in unsaturated fatty acids, consistent with current nutrition science and Federal dietary

guidance) are eligible to bear the ''healthy'' nutrient content claim.

We also propose allowing oil-based dressings to bear the claim ''healthy'' when they meet certain requirements. Similar to oil-based spreads, use of dressings made with vegetable oils can help shift intake away from use of dressings made with fats that are high in saturated fat. For oil-based dressings to bear the claim ''healthy,'' we are proposing they must contain at least 30 percent oil, which is consistent with the oil content in the standard of identity for salad dressing (21 CFR 169.150). Dressings must be made from oils that meet the requirements in § 101.65(d)(2)(ii)(F)(*1*) (*i.e.,* saturated fat level of the oil must be ≤20 percent of total fat).

We are proposing that oil-based dressings be permitted to contain up to 2 percent DV of added sugars per RACC. Many dressings contain a small amount of added sugars. We are proposing to allow a small amount of added sugars because dressings are typically consumed with vegetables, another highly recommended and underconsumed food group. We are also proposing a sodium limit of ≤5 percent DV per RACC for dressings, due to their small RACCs. As with spreads, this approach is reasonable given that many of these products already contain less than 5 percent DV of sodium per RACC (Ref. 20). Finally, we propose that the dressings must meet a saturated fat limit of ≤20 percent of total fat. We seek comment on the proposed criteria for oil-based dressings; in particular, we seek comment on whether the proposed 30 percent oil level is an appropriate requirement for oil-based dressings, and on whether the proposed saturated fat criteria adequately ensure that dressings that are part of a healthy dietary pattern because they are lower in saturated fat and higher in unsaturated fatty acids, consistent with current nutrition science and Federal dietary guidance, are eligible to bear the ''healthy'' claim.

TABLE 8—OIL PRODUCT REQUIREMENTS PER RACC

	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
100% Oil	N/A	0% DV	0% DV	20% of total fat.
Oil-based Spreads	N/A	0% DV	5% DV	20% of total fat.
Oil-based Dressing (must contain at least 30% oil and saturated fat level of the oil must be ≤20 percent of total fat).	N/A	2% DV	5% DV	20% of total fat.

c. Combination Foods

(1) Overview

As explained previously, individual foods are foods that are primarily comprised of one food group. In some cases, individual foods can contain ingredients from multiple food groups, but not in high enough quantities to equal a food group equivalent in more than one food group. These types of foods are subject to the proposed requirements in section VI.B.3.b (''Individual foods''). However, many foods on the market contain multiple ingredients in combinations more complex than those that would fit in the individual food groups. For purposes of this rule, we refer to these foods as ''combination foods.'' Combination foods are comprised of meaningful amounts of more than one food group as described in more detail in the next few paragraphs, and therefore are subject to different criteria in order to bear the nutrient content claim ''healthy.''

The *Dietary Guidelines, 2020–2025* food group recommendations are discussed in section V.A (''Overview of Approach''). In that section, we discussed the daily intake recommendations of each of the food groups and subgroups (vegetables, fruits, grains, dairy, and protein foods) in the ''Healthy U.S.-Style Dietary Pattern,'' and explained that we are proposing that individual foods must contain at least one food group equivalent to be eligible for ''healthy.'' We propose similar requirements for combination foods, taking into account the varying composition of food groups and subgroups they contain. The nutrients-to-limit criteria for combination foods are also based on the criteria for individual foods, depending on the number of food group servings contained in the combination food. The food group equivalent and nutrients-to-limit requirements for combination foods are discussed in more detail below.

We are proposing different criteria for combination foods depending on their role in the diet, which we have categorized into mixed products, main dish products, and meal products:

- *Mixed products* are similar in size to an individual food but contain more than one food group. For example, a mixed product could include a granola product that is half whole grains and half nuts. We are proposing to require that a mixed product contain at least half a food group equivalent each of two different food groups per RACC. We are also proposing nutrients-to-limit requirements that reflect the food group composition of mixed products.
- *Main dish products,* defined at § 101.13(m), are larger in size (weighing at least 6 oz per labeled serving) than individual foods and mixed products, and are intended to make a major contribution to a meal. A main dish product might include, for example, a frozen entrée that is intended to be eaten with additional items to form a full meal. Because of their size and purpose in the diet, we are proposing to require that main dish products contain at least a food group equivalent each of two different food groups per labeled serving. We are also proposing specific nutrients-to-limit criteria to take into account their purpose in the diet and their larger RACCs.
- *Meal products,* defined at § 101.13(l), are larger in size (weighing at least 10 oz per labeled serving) than main dish products, and are intended to comprise all of the food for a single eating occasion (*i.e.,* a full meal). An example of a meal would be a frozen dinner. Because of their size and purpose in the diet, we are proposing to require that meal products contain at least a food group equivalent each from three different food groups per labeled serving. We are also proposing nutrient-to-limit criteria to take into account their purpose in the diet and their larger RACCs.

(2) Additional considerations for combination foods

There are a few special considerations that apply to all combination foods. First, under the proposed criteria for combination foods, oils do not count as a food group equivalent. This is because oils are not considered a food group under the *Dietary Guidelines, 2020–2025,* but instead an element that should be included in a healthy dietary

pattern as a substitute for fats high in saturated fat. Individual oil products that are eligible to bear the ''healthy'' claim include 100 percent oil products, oil-based spreads, and oil-based dressings. This category does not include oils as an ingredient in formulated foods (*e.g.,* foods fried in a vegetable oil). Thus, under the proposed criteria for combination foods, oils are not considered a food group equivalent. This does not mean that combination foods cannot contain oils and still qualify for the ''healthy'' claim; it means that such oils do not contribute to the food group equivalent requirements in order to meet the criteria to be labeled ''healthy.'' We are proposing saturated fat limits for combination foods to help encourage the use of healthy oils instead of fats high in saturated fat in combination foods.

