Label Changes

Your Comprehensive Guide to the New Nutrition and Supplement Facts Panels

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Part 1: Introduction

The Food and Drug Administration (FDA) has changed the regulations for the nutrition and supplement facts panels in order to combat some of the health problems in the country and provide people with better solutions. Its goal is "to assist consumers in maintaining healthy dietary practices."

In addition to material covered in the regulation itself, FDA has also responded to questions and comments from the public. The federal register publication is over 200 pages long, and much of the regulation interpretation can be found in FDA responses to comments.

While the media has focused mostly on the sweeping changes to sugars and fibers in the nutrition facts panels, there are also significant changes to the recommended daily intakes for vitamins and minerals.

A draft guidance published in January of 2017 answers twenty questions about compliance dates, added sugars, and the declaration of quantitative amounts of vitamins and minerals. Other regulations will need to be updated based on the final ruling, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels." FDA has said that these other regulations will be updated at a later date.

This guide covers the 2015–2020 Dietary Guidelines for Americans that the nutrition label changes are based on. It then details the changes in daily values for nutrients and describes the changes to the Nutrition Facts and Supplement Facts label regulations.

The Institute of Medicine

The Institute of Medicine (IOM) collects data on the dietary patterns of consumers and combines this data with scientific evidence to create Dietary Reference Intake reports (DRI). There are four categories of these reports.



Figure 1. Dietary Reference Intakes. Adapted from DRI Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids (p.5), by the National Academy of Sciences, 2000, National Academy Press.

Dietary Guidelines for Americans

The Dietary Guidelines for Americans (DGA) were developed jointly by the United States Department of Agriculture and the U.S. Department of Health and Human Services. The DGA recommends dietary patterns and quantitative intake for macro- and micronutrients to the US population. The last DGA is based on the 2010 IOM data; the label changes are based off that report. The DGA also released an interim report in 2015, from which FDA took information about added sugars for use in planning the label changes. The next full DGA is scheduled to come out in 2020.

Daily Values

FDA daily values are based on the recommendations made by the DGA and information from the IOM. Nutrients appear on the nutrition facts panel in percent daily values based on a 2,000 or 1,000 calorie diet. Daily values are not precise requirements for individuals, but are to be used as a general guide.

There are two categories of daily values: Reference Daily Intakes (RDIs) and Daily Reference Values (DRV's). RDI's are the daily values for small components like vitamins and minerals. DRV's are either for nutrients to limit, like sodium and cholesterol, or they are for nutrients with recommended levels based on specific calorie intakes such as fat, carbohydrates, protein, and fiber – the macronutrients.

Part 2: 2015–2020 Dietary Guidelines for Americans

5 Principle Guidelines

The DGA gives Americans five guiding principles to follow in their food choices:

The DGA has shifted the focus back to counting calories and keeping appropriate calorie levels. This principle also implies that one's diet affects one's health, which is a notable development.

5. SUPPORT healthy eating patterns for all. Everyone has a role in helping to create and support healthy eating patterns in homes, schools, work, and communities nation-wide. It takes healthy eating and information in all areas of the community for people to be healthy – at school, at home, at the doctor's office, and in the community at large.

FOLLOW a healthy eating pattern across the lifespan. All food and beverage choices matter – you can't make healthy choices one day and not the next. Americans should choose a healthy eating pattern at an appropriate calorie level to help achieve and maintain a healthy body weight, support nutrient adequacy, and reduce the risk of chronic disease.

It is difficult to stay within calorie levels while meeting the nutrient requirements that FDA has set, so consumers really will have to focus on eating nutrient-dense foods.

2. FOCUS on variety, nutrient density, and amount. To meet one's nutrient needs within calorie limits, Americans should choose a variety of nutrient-dense foods across and within all food groups in recommended amounts.

