

2021

FDA Guidelines & Food Product Labeling: What to Know As of Early 2021

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Those who follow printing industry trends may know that:

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2. Shortly thereafter, these updates were put on indefinite hold.
3. Under the new executive branch administration in 2021, the updated regulations have been put back into effect.

So, for anyone planning a new label project or an upgrade in order to comply with the latest regulations, here is what we believe you should know for your business.

FDA Nutritional Label Revisions: A Timeline

In May of 2016, the FDA debuted a new label format for packaged foods and beverages — the first such revision in 20 years.¹ The changes took into account the findings of new nutritional research as well as public input gathered during hearings. The updated labels reflected a greater understanding of the impact of diet on obesity and disease, with a renewed format to make them easier to read and understand, in hopes of promoting a lifetime's worth of healthy eating habits. The new requirements were first intended to go into effect by July 26, 2018, for manufacturers earning over \$10 million annually, and July 26, 2019, for those earning less.²

However, in light of continued concerns brought to them by companies and the trade associations about the time needed to implement the required changes, the FDA chose to compromise.

FDA Attempts to Minimize Economic Impacts of New Regulations on the Food and Beverage Industries

On Sept. 29, 2017, the FDA formally extended the time needed to comply. For the Nutrition Facts and Supplement Facts label final rule, and the Serving Size final rule, the compliance dates were pushed to January 1, 2020, for companies earning \$10 million or more annually, and January 1, 2021, for those earning less.³

Certain food manufacturers — those selling most single-ingredient sugars, such as honey and maple syrup, as well as certain cranberry products — have been given even more latitude. Under the direction of a new presidential administration, these manufacturers still have until July 1, 2021, to make these changes. And while all of the compliance dates are still in place, the FDA is working cooperatively with manufacturers to meet the new Nutrition Facts label requirements.⁴

Additionally, while the FDA expects companies to make reasonable efforts to comply as quickly as possible with new labeling regulations, it attempts to minimize the economic impacts on companies of having to respond separately to each labeling change. So the FDA periodically announces uniform compliance dates for new nutrition labeling requirements. Recently, the FDA announced January 1, 2024, as the uniform compliance date for any regulations issued in 2021 and 2022. However, this action does not change the existing requirements for compliance dates in any of the final rules published before January 1, 2021.⁵

For some food labeling regulations, if special circumstances warrant it, the FDA will set a different date for regulatory compliance. The FDA then will publish a specific compliance date whenever a final regulation is issued.



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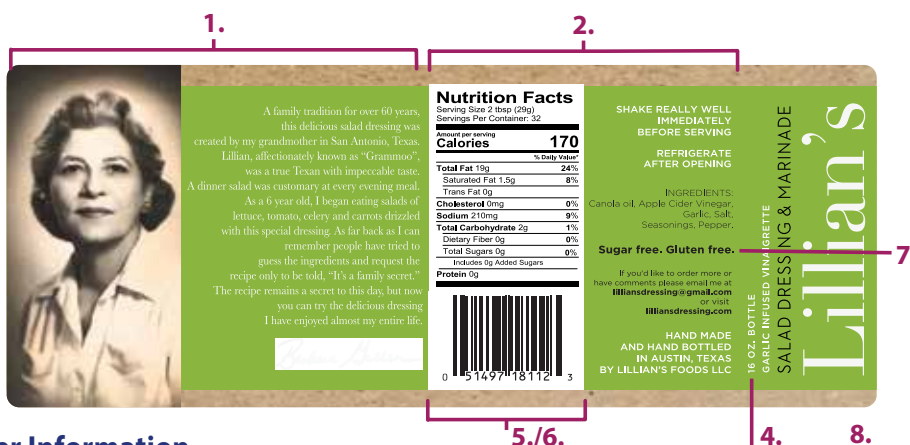
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The Most Important FDA Guidelines Changes

- 1. Principle Display Panel (PDP)** - the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale - must contain the Product Identity and the Net Weight Statement.
- 2. Nutritional Facts, Ingredients, Allergen Statements and Manufacturer Information** must be kept on the right side of the label. The Barcode placement, however, is flexible for either side of the label.
- 3. Preferred Type Size** is 1/16" or more for the lowercase "o" in any word. Some packaging will obviously need smaller type. Typeface Preferences, on the other hand, are flexible. The FDA uses Helvetica typeface for its example label, but does not require any specific typefaces for the Nutrition Facts label. However, it would require that a food label present its information in a single, easy-to-read type style. In addition, in the United States, certain information must be listed in the English language, per the direction of the FDA and the USDA.