Second, similar to the criteria for individual foods, we are proposing that the saturated fat from nuts and seeds does not contribute toward the saturated fat limit for nut and seed products. This is because nuts and seeds are nutrient dense foods and consumption of nuts and seeds has been found to be beneficial to health despite the fact that some varieties contain levels of saturated fat that exceed the limits set for other protein foods. Based on the scientific evidence demonstrating beneficial effects of nut consumption, FDA has multiple qualified health claims for nuts, and consumption of nuts and seeds is encouraged by the *Dietary Guidelines, 2020–2025,* as discussed in more detail in the individual foods section. Therefore, to make the criteria for combination foods consistent with the criteria for individual foods, we are proposing that when nuts and seeds are included as ingredients in combination foods, the saturated fat contained in the nuts and seeds does not contribute toward the saturated fat limit. For example, for a mixed product that contains one half serving of nuts and one half serving of whole grains, the food would have a saturated fat limit of 5 percent DV, but the saturated fat from nuts and seeds would not contribute to this limit.

Finally, we are proposing that beans, peas, and lentils may be counted as either a protein food or as a vegetable in a combination food. As noted previously, beans, peas, and lentils (which include foods such as kidney beans, pinto beans, white beans, black beans, garbanzo beans, lentils, and split peas) are considered both vegetables and protein foods in the *Dietary Guidelines, 2020–2025,* because their nutrient content is similar to both protein foods and to vegetables. Consistent with the *Dietary Guidelines, 2020–2025,* we propose that beans, peas, and lentils may count as either a vegetable or a protein food in a combination food for purposes of food group equivalent criteria. If a combination food has more than one type of food from the beans, peas, and lentils subgroup, in amounts such that each food meets the food group requirements individually, the amount of one food from the beans, peas, and lentils subgroup can meet the vegetable group requirement while another food from the same subgroup can be used to meet the protein food requirement. However, if the food product has only one type of food from the beans, peas, and lentils subgroup, the one type cannot count toward both the vegetable and protein food group requirements in the same combination food. For example, if a food product had a ½ cup of split peas and a ½ cup of black beans, the black beans could be counted as one food group equivalent of protein foods and the split peas as one food group equivalent of vegetables in a combination food. However, if a food product had one cup only of black beans, it could be counted as one food group equivalent of vegetables or one food group equivalent of protein foods, but not as both.

(3) Combination foods criteria.

In addition to the special considerations just described, we are proposing specific criteria for food group equivalents and nutrients to limit for mixed products, main dishes, and meals. These criteria are detailed in the following sections.

(i) Mixed products—Mixed products are foods that contain multiple ingredients but do not contain a full food group equivalent per RACC of any single *Dietary Guidelines, 2020–2025* food group. A mixed product could include, for example, a trail mix that contains fruit and nuts, where neither of these components are in sufficient quantities to equal a full food group equivalent. Where a product contains more than one food group and does not contain a full food group equivalent of any one food group, we are proposing that it can bear the ''healthy'' claim if it contains a sufficient amount from two different food groups. Specifically, we propose that a mixed product must contain at least half of a food group equivalent each of two different food groups per RACC. The amount in a food group equivalent is specified in proposed § 101.65(d)(2)(ii). For example, the aforementioned trail mix could meet the food group equivalent requirement if it contains ¼ c-eq fruit (half a fruit food group equivalent) and ½ oz-eq nuts (half a food group equivalent of nuts and seeds). One food group equivalent equals ¼ of the total daily recommended amount of each of the recommended food groups. For individual foods we have set a minimum amount of one full FGE. For mixed products, we reduce this amount to half of a food group equivalent in order to allow multi-component foods, that contribute to meeting the daily recommended amounts of food groups, to bear a ''healthy'' claim. For consumers who use the ''healthy'' claim in constructing their diets, mixed products bearing a ''healthy'' claim that contain less than half of a food group equivalent may make it difficult for consumers to meet their total daily amounts of recommended food groups. However, we request comments on whether lower amounts of food group equivalents (*e.g.,* ¼ FGE) would be similarly effective as ½ FGE in helping consumers meet their total daily amounts of recommended food groups for multicomponent foods.

We also propose that mixed products would have to meet certain nutrients-to-limit criteria to bear the ''healthy'' claim. Because they contain at least two half food group equivalents, mixed products contain an overall food group equivalent similar to that of individual foods. We calculated the nutrients-to-limit criteria for mixed products by finding the average of the nutrients to limit for their component food groups. For example, for a mixed product that contains a half food group equivalent of dairy and a half food group equivalent of fruit, the added sugars limit would be 2½ percent DV per RACC (the average of 5 percent DV for dairy and 0 percent DV for fruit), sodium limit would be 10 percent DV per RACC (as both food groups have the same sodium limit), and the saturated fat limit would be 7½ percent DV per RACC (the average of 10 percent DV for the dairy and 5 percent DV for the fruit). Because there is variation in the saturated fat limits for different subgroups of protein foods, the saturated fat limit for mixed products containing protein also varies depending on the type of protein in the product. The proposed nutrients to limit criteria per RACC for each type of mixed product are reflected in table 9.