4. SHIFT to healthier food and beverage choices.

3. LIMIT calories from added sugars and saturated fats, and reduce sodium intake.

Key Recommendations

The DGA recommends healthy eating patterns that account for all foods and beverages within an appropriate calorie level. A healthy eating pattern includes:



A variety of vegetables from all of the subgroups – dark green, red and orange, legumes, and starchy Fruits, especially whole fruits

Grains, at least half of which are whole grains Fat-free or low-fat dairy, including milk, yogurt, cheese, and/or fortified soy beverages A variety of proteins, including seafood, lean meats and poultry, eggs, legumes, nuts, seeds, and soy products Oils, including olive oil and soybean oil

Dietary Components to Limit

Following a healthy eating pattern also means limiting certain dietary components:

Added Sugars

Consume less than 10 percent of calories per day from added sugars

Saturated Fats

Consume less than 10 percent of calories per day from saturated fats

Sodium

Consume less than 2,300 milligrams (mg) per day of sodium (reduced from 2,400 mg)

While "less than 10 percent of calories per day" is a concise way for the DGA to release these guidelines, it is not how added sugars and saturated fats are being measured on the label. Instead, sugar and saturated fats are to be labeled in quantitative amount and percent daily value. The DGA also emphasizes that individuals should meet their nutrition needs primarily from foods; however, they acknowledge that fortified foods, beverages, and supplements can help meet unachievable nutrient levels.

Underconsumed Nutrients

The DGA identifies nutrients that are underconsumed by Americans. It also specifies that iron is underconsumed by adolescent girls and women ages 19 to 50. Calcium, potassium, dietary fiber, and vitamin D are now considered nutrients of public health concern and are required on labeling.



Dietary Principles

The DGA claims that there are many ways to meet one's nutrient needs through foods.

- The DGA suggests three dietary principles to follow in order to meet their Key Recommendations: 1. An eating pattern represents the totality of all foods and beverages consumed
- 2. Nutritional needs should be met primarily from foods
- 3. Healthy eating patterns are adaptable

Healthy Eating Patterns

The DGA defines three healthy eating patterns to accommodate cultural and personal preferences: the Healthy U.S.-Style eating pattern, a healthy Mediterranean eating pattern, and a healthy vegetarian eating pattern.

The Healthy U.S.-Style Pattern

The Healthy U.S.-Style Pattern is the same as the primary USDA Food Pattern from the 2010 DGA, and is similar to the old DASH diet. It is based on proportions of food that Americans typically eat, and promotes the consumption of nutrient dense foods. The Healthy Mediterranean-Style Pattern

This pattern is really a version of the Healthy U.S.-Style Pattern, but it emphasizes seafood and fruits, and suggests less dairy. This pattern yields lower levels of calcium and vitamin D because of the reduction in dairy consumption.

The Healthy Vegetarian Pattern

The vegetarian pattern is also adapted from the Healthy U.S.-Style Pattern. Meat, poultry, and seafood are eliminated. Dairy and eggs are included because they are still consumed by most vegetarians, which is probably how the DGA was able to balance this pattern. It would likely be very difficult to balance a vegan diet with the guidelines that they have released. Comparatively, the vegetarian approach is higher in calcium and fiber but lower in vitamin D than the Healthy U.S.-Style Pattern.

Part 3: Daily Value Changes

Changes for All Vitamins and Minerals

All vitamins and minerals will now be declared in both quantitative amount and percent daily value. The rounding laws are therefore a bit confusing because the rounded values for quantity and percentage could be different. Any vitamin or mineral present at 2% or less of the daily value can be called 0%. This does need to align with the quantitative amount – if the percent daily value is written as zero, then the quantitative amount must also be written as zero.

Required Nutrients

Vitamin D and potassium will now be required on labels, as deficiencies of these vitamins represent public health concerns: vitamin D is essential for bone health, and potassium is important for lowering blood pressure. Potassium is a challenging nutrient to fortify with: it has flavor notes and a large daily value.

Vitamin A and C will no longer be required on the nutrition panel, although manufacturers will still be allowed to voluntarily label them. IOM data has shown that Americans no longer lack vitamins A and C in their diets.

FDA has said that it does not expect manufacturers to stop fortifying with A and C, nor does it expect manufacturers to start fortifying with vitamin D and potassium.

| vitamin D znicy | 10.70 |
|-----------------|-------|
| Calcium 260mg | 20% |
| Iron 8mg | 45% |
| Potassium 235mg | 6% |
| | |

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Rounding Rules

Since manufacturers can choose to declare a nutrient which is present in quantities as low as or less than 2% of the daily value, it is important that they have enough decimal places to declare quantitative amounts accurately. It is equally as important to avoid such amounts appearing to be more accurately measured than they are. Therefore, FDA has created recommendations for how to round quantitative amounts of nutrients with RDIs, to be used on both the Nutrition Facts and Supplement Facts labels.

| Reference Daily Intake (RDI) | Rounding Rule |
|-------------------------------|---|
| Less than 25 mg or mcg | Declare to the nearest 0.1 mg or mcg per serving. |
| | However, the quantitative amount may be declared to the nearest 0.01 or 0.001 mg or mcg if that many decimal places are needed to get a value that is at least 2% DV. |
| Between 25 and 250 mg or mcg | Declare to the nearest mg or mcg per serving. |
| Between 250 and 500 mg or mcg | Round to the nearest 5 mg or mcg per serving. |
| Greater than 500 mg or mcg | Round to the nearest 10 mg or mcg per serving. |

Table of Daily Value Changes Nutrients are listed in the order in which they appear on the supplement facts panel.

| Nutrient | Increase / Decrease | Previous Daily Value | New Daily Value | Recommended Rounding Increment |
|---------------------------|------------------------|-------------------------|-------------------------|--------------------------------------|
| Vitamin A | - 40% | 5000 IU | 900 mcg RAE* | Nearest 10 mcg |
| Vitamin C (ascorbic acid) | + 50% | 60 mg | 90 mg | Nearest mg |
| Vitamin D | + 100% | 400 IU | 20 mcg † | Nearest 0.1 mcg |
| Vitamin E | - 25.5% | 30 IU | 15 mg alpha-tocopherol* | Nearest 0.1 mg |
| Vitamin K | + 50% | 80 mcg | 120 mcg ‡ | Nearest mcg |
| Thiamin (Vitamin B1) | - 20% | 1.5 mg | 1.2 mg | Nearest 0.1 mg |
| Riboflavin (Vitamin B2) | - 23.53% | 1.7 mg | 1.3 mg | Nearest 0.1 mg |
| Niacin (Vitamin B3) | - 20% | 20 mg | 16 mg* | Nearest 0.1 mg |
| Vitamin B6 | - 15% | 2 mg | 1.7 mg | Nearest 0.1 mg |
| Folate & Folic Acid | - 40.03% | 400 mcg | 400 mcg DFE* | Nearest 5 mcg |
| Vitamin B12 | - 60% | 6 mcg | 2.4 mcg | Nearest 0.1 mcg |
| Biotin | - 90% | 300 mcg | 30 mcg | Nearest mcg |
| Pantothenic Acid | - 50% | 10 mg | 5 mg | Nearest 0.1 mg |
| Choline | N/A | N/A | 550 mg | Nearest 10 mg |
| Calcium | + 30% | 1000 mg | 1300 mg | Nearest 10 mg |
| Iron | No Change | 18 mg | 18 mg | Nearest 0.1 mg |
| Phosphorus | + 25% | 1000 mg | 1250 mg | Nearest 10 mg |
| Iodine | No Change | 150 mcg | 150 mcg | Nearest mcg |
| Magnesium | + 5% | 400 mg | 420 mg | Nearest 5 mg |
| Zinc | - 26.67% | 15 mg | 11 mg | Nearest .1 mg |
| Selenium | - 21.43% | 70 mcg | 55 mcg | Nearest mcg |
| Copper | - 55% | 2 mg | 0.9 mg | Nearest 0.1 mg |
| Manganese | + 15% | 2 mg | 2.3 mg | Nearest 0.1 mg |
| Chromium | - 70.83% | 120 mcg | 35 mcg | Nearest mcg |
| Molybdenum | - 40% | 75 mcg | 45 mcg | Nearest mcg |
| Chloride | - 32.35% | 3400 mg | 2300 mg | Nearest 10 mg |
| Sodium | - 4.17% | 2400 mg | 2300 mg | N/A |
| Potassium | + 34.29% | 3500 mg | 4700 mg | Nearest 10 mg |
| Fluoride | N/A | N/A | N/A | N/A |
| Dietary Fiber | + 12% | 25 g | 28 g | N/A |

* See Unit Conversions

† Can voluntarily declare in International Units

‡ See Further Nutrient Discussion

New Unit Conversions



Vitamin A

The daily value for vitamin A used to be in international units. The new daily value is in Retinol Activity Equivalents (RAE). FDA gives specific conversion factors from different forms of vitamin A to RAE.