TABLE 9—MIXED PRODUCT REQUIREMENTS

Food group equivalents (FGE)	Added sugar limit	Sodium limit	Saturated fat limit
½ FGE fruit, vegetable, or protein + ½ FGE fruit, vegetable, or protein.	0% DV	10% DV	5% DV or 7½% DV if the protein is game meat, seafood, or egg.
½ FGE whole grain + ½ FGE fruit, vegetable, or protein.	2½% DV	10% DV	5% DV or 7½% DV if the protein is game meat, seafood, or egg.
½ FGE dairy + ½ FGE fruit, vegetable, or protein	2½% DV	10% DV	7½% DV or 10% DV if protein is game meat, seafood, or egg.
½ FGE dairy + ½ FGE whole grain	7½% DV	10% DV	7½% DV.

(ii) Main dish products—A main dish product is defined by our regulations at § 101.13(m) as a food that makes a major contribution to a meal by weighing at least 6 oz per labeled serving; and containing not less than 40 g of food, or combinations of foods, from each of at least two food groups (as specified in § 101.13(m)(1)(ii)). In addition to the food group requirements, the product must be represented as, or in a form commonly understood to be, a main dish (*e.g.,* not a beverage or dessert). Such representations may be made either by statements, photographs, or vignettes.

Main dish products are food products of significant size intended to contain most of the components of a meal. Because of their size and purpose in the diet, we propose that these types of food products must contain at least one food group equivalent each of two different food groups or subgroups as specified by proposed § 101.65(d)(2)(ii). These food group requirements are different and distinct from the food groups specified in § 101.13(m)(1)(ii). In particular, fruits and vegetables are two separate food groups for the purposes of the ''healthy'' claim (where they are one combined food group under § 101.13(m)(1)(ii)), consistent with the *Dietary Guidelines, 2020–2025.* An example of a main dish product that might bear the ''healthy'' claim would be a vegetable lasagna product that contains a ½ c-eq of mixed vegetables (vegetable food group equivalent) and ¾ oz-eq of whole grains (whole grain equivalent) per labeled serving.

Main dish products would also be subject to specific nutrients-to-limit criteria, which would apply per labeled serving. We calculated the nutrients-to-limit criteria for main dish products by adding together the nutrient limits for the two individual food groups that make up the main dish. For example, for the vegetable lasagna main dish, the added sugars limit would be 5 percent DV (5 percent DV for whole grains plus 0 percent DV for vegetables), the sodium limit would be 20 percent DV (10 percent DV for whole grains plus 10 percent DV for vegetables), and the saturated fat limit would be 10 percent DV (5 percent DV for whole grains plus 5 percent DV for vegetable).

As with mixed products, because there is variation in the saturated fat limits for different subgroups of protein foods, the saturated fat limit for mixed products containing protein foods also varies depending on the protein subcategory in the product. For example, a main dish containing salmon and brown rice would have a higher saturated fat limit (15 percent DV) than a main dish containing tofu and brown rice (10 percent DV). The proposed nutrients to limit criteria per labeled serving for each type of main dish product are reflected in table 10.

TABLE 10—MAIN DISH REQUIREMENTS

Food group equivalents (FGE)	Added sugar limit	Sodium limit	Saturated fat limit
1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	0% DV	20% DV	10% DV or 15% DV if the protein is game meat, seafood, or egg.
1 FGE whole grain + 1 FGE fruit, vegetable, or protein.	5% DV	20% DV	10% DV or 15% DV if the protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE fruit, vegetable, or protein	5% DV	20% DV	15% DV or 20% DV if protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE whole grain	10% DV	20% DV	15% DV.

(iii) Meal products—A meal product is defined by our regulations at § 101.13(l) as a food that makes a major contribution to the total diet by weighing at least 10 oz per labeled serving and containing no less than three 40 g portions of food, or combinations of foods, from two or more of the food groups specified at § 101.13(l)(1)(ii). In addition to the food group contribution requirements, the product must be represented as, or must be in a form commonly understood to be, a breakfast, lunch, dinner, or meal. As with main dishes, such representations may be made either by statements, photographs, or vignettes.

For a meal product to be eligible to bear the ''healthy'' claim, we propose in § 101.65(d)(3)(iv) that it must contain at least one full food group equivalent each of three different food groups or subgroups specified by the proposed regulation in § 101.65(d)(2)(i) through (iv) (vegetable, fruit, whole grain, dairy, or protein foods) per labeled serving. As with main dish products, these food group requirements are different and distinct from the food groups in § 101.13(l)(1)(ii). An example of a meal product containing the necessary food group equivalents to bear the ''healthy'' claim would be a frozen salmon dinner containing 1 oz-eq salmon, ½ c-eq green beans, and ¾ oz-eq brown rice, representing a food group equivalent each of seafood (protein food), vegetables, and whole grains.

As with mixed products and main dish products, meal products would also be subject to specific nutrients-to-limit criteria, which would apply per labeled serving. The nutrients-to-limit criteria for meals are the sum of the requirements for the three individual food groups that comprise the meal. For example, in the salmon meal, the added

sugars limit would be 5 percent DV (0 percent DV for vegetable, 0 percent DV for seafood, and 5 percent DV for whole grain), the sodium limit would be 30 percent DV (10 percent DV each for vegetable, seafood, and whole grain), and the saturated fat limit would be 20 percent DV (5 percent DV for vegetable, 10 percent DV for seafood, and 5 percent DV for whole grain).

As with mixed products and main dish products, because there is variation in the saturated fat limits for different subgroups of protein foods, the saturated fat limit for mixed products containing protein foods also varies depending on the protein subcategory in the product. The proposed nutrients-to-limit criteria per labeled serving for each type of meal product are reflected in table 11.