Old DV = 5000 IU New DV = 900 mcg RAE (equivalent to ~3000 IU)

- 1 mcg of RAE (Retinol Activity Equivalents)
- = 1 mcg retinol
- = 2 mcg supplemental Beta Carotene
- = 12 mcg naturally occurring Beta Carotene
- = 24 mcg Alpha Carotene
- = 24 mcg Beta Cryptoxanthin

Niacin

Niacin (B3)

Vitamin B3 is now measured in Niacin equivalents. Sixty milligrams of tryptophan is equivalent to one milligram of niacin, so any product with protein in it that contributes more than 19 milligrams of tryptophan will also have to declare niacin, because the niacin equivalent will be greater than the 2% threshold for declaring as zero.

Old DV = 20 mg Niacin New DV = 16 mg NE (niacin equivalents)

1 mg NE = 1 mg Niacin = 60 mg Tryptophan

Vitamin E

The old daily value for vitamin E was in international units. The new daily value is in milligrams of alpha-tocopherol. FDA has recognized that there are eight different isomers of vitamin E. These isomers have been split into two categories: RRR or d-alpha-tocopherol, and all-racemic or d,l-alpha-tocopherol. RRR is generally recognized as natural, while all-racemic is usually synthetic. In the new conversion factors, natural alpha-tocopherol will be worth twice the amount of vitamin E as synthetic alpha-tocopherol. FDA will be relying on manufacturing records to tell the difference between the two types.

Old DV = 30 IU New DV = 15 mg alpha-tocopherol (22.35 IU)

1 mg alpha-tocopherol = 1 mg RRR-alpha-tocopherol (natural) = 2 mg all-racemic alpha-tocopherol (synthetic)

Folate and Folic Acid

Folate will now be measured in micrograms of Dietary Folate Equivalents (DFE). One mcg of natural food folate is equivalent to one mcg DFE, while one mcg of synthetic folic acid is equivalent to 1.7 mcg DFE. As of yet there are no conversions for other forms of folate such as quatrefolic acid. FDA has said that the conversion factor for other forms of folate can go as high as 1.7, but cannot exceed 1.7. FDA still does not permit the addition of any folate form other than synthetic folic acid to standard food products; quatrefolic acid can only be used in supplements.

Old DV = 400 mcg Folic Acid (equivalent to 667 mcg DFE) New DV = 400 mcg DFE (Dietary Folate Equivalents)

1 mcg naturally occuring folate = 1 mcg DFE 1 mcg synthetic folic acid = 1.7 mcg DFE

Further Nutrient Discussion

Vitamin K

Vitamin K is the only nutrient set from an Adequate Intake Level rather than an Estimated Average Requirement. The Institute of Medicine only had data on vitamin K1, so the only vitamin K that FDA will allow standard foods to be fortified with is vitamin K1 – vitamins K2 and K3 can continue to be used in supplements.

Potassium

Potassium is now required on nutritional labels, and the daily value for potassium increased from 3500 mg to 4700 mg. FDA has said that it does not expect people to start fortifying their products with potassium. Fortifying with potassium is a challenge: it takes up a lot of space. The most active source available is potassium chloride, which has a metallic aftertaste. Potassium chloride is also problematic because the daily value for chloride has been reduced from 3400 mg to 2300 mg. Potassium phosphate is also available, but unfortunately also has taste concerns and can change the buffering within a finished product.

Fluoride

Previous FDA regulations did not require or permit fluoride to be listed on the nutrition facts panel. Fluoride has now been added as a voluntary declaration. It is considered a non-essential nutrient, but FDA has acknowledged the importance of fluoride in preventing dental caries. FDA does not expect people to fortify their products with fluoride: if a manufacturer wanted to add additional fluoride to a food product, they would have to petition the FDA for a food additive regulation. FDA only expects people to label the fluoride that's naturally occurring in products, mostly that from water sources.

Fluoride does not have a daily value, and should be declared as follows: <0.1 mg = 0Declare in 0.1 mg increments up to 0.8 mg Declare in 0.2 mg increments for amounts greater than 0.8 mg

Part 4: The Food Nutrition Label

FDA begins by giving their reasons for the label changes:

- A large proportion of US population is at risk for chronic disease The new label will be easier to understand
- The new label design will increase use of the label
- If more people read the label, Americans will make more informed choices
- Americans will make healthier food and beverage choices

There are nine basic areas of the label where changes have been made:



Daily Value Footnote

125

Serving Size

Serving size will now be changed to reflect what people actually consume, rather than what they are suggested to consume. For example, a can of soup used to be labeled as two servings, but most people eat a whole can. As a result, a can of soup will now be labeled as one serving. This isn't meant to encourage people to eat more; instead, FDA wants people to be aware of the calories that they're actually consuming. Similarly, packages between one and two servings will now be labeled as one serving.

8 servings per container Serving size 2/3 cup (55g)

Total Calories

The total calorie count is now highlighted. The number of calories is written in a much larger font to make it more noticeable to the consumer. The serving size is now written in household measurements to make it resonate more with the consumer and emphasize the calories consumed.



Added Sugars

The "Added Sugars" category has been added to the nutritional label, and is measured in both grams and percentages. FDA hopes that this category will encourage people to cut down on their sugar intake. The DGA has told consumers that it is very difficult to meet nutrient needs while staying within calorie limits if you consume more than 10% of your daily calories from added sugars. Added sugars will be labeled in a quantitative amount (grams) and percent daily value.

This change requires manufacturers to keep additional records. Since there is no way to differentiate analytically between added sugars and naturally occurring sugars, FDA will be relying on manufacturing records to tell the difference. These records will not only have to take into account sugars that were added, but also any ways in which those added sugars might have been reduced: for example, through non-enzymatic browning or fermentation in the product.

> Total Sugars 12g Includes 10g Added Sugars 20%

Multi-Serving Products

If a package can be consumed in single or multiple sittings, there will now be multiple columns on the label to show the percent and quantitative daily values, calories, and macrocomponents for each possible serving size. For example, if a package could be consumed in one or two sittings then it would have two columns on the nutrition facts panel with two different sets of nutritional information.

| Per s | erving | Per cor | ntainer |
|-------|--|--|---|
| _2 | <u>20</u> | _4 | <u>40</u> |
| | % DV* | | % DV* |
| 5g | 6% | 10g | 13% |
| 2g | 10% | 4g | 20% |
| 0g | | Og | |
| 15mg | 5% | 30mg | 10% |
| 240mg | 10% | 480mg | 21% |
| 35g | 13% | 70g | 25% |
| 6g | 21% | 12g | 43% |
| 7g | | 14g | |
| 4g | 8% | 8g | 16% |
| 9g | | 18g | |
| 5mcg | 25% | 10mcg | 50% |
| 200mg | 15% | 400mg | 30% |
| 1mg | 6% | 2mg | 10% |
| 470mg | 10% | 940mg | 20% |
| | Per s 2 5g 2g 0g 15mg 240mg 35g 6g 7g 4g 9g 5mcg 200mg 1mg 470mg | Per serving 220 % DV* 5g 6% 2g 10% 0g 15mg 5% 240mg 10% 35g 13% 6g 21% 7g 4g 8% 9g 5mcg 25% 200mg 15% 1mg 6% 470mg 10% | Per serving Per cor 2200 4 % DV* 5g 5g 6% 2g 10% 2g 10% 0g 0g 15mg 5% 30mg 240mg 240mg 10% 35g 13% 7g 14g 4g 8% 9g 18g 5mcg 25% 200mg 15% 400mg 10mcg 200mg 15% 470mg 10% |

Notes on New Manufacturing Records

The industry will have to keep additional manufacturing records for any nutrient that requires distinguishing between multiple sources where the sources cannot be verified through analytical testing. This will include dietary fibers (soluble and insoluble), sugars (added and inherent), Vitamin E (natural and synthetic), Vitamin A (when using natural and synthetic beta carotene), and folate (folate and folic acid). These records will need to be maintained for two years past the last date of introduction into interstate commerce. The record retention period is a change from the current industry standards as it requires additional focus on the date of shipment as opposed to the date of manufacture and the date of expiration.