TABLE 11—MEAL PRODUCT REQUIREMENTS

Food group equivalents (FGE)	Added sugar limit	Sodium limit	Saturated fat limit
1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	0% DV	30% DV	15% DV or 20% DV if the protein is game meat, seafood, or egg.
1 FGE whole grain + 1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	5% DV	30% DV	15% DV or 20% DV if the protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE fruit, vegetable, or protein + 1 FGE fruit, vegetable, or protein.	5% DV	30% DV	20% DV or 25% DV if protein is game meat, seafood, or egg.
1 FGE dairy + 1 FGE whole grain + 1 FGE fruit, vegetable, or protein.	10% DV	30% DV	20% DV or 25% DV if the protein is game meat, seafood, or egg.

(iv) Water—We are proposing to include plain and plain, carbonated water in the updated definition of ''healthy.'' According to the National Academies (Ref. 23), water is the largest single constituent of the human body and is essential for cellular homeostasis and life. It provides the solvent for biochemical reactions, is the medium for material transport, and has unique physical properties (high specific heat) to absorb metabolic heat. Water is essential to maintain vascular volume, to support the supply of nutrients to tissues, and to remove waste. Body water deficits challenge the ability of the body to maintain homeostasis during perturbations (*e.g.,* sickness, physical exercise, or climatic stress) and can impact function and health (Ref. 23). The total water intake needed to prevent the deleterious effects of dehydration comes from drinking water, water in other beverages, and water (moisture) in food. Approximately 80 percent of total water intake comes from drinking water and other beverages.

Water itself is not categorized under a recommended food group in the *Dietary Guidelines, 2020–2025.* However, water is emphasized in the *Dietary Guidelines, 2020–2025* beverage recommendations. The *Dietary Guidelines, 2020–2025* recommends that the ''primary beverages consumed'' should be ''beverages that are calorie-free—especially water—or that contribute beneficial nutrients, such as fat-free and low-fat milk and 100 percent fruit juice'' (Ref. 1). Organizations, such as the National Academy of Medicine, and public health agencies, such as the Centers for Disease Control and Prevention, widely recognize the benefits of water, that it is a preferred source of hydration, and is necessary for proper functioning of the human body, and, accordingly, recommend increased availability of drinking water (Refs. 24–26).

Under the existing regulation at § 101.65(d), water cannot be labeled ''healthy'' because it does not meet the existing nutrient-related criteria. Beverages included in a healthy dietary pattern, such as water, are those that allow nutrient needs to be met through the dietary pattern by allowing consumers to meet the food group recommendations without exceeding calorie needs. Thus, consideration of water under the ''healthy'' claim is appropriate as water is an important beverage for maintaining healthy dietary practices due to its nutrient content and how the profile affects the overall dietary pattern. Further, the *Dietary Guidelines, 2020–2025* recommends making shifts toward healthier food and beverage choices, such as choosing water in the place of sugar-sweetened beverages and emphasize choosing nutrient-dense foods to help achieve healthy dietary patterns within calorie limits. To help achieve this, the *Dietary Guidelines, 2020–2025* further recommends limiting added sugars in the diet, since a healthy dietary pattern within calorie limits is difficult to achieve when added sugars exceed 10 percent of calories. The major source of added sugars in the typical U.S. diet is beverages, including sugar-sweetened beverages and sweetened coffees and teas, which account for 35 percent of all added sugars consumed by the U.S. population (Ref. 1). Thus, the absence of added sugars is particularly relevant to inclusion of water when defining the implied nutrient content claim ''healthy.'' Further, the *Dietary Guidelines, 2020–2025* recommends selecting calorie-free beverages, such as water, to help achieve a healthy dietary pattern within calorie limits.

In addition, the *Dietary Guidelines, 2020–2025* specifically calls out water, 100 percent fruit juice, and fat-free/low-fat milk as beverages to consume in a healthy dietary pattern. As discussed previously, 100 percent vegetable juice, 100 percent fruit juice, and fat-free and low-fat milk are eligible to bear the nutrient content claim ''healthy'' under this proposed rule; therefore, it would be consistent with a healthy dietary pattern to also allow water to bear the ''healthy'' claim. Moreover, the *Dietary Guidelines, 2020–2025* recommends water without restriction, in contrast to milk and 100 percent juice beverages, which should be consumed in the context of the recommended intake amounts of each individual food group and within calorie limits.

Based on these considerations, we propose including plain water—both still and carbonated—in the definition of ''healthy.'' We seek comment on whether water should be included in the definition, and whether ''water'' should be expanded, for example, to include waters containing non-caloric flavors or other non-caloric ingredients. In addition, because only labeled water (*e.g.,* bottled water) would commonly bear the ''healthy'' claim, we also seek comment on whether allowing bottled water to be labeled ''healthy'' could potentially lead some consumers to believe that bottled water is healthier than tap water. Beyond water, the *Dietary Guidelines, 2020–2025* states that beverages that are calorie-free should be primary beverages consumed and that coffee and tea with little, if any, sweeteners or cream are also beverage options that can be part of a healthy

dietary pattern. Therefore, we also seek comment on the eligibility of calorie-free beverages, coffee, and tea to bear the ''healthy'' claim.

4. Records Requirements

We are proposing limited recordkeeping requirements on manufacturers to facilitate FDA's ability to verify compliance with certain aspects of the proposed rule. See section V. (''Legal Authority'') for the discussion of our legal authority for proposing recordkeeping and records access requirements. Compliance with the requirements for nutrients to limit will be verifiable for all food products using the Nutrition Facts Label; that is, it will be apparent from the Nutrition Facts Label whether a food meets the applicable criteria for saturated fat, sodium, and added sugars content, and thus no additional records are required. For some foods, we will also be able to use the product label (including the Nutrition Facts Label, the ingredient list, the statement of identity, and any other information) to verify compliance with the food group requirements. For example, it would be apparent from the ingredient list of an oil product whether the product contains 100 percent oil. Similarly, it would likely be ascertainable from the ingredient list of a frozen spinach product that contains only spinach and salt whether the product contains enough spinach (vegetable food group) to bear the ''healthy'' claim.