Daily Value Footnote

The footnote that defines daily values has been changed to be more streamlined.

Old Footnote: "Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs."

New Footnote: "The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice."

The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Dietary Fiber

The daily value for dietary fiber has increased from 25 g to 28 g. Interestingly, FDA has limited what qualifies as dietary fiber. Only fibers which have been determined by FDA to have physiological effects beneficial to human health may be called dietary fibers. FDA gives a short list of the qualifying fibers: beta glucan, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and HPMC. This list leaves out many of the fibers that manufacturers have traditionally used.

To date, manufacturers have already filed petitions for 26 other fibers. Some of these petitions were made by individual companies for specific fibers, while others were made by groups of companies working together. At this time, there has been no response to any of the petitions.

Manufacturers will also have to keep additional manufacturing records for dietary fibers, since analytically there is no way to distinguish these fibers from the other carbohydrates that have traditionally been called dietary fibers.

| Total Carbohydrate 37g | 13% | |
|---------------------------|-----|--|
| Dietary Fiber 4g | 14% | |
| Total Sugars 12g | | |
| Includes 10g Added Sugars | 20% | |

Calories from Fat

MAGE

FDA has removed the "Calories from Fat" line in response to research which shows that the type of fat is more important than the amount of fat consumed. Space had to be made for some of the other label changes. This could give conflicting messages to consumers: the DGA says that consumers should get less than 10% of their calories per day from saturated fats, but those calories will not be indicated on the label.

Nutrients Less Than 2% DV

Any vitamin or mineral present at 2% or less of the daily value is not required to be declared on the label. However, a manufacturer may choose to declare such a vitamin or mineral using a zero or an asterisk. The asterisk must refer to one of the following statements, located below the table of nutrient values:

"Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)."

"Contains <2 percent of the Daily Value of this (these) nutrient (nutrients)."

Vitamin D, calcium, iron, and potassium are usually required on the nutrition facts label. However, if any of them are present in amounts less than 2% of the daily value, then one may choose instead to write below the table of nutrient values:

"Not a significant source of _____ (listing the vitamins or minerals omitted)."

Part 5: The Supplement Facts Panel

Calories

Manufacturers can choose whether to declare calories on the label, depending on whether or not they believe calories to be a significant contributor. FDA has said that since supplements aren't typically a significant contributor of calories, it is acceptable to either list or not list calories. FDA originally stated that total calories should be listed in the new larger font on both the food and supplement panels, but this was an error. FDA has said that it will correct this in a future amendment. The larger font is only to be used on the nutrition facts panel.

Dietary Ingredients to be Declared

The dietary ingredients that are required to be declared on the supplement panel are the same ones required on the nutrition facts panel for foods. Dietary ingredients can be declared as zero on the supplement panel if they are present in amounts less than 2.0% of the daily value. FDA has also stated that proteins cannot be declared for individual amino acids.

Dietary Ingredients to Declare: • Total Calories

- Total Fat
- Trans Fat
- Cholesterol
- Sodium
- Total Carbohydrate
- Dietary Fiber
- Total Sugar
- Added Sugar
- Protein
- Vitamin D
- Calcium
- Iron
- Potassium

Order of Vitamins and Minerals on Label

The order of vitamins and minerals on the label has changed. FDA has added choline after pantothenic acid, and it has added the voluntary nutrient fluoride near the end of the list. (See the Table of Daily Value Changes for the full order.)

Ingredient Listing

Quantitative amounts must now be listed on the supplement facts panel in addition to percent daily value. The supplement facts panel allows manufacturers to label their ingredients inside the panel if they have enough space. If an ingredient is labeled in the panel, then it does not have to be labeled in the list below the panel. Ingredients can be labeled in one location or the other, or both. This will make some nutrients clearer and more understandable for consumers. For example vitamin D2, which has the intimidating name ergocalciferol, can be labeled on the panel.