However, for certain foods bearing the ''healthy'' claim, the label will not be sufficient to verify that the food meets the requirements for ''healthy'' as described in § 101.65(d)(3). Specifically, the label will not provide sufficient information for FDA to verify that certain foods containing multiple components (such as most grain products and all combination foods) meet the food group equivalent requirements to bear the claim. For these foods, we are proposing to require recordkeeping to demonstrate compliance with the food group equivalent requirements, given the nature of the information necessary to determine compliance and the number of foods potentially affected. We are proposing to require the manufacturer of a food bearing the implied nutrient content claim ''healthy'' to make and keep records, identified in proposed § 101.65(d)(4), where the food group equivalent(s) is/are not apparent based on the label of the food. These records would verify that the food bearing the ''healthy'' claim meets the food group equivalent requirements. This recordkeeping requirement would not apply to water or to raw, whole fruits and vegetables, which do not have food group equivalent requirements.

This recordkeeping requirement would always apply to manufacturers of mixed products, main dish products, and meal products, as these products contain multiple components and it will not be clear how much of each food group is contained in the products without additional information. For individual foods, it will depend on the food whether such records are required. For example, a manufacturer of a multigrain bread containing both whole wheat and refined wheat flours would be required to keep records under this section. This is because it would not be apparent based on the label whether a serving of the bread contains at least ¾ oz-equivalent of whole grains. By contrast, a manufacturer would *not* be required to keep such records for a 100 percent whole wheat bread, because the ingredient statement on the information panel would indicate that the bread contains *only* whole-grain flour, and therefore, it would be apparent from the label that the bread contains the required ¾ oz-eq of whole grains (as one slice of whole wheat bread would be a 1 oz-eq of whole grains). Other examples of individual foods that would not be subject to the recordkeeping provision include dried fruit, plain yogurt, and brown rice.

Where the proposed requirements cannot be verified using the label, only the manufacturer will have the information required to determine whether the product meets the food group equivalent requirements for bearing the ''healthy'' claim. The information contained in manufacturers' records is an accurate and practical method for ensuring that the nutrient content claim is used in accordance with § 101.65(d) and that the food labeling complies with section 403(r) of the FD&C Act. We tentatively conclude that the records will provide FDA with the necessary means to determine compliance with the food group equivalent requirements for bearing the ''healthy'' nutrient content claim.

Manufacturers will be responsible for the type of records they maintain and are not required to produce any specific form or document. The manufacturer is in the best position to know which of its records provide the documentation required to determine compliance. Records used to verify that a food meets the food group equivalent requirements for ''healthy'' could include recipes or formulations, batch records providing data on the weight of certain ingredient contributions to the total batch, certificates of analysis from ingredient suppliers, or other appropriate verification documentation that provides the needed assurance that a food bearing the ''healthy'' claim complies with the food group equivalent requirements. We expect that manufacturers choosing to use the ''healthy'' claim will have the type of records needed to verify that the food meets the requirements, given that they will have to analyze their product to determine whether it meets the requirement in order to bear the claim. The proposed records requirement is intended to provide flexibility in what records the manufacturer makes available to FDA to verify the claim. The records provided during an inspection by FDA would only need to provide information on the food group equivalents because the information on nutrients to limit will be available on the food package. Other information about the food can be redacted if necessary to ensure confidentiality of a food product formulation.

We recognize that the composition of processed foods can vary depending on the recipe or formulation, the suppliers of ingredients, etc. For example, the amounts of given components in a mixed product, such as granola, may change if a manufacturer changes ingredient suppliers or changes a recipe. In order to verify the composition of a packaged food, the manufacturer would need to ensure that the records it provides to us to verify that the food bearing the ''healthy'' claim meets the food group equivalent requirements of § 101.65(d)(3), and, as appropriate, can distinguish among the same or similar product that the manufacturer has in the marketplace that may contain differing amounts of its components. For example, the manufacturer may have to distinguish among different granola bars with different amounts of qualifying food groups or the same granola with different formulations.

Although some manufacturers may have large numbers of foods bearing the ''healthy'' claim that would necessitate recordkeeping to verify that they meet the requirements, we do not think that determining the composition of the foods and maintaining that information would present undue difficulty for manufacturers. With or without a ''healthy'' claim, manufacturers are required to know what ingredients and nutrients are in the foods they produce and to provide that information truthfully to consumers. Manufacturers have experience with determining the ingredient composition of the food they produce and with the maintenance of related records, either written or

electronic. We seek comment on the accuracy of these assumptions.

We recognize that manufacturers frequently obtain ingredients from suppliers in a (sometimes extensive) supply chain, and that these ingredients often contain multiple ingredients themselves. Manufacturers should be able to work with their suppliers to obtain the necessary information to ensure that any food bearing the claim ''healthy'' meets the regulatory requirements to bear the claim. Ingredient suppliers should know the contents of the ingredients they provide to food manufacturers, and this information will need to be properly communicated.

We are proposing that such records must be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. We selected this period to ensure that records can be made available for review and copying as long as the product is available for purchase in the marketplace. Due to the significant number of packaged food products in the marketplace that could meet the requirements under § 101.65(d), we recognize that there could be a wide variation of manufacturing practices, shipping practices, and shelf lives among packaged foods bearing the ''healthy'' claim. We believe that it is most practical to establish a single recordkeeping period for this provision rather than establishing different recordkeeping periods for different products or for different manufacturing or shipping practices. It would be more difficult for FDA to establish a compliance program for one segment of the regulated industry that starts the recordkeeping process when the food is made, and a different compliance program for another segment of the industry that starts the recordkeeping process when the food is shipped. For manufacturers who make several food products, we expect it would be easier for them to use the same recordkeeping period for all products rather than use different recordkeeping periods for different products. Therefore, we have designed a compliance program that involves a single recordkeeping period. The proposed record requirements for purposes of verifying the ''healthy'' claim are separate and distinct from other record requirements.

We are proposing that records must be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610, and 81 FR 33742). The records would need to be reasonably accessible (access to records within 24 hours can be considered reasonable) to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food meets the requirements for bearing the ''healthy'' claim. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

We anticipate that manufacturers may have concerns about the confidentiality of the information inspected by us under this proposal. We would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20. Thus, we are proposing to require that manufacturers must make and keep records to verify that the food meets the food group equivalent requirements of § 101.65(d)(2) where the food group equivalent contained in the product is not apparent based on the label of the food.

We are also proposing, in § 101.65(d)(4), that such records must be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. In addition, we are proposing to require that such records must be provided upon request, during an inspection, for official review and photocopying or other means of reproduction, and that records may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. All electronic records that are maintained to comply with the proposed requirements would need to comply with 21 CFR part 11.

We seek comment on the proposed requirements for the types of records that must be made and kept and the length of time that the records must be kept.

VII. Proposed Effective and Compliance Dates

We intend that any final rule resulting from this rulemaking become effective 60 days after the date of the final rule's publication in the **Federal Register** with a compliance date 3 years after the effective date. We recognize that it may take industry time to analyze products, update their records of product labels, and print new labels. A compliance date that is 3 years after the effective date is intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to have the information in a timely manner. We seek comment on the proposed compliance date.

VIII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Information and Regulatory Affairs has designated this proposed rule to be an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a large proportion of covered entities are small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in at least one year that meets or exceeds this amount.

B. Summary of Costs and Benefits

Some consumers use nutrient content claims such as ''healthy'' to inform their food purchases. We estimate that a small number (0 to 0.4 percent of people that try to follow current dietary guidelines) of these consumers would use the ''healthy'' implied nutrient content claim to make meaningful, long-lasting food purchasing decisions. If the foods using the ''healthy'' claim more closely align with Federal dietary guidance, the claim can assist consumers who are selecting those products in choosing a more healthful diet, which may result in lower chronic, diet-related diseases, including

cardiovascular disease and type 2 diabetes.

Quantifiable benefits of the proposed rule are the estimated reduction over time in all-cause morbidity stemming from consumers selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. Discounted at three percent over 20 years, the mean present value of benefits accrued to consumers using the ''healthy'' nutrient content claim is $455 million, with a lower bound estimate of $15 million and an upper bound estimate of $1.3 billion. Discounted at seven percent over 20 years, the mean present value of benefits of the proposed rule is $290 million, with a lower bound estimate of $9 million and an upper bound estimate of $857 million.

Quantified costs to manufacturers associated with updating the ''healthy'' claim are labeling, reformulating, and recordkeeping. Overall, about 34,000 UPCs, or 14 percent of total UPCs, qualify for the existing ''healthy'' implied nutrient content claim but only 5 percent (12,000 UPCs) choose to label. The use of the ''healthy'' nutrient content claim is voluntary, but if the proposed rule results in some products needing to remove the claim to avoid being misbranded, manufacturers would incur costs due to the rule. Manufacturers with food products currently using the ''healthy'' nutrient content claim would need to confirm whether the products meet the proposed criteria and decide whether a label change is needed. Manufacturers with products that currently do not meet the ''healthy'' criteria but do meet the proposed criteria have the option of labeling these products. In some cases, manufacturers may choose to reformulate a product so that it meets the proposed criteria. Some recordkeeping is required for certain products using the proposed ''healthy'' claim because the required food components equivalents are likely to increase time spent on recordkeeping. It is possible that manufacturers of products that include the term ''healthy'' within the brand name may choose to rebrand products instead of reformulating. We lack the data to quantify this effect but discuss it qualitatively. Discounted at three percent over 20 years, the mean present value of costs accrued to manufacturers using the ''healthy'' nutrient content claim, assuming the current 5 percent adoption rate, is $276 million, with a lower bound of $128 million and an upper bound of $505 million. Discounted at seven percent over 20 years, the mean present value of costs of the proposed rule is $237 million, with a lower bound of $110 million and an upper bound of $434 million.

TABLE 12—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

[In millions 2020$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	$27.4 30.6	$0.89 0.99	$80.9 90.4	2020 2020	7 3	20 20	Monetized benefits account for consumer's lost pleasure from eating less healthy foods they may nevertheless prefer.
Annualized Quantified					7 3		
Qualitative	To the extent consumers use the ''healthy'' nutrient content claim to maintain healthy dietary practices, following a healthy diet could reduce the risk of morbidity and prolong life.						
Costs:							
Annualized Monetized $millions/year	22.3 18.5	10.4 8.6	40.9 33.9	2020 2020	7 3	20 20	
Annualized Quantified					7 3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year.					7 3		
From/To	From:			To:			
Other Annualized Monetized $millions/year.					7 3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government: None.							

TABLE 12—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued
[In millions 2020$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Distributional: American Indian, Alaskan Native, Hispanic, and Non-Hispanic Black adults and children, as well as the lower-income or publicly insured may accrue a larger proportion of the estimated health benefits. However, this distributional shift may be reduced if these populations do not use, or do not have access to, products that bear the ''healthy'' nutrient content claim to meaningfully change their diet. Finally, any distributional shift may be dampened if costs are passed onto consumers in the form of increased prices of foods labeled as ''healthy''. Small Business: Potential impacts on small manufacturers of packaged food and beverages due to removing the ''healthy'' claim or reformulating some products. *Wages:* None. *Growth:* None.							