Other Units of Measure

Daily values are specifically measured in micrograms and milligrams, but there are many ingredients that are not measured in these units. For example, the quantity of bacteria in a probiotic is often measured in CFUs/g. FDA has declined to permit these other units of measure on the supplement facts panel. However, it has also recognized that this is a problem, and that it will need to issue more information at a later date. Therefore, manufacturers may have some leeway while FDA makes decisions on this issue.

Daily Value Footnote

When a manufacturer claims Daily Reference Values (total fat, saturated fat, carbohydrates, dietary fibers, protein, and added sugars) on the supplement facts panel, the daily value footnote must be included on the panel. If no DRV's are claimed, then the daily value footnote is not required. Manufacturers should choose the appropriate footnote depending on who the product is intended for.

For most products: Percent Daily Values are based on a 2,000 calorie diet.

If the product is for children 1 to 3 years of age: Percent Daily Values are based on a 1,000 calorie diet.

Declaring Vitamins and Minerals

Vitamins and minerals should be declared in accordance with the same rules as on the Nutrition Facts label. In supplements, vitamins and minerals with an RDI are not declared when they are present in amounts less than 2% of the daily value. Vitamins and minerals must be declared when they are added to the product for purposes of supplementation, or when a claim is made about them.

Part 6: Other Topics

Potassium in Supplements

In light of the substantial increase to potassium's daily value, FDA has received several questions on its position about gastrointestinal injury and potassium. In 1975, FDA made a statement that if any tablet or capsule containing more than 99 milligrams of potassium is designed to be consumed without being diluted in water to a suitable amount, then that tablet or capsule must bear a warning label for gastrointestinal injury, specifically lesions. In response to the comments FDA maintained that it has "not established any limits on potency or recommended uses for dietary supplements containing potassium salts. ... Under the FD&C act a manufacturer is responsible for ensuring that dietary supplements are safe."

It is possible, therefore, that if a manufacturer could prove the safety of their product, FDA might be persuaded that the warning label is unnecessary. However, this does put the burden of proof on manufacturers. FDA has not said anything specifically about soft gels, which had yet to be invented at the time of the original 1975 statement.

Overages

The regulation implies that testing of products should result in 100% of label claim without allowance for being above that amount. There were several comments asking what this means for overages: manufacturers usually add overages so that at the end of a product's shelf life the product is at 100% of label compliance. FDA's guidance for testing makes it difficult for manufacturers to add these overages. FDA did comment that this warrants further consideration, but have given no ruling on the matter at this time.

Limits to the Regulation

Many comments referenced other regulations including approved health and structure/function claims. FDA responded that anything outside of the nutritional panel is completely outside the scope of this regulation. This ruling touches many other regulations which will need to be updated in the future.

Synthetic and Natural Nutrients

FDA indicated that a product would be misbranded if its labeling implied that a natural vitamin was superior to an added or synthetic vitamin.

Part 7: Conclusion

We are all facing a year of change. The decision to change what is added to a product or to make significant label changes is not a simple one: in either case, consumers may react unpredictably. If we change our inputs to maintain label claims, the product may change significantly. It isn't easy to add an additional thirty percent calcium to a product to maintain a 25% daily value claim. If we choose not to alter our products and instead alter the label, consumers may be surprised: for example, a product that currently contains 20% DV of biotin would 200% DV on a new label. We must consider consumer reactions as we make our adjustments.

For most companies, product packaged on or after July 26, 2018 needs to comply with the new label regulations. For companies which did less than 10 million dollars in total sales in one of the last three years, the date is extended to July 26, 2019.

We hope that this guide, and Watson, can be a resource to you in the label-changing process. In addition to this guide, Watson has released a lecture video on this subject, and will be releasing further information as it becomes available from FDA.

This guide was created by



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We believe in giving back. Every year we work together to grow fresh food in our employee garden. Employees take some of what they grow back to their families, and donate the rest to the local food pantry.



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One hundred percent of our electrical energy comes from wind power. We recycle cardboard, mixed paper, plastic, electronic waste, batteries, and copier toner cartidges.





Watson hopes that this guide can be a resource to companies as we all work to change our labels and recipes.