We seek comment on our estimates of costs and benefits of this proposed rule.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 26) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual recordkeeping and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA seeks comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food Labeling Regulations, OMB Control Number 0910–0381—Revision.

Description of Respondents: The respondents to this information collection are manufacturers of food products using the ''healthy'' implied nutrient content claim marketed in the United States.

Description: The proposed rule would revise § 101.65(d) to require manufacturers using the ''healthy'' implied nutrient content claim on their products to make and keep written records to verify that the products comply with this requirement. Examples of these records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. Manufacturers must provide these records upon request from FDA during an inspection for official review and photocopying or other means of reproduction.

The proposed rule would also require some manufacturers to relabel products to comply with the criteria for the ''healthy'' implied nutrient content claim. A product that does not meet the criteria would need to have the term removed from its label, and a product that became eligible would be permitted to use the term in its label.

We estimate the recordkeeping burden of this collection of information as follows:

TABLE 13—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.65; recordkeeping to verify ''healthy'' nutrient content claim.	1,839	1	1,839	0.5 (30 minutes)	920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The proposed rule requires that each manufacturer of a food that bears the implied nutrient content claim ''healthy'' must make and keep written records to verify that the food meets the food group equivalent requirements when it is not apparent from the label of the food. Examples of records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. However, the product label (including the Nutrition Facts label (NFL), the ingredient list, the statement of identity, and any other information) may be used to verify compliance with the food group requirements for certain foods. For example, it would be apparent from the ingredient list of an oil product whether the product contains 100 percent oil. Similarly, it would likely be ascertainable from the ingredient list of a frozen spinach product that contains only spinach and salt whether the product contains enough spinach (vegetables) to bear the ''healthy'' claim. Thus, this recordkeeping estimate does not include food groups where the equivalent requirements are apparent from the label of the food. The estimates in table 13 are based on the 5,516 products estimated to need recordkeeping in table 11 of the Preliminary Regulatory Impact Analysis (PRIA) (Ref. 26). A PRA analysis covers a 3-year period, so this number is divided by 3 to get 1,839 as an annual number of records maintained (1 record for each product). In table 13, FDA estimates that each year 1,839 manufacturers will each make and keep 1 written record for a total of 1,839 records. We estimate that each record will require 15 to 30 minutes of recordkeeping for an annual recordkeeping burden of 919.5 hours, rounded to 920 (1,839 records × 0.5 hour).

TABLE 14—ESTIMATED ONE-TIME RELABELING BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [2]
Relabel for ''healthy'' claim	5,987	1	5,987	1	5,987	$14,715,909

[1] One-time labeling burden.
[2] There are no operating and maintenance costs associated with this collection of information.

We assume there are two categories of UPCs that could require re-labeling. First, if a UPC currently labeled ''healthy'' does not meet the proposed criteria, the manufacturer could choose to remove the ''healthy'' claim or reformulate. In either case, the label would need to be changed, either to remove the ''healthy'' claim or to change the NFL after reformulation. Given the current UPCs labeled ''healthy'' that would not qualify for the proposed criteria, we estimate the number of UPCs that would remove the ''healthy'' claim or reformulate. Second, if a UPC does not currently qualify as ''healthy'' but would meet the proposed criteria, the manufacturer could choose to add the ''healthy'' claim. Table 7 of the PRIA estimates the need for 17,960 total label changes. Because this claim is voluntary, we do not know how many establishments will make labeling changes. For the purpose of this analysis, we assume that the number of respondents is the same as the number of disclosures.

We estimate that each manufacturer will relabel 1 product. A PRA analysis covers a 3-year period, so the total number of label changes, 17,960, is divided by 3 to get 5,987 annual disclosures. Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 5,987 hours. Based on table 7 of the PRIA, we estimate that there will be an annual capital cost of $14,715,909 over 3 years associated with relabeling with the total capital cost being $44,147,727. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden.

To ensure that comments on this information collection are received, OMB recommends that written comments be submitted through reginfo.gov (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides, with minor exceptions, that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to

requirements established under section 403(r) of the FD&C Act.

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Public Law 101–535 (1990)); however, it is possible that such a requirement could be preempted on another basis, such as under principles of implied preemption. If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. We solicit comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIII. References

The following references marked with an asterisk (*) 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 also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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.

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, FDA proposes to amend 21 CFR part 101 as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Revise § 101.13(b)(2)(ii) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) * * *

(2) * * *

(ii) Suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food (*e.g.,* healthy).

* * * * *

■ 3. Revise § 101.65(d) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) *General nutritional claims.* (1) This paragraph (d) covers labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices due to its nutrient content, where there is also implied or explicit information about the nutrition content of the food.

(2) For purposes of this section, a ''food group equivalent'' is the minimum amount of a food group that must be contained in a food for it to bear the ''healthy'' implied nutrient content claim. Food group equivalents identify the amounts of foods from each food group with qualifying nutritional content. A food group equivalent is equal to the following:

Food group	Food group equivalent	Examples
(i) Vegetable	½ cup equivalent vegetable	½ cup cooked green beans; 1 cup raw spinach.
(ii) Fruit	½ cup equivalent fruit	½ cup strawberries; ½ cup 100% orange juice; ¼ cup raisins.
(iii) Grains	No less than ¾ oz equivalent whole grain	1 slice of bread; ½ cup cooked brown rice.
(iv) Dairy	¾ cup equivalent dairy	6 oz fat free yogurt; 1⅛ oz nonfat cheese.
(v) Protein foods	1½ oz equivalent game meat	1½ oz venison.
	1 oz equivalent seafood	1 oz tuna.
	1 oz equivalent egg	1 large egg.
	1 oz equivalent beans, peas, or soy products	¼ cup black beans.
	1 oz equivalent nuts and seeds	½ oz walnuts.

(3) You may use the term ''healthy'' or related terms (*e.g.,* ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''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 consistent with dietary recommendations if the food meets one or more of the criteria in paragraphs (d)(3)(i) through (vi) of this section:

(i) A raw, whole fruit or vegetable.

(ii) An individual food that meets the following conditions per reference amount customarily consumed per eating occasion (RACC):

If the food is . . .	It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
(A) A vegetable product	1/2 c-eq vegetable	0% DV	10% DV	5% DV.
(B) A fruit product	1/2 c-eq fruit	0% DV	10% DV	5% DV.
(C) A grain product	¾ oz equivalent whole grain	5% DV	10% DV	5% DV.
(D) A dairy product	¾ cup equivalent dairy	5% DV	10% DV	10% DV.
(E) Protein Foods				
(*1*) Game meats	1½ oz equivalent	0% DV	10% DV	10% DV.
(*2*) Seafood	1 oz equivalent	0% DV	10% DV	10% DV.
(*3*) Egg	1 oz equivalent	0% DV	10% DV	10% DV.
(*4*) Beans, peas, and soy products	1 oz equivalent	0% DV	10% DV	5% DV.
(*5*) Nuts and seeds	1 oz equivalent	0% DV	10% DV	5% DV, excluding saturated fat derived from nuts and seeds.
(F) Oils				

If the food is . . .	It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
(*1*) 100% Oil		0% DV	0% DV	20% of total fat.
(*2*) Oil-based spreads whose fats come solely from oil.		0% DV	5% DV	20% of total fat.
(*3*) Oil-based dressing containing at least 30% oil and oils meet the requirements in paragraph (d)(3)(ii)(F)(*1*) of this section.		2% DV	5% DV	20% of total fat.

(iii) A mixed product that:

(A) Contains at least half a food group equivalent each of two different food groups as specified in paragraph (d)(2) of this section; and

(B) Meets the following conditions per RACC:

If the mixed product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*1*) ½ food group equivalent each of two of the following: fruit, vegetable, and/or protein.	0% DV	10% DV	5% DV; or 7½% DV if the protein is a game meat, seafood, or egg.
(*2*) ½ food group equivalent of whole grain and ½ food group equivalent of fruit, vegetable, or protein.	2½% DV	10% DV	5% DV; or 7½% DV if the protein is a game meat, seafood, or egg.
(*3*) ½ food group equivalent of dairy and ½ food group equivalent of fruit, vegetable, or protein.	2½% DV	10% DV	7½% DV; or 10% DV if the protein is a game meat, seafood, or egg.
(*4*) ½ food group equivalent of dairy and ½ food group equivalent of whole grain.	5% DV	10% DV	7½% DV.

(iv) A main dish product as defined in § 101.13(m) that:

(A) Contains at least one full food group equivalent each of two different food groups as specified in paragraph (d)(2) of this section; and

(B) Meets the following conditions per labeled serving:

If the main dish product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*1*) A food group equivalent each of two of the following: fruit, vegetable, and/or protein.	0% DV	20% DV	10% DV; or 15% DV if the protein is a game meat, seafood, or egg.
(*2*) A food group equivalent of whole grain and a food group equivalent of fruit, vegetable, or protein.	5% DV	20% DV	10% DV; or 15% DV if the protein is a game meat, seafood, or egg.
(*3*) A food group equivalent of dairy and a food group equivalent of fruit, vegetable, or protein.	5% DV	20% DV	15% DV; or 20% DV if the protein is a game meat, seafood, or egg.
(*4*) A food group equivalent of dairy and a food group equivalent of whole grain.	10% DV	20% DV	15% DV.

(v) A meal product as defined in § 101.13(l) that:

(A) Contains at least one full food group equivalent each of three different food groups as specified in paragraph (d)(2) of this section; and

(B) Meets the following conditions per labeled serving:

If the meal product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*1*) A food group equivalent each of fruits, vegetables, and protein foods.	0% DV	30% DV	15% DV; or 20% DV if the protein is a game meat, seafood, or egg.
(*2*) A food group equivalent of whole grain and a food group equivalent each of fruit, vegetable, and/or protein.	5% DV	30% DV	15% DV; or 20% DV if the protein is a game meat, seafood, or egg.

If the meal product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat content from nuts and seeds (if applicable), the saturated fat content must be no greater than . . .
(*3*) A food group equivalent of dairy and a food group equivalent each of fruit, vegetable, and/or protein.	5% DV	30% DV	20% DV; or 25% DV if the protein is a game meat, seafood, or egg.
(*4*) A food group equivalent of dairy, a food group equivalent of whole grain, and a food group equivalent of fruit, vegetable, and/or protein.	10% DV	30% DV	20% DV; or 25% DV if the protein is a game meat, seafood, or egg.

(vi) Plain water and plain carbonated water without any flavoring or additional ingredients.

(4) Each manufacturer of a food (other than raw, whole fruits, raw whole vegetables, water, and individual foods where the standard information required on the food label, such as the list of ingredients, provides sufficient information to verify that the food meets the food group equivalent requirements to bear the claim) that bears the implied nutrient content claim ''healthy'' must make and keep written records (*e.g.,* analyses of databases, recipes, formulations, information from recipes or formulations, or batch records) to verify that the food meets the food group equivalent requirements of paragraph (d)(2) of this section where the food group equivalent contained in the product is not apparent from the label of the food. These records must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records which must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible.

Dated: September 22, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–20975 Filed 9–28–22; 8:45 am]

BILLING CODE 4164–01–P