Sample shown above is an all-in-one label. Another option is to do a multi-color front label and then a one-color back label for barcode, ingredients, etc.

- 4. Net Wt. and Net Contents:** The Net Weight must be in the bottom 30% of the PDP. The height of the panel, multiplied by 0.30", will need to be equal to the bottom 30% in inches. The Net Contents should be expressed in both metric terms (grams, kilograms, milliliters, and liters) as well as in the U.S. Customary System (ounces, pounds, fluid ounces) terms, as shown in the above label. Minimum point size for the statement should be no less than 1/16" high, when measuring the lowercase "o". A large package (over 400 square inches) would be required to have 1/2" type for the Net Weight statement. For more info on the height of type, refer to the www.FDA.gov website.
- 5. Nutritional Panel** can be either vertical or horizontal. It must show the total calorie count in enlarged bold type, and on a separate line, list any added sugars. In addition, the actual amounts of certain nutrients, including Vitamin D, Potassium, Sodium, and Fiber, must be declared, to reflect the latest nutritional guidelines, which would change the percent daily values for many different foods as well.

6. Nutrition Facts: These specific alterations would be at least in part a response to the perception that consumers both want and need better, clearer guidelines for shopping and food choices. The most significant of these modifications include such elements as:

a. How serving sizes are presented. The FDA wants to change how serving sizes are shown, realistically to reflect how buyers consume their food and beverages. The goal is to label any packaged foods and drinks normally eaten at a sitting as a single serving. The number of calories and the nutritional information would be given for the entire package or bottle. So, for example, both an 8-ounce and a 12-ounce package of chips would be designated as a single serving, even though they are of different sizes. In addition, the serving size is now shown in a larger, bolder font, and some serving sizes have been updated.⁶

b. How calorie counts are presented. The total count of calories would now need to stand out with a greatly enlarged type size and bolder font, to meet the FDA's concern about the growing incidence of obesity in the United States. The labels for any package large enough to be consumed in more than one sitting would need to show two side by side columns, with nutrient and calorie information both "per serving" and "per package", to show consumers the real calorie counts and nutrients if the entire amount of product is eaten at one time, which people tend to do.⁷

Nutrition Facts		Amount/Serving	% DV*	Amount/Serving	% DV*
Servings Per Container About 5.5		Total Fat 8g	12%	Total Carb. 14g	0%
Serving Size 1/2 cup (125g)		Sat. Fat 1g	13%	Dietary Fiber 2g	8%
Calories 140		Cholest. 0mg	4%	Total Sugars 9g	
		Includes 0g Added Sugars 0%			
		Sodium 500mg	21%	Protein 0g	
* 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.					
Vitamin A 2mcg 8% • Vitamin C 1mcg 6% • Calcium 1mg 4% • Iron 6mg 6%					

c. How the amounts of sugar are presented. Sugars such as table sugar or high-fructose corn syrup would need to be shown on a separate line, not simply added into the total sugar count, and be measured both in grams and as a percent daily value, to assist consumers in reducing the amount of processed sugars in their diets.⁸

d. How nutrient information is presented. The new 2015-2020 Dietary Guidelines for Americans, as well as the newest Institute of Medicine nutritional recommendations, have been taken into consideration in creating these new label requirements.⁹

Nutrition Facts			
2 servings per container			
Serving size		1 cup (255g)	
Calories	Per serving	Per container	
	220	440	
	% DV*	% DV*	
Total Fat	5g 6%	10g 13%	
Saturated Fat	2g 10%	4g 20%	
Trans Fat	0g	0g	
Cholesterol	15mg 5%	30mg 10%	
Sodium	240mg 10%	480mg 21%	
Total Carb.	35g 13%	70g 25%	
Dietary Fiber	6g 21%	12g 43%	
Total Sugars	7g	14g	
Incl. Added Sugars	4g 8%	8g 16%	
Protein	9g	18g	
Vitamin D	5mcg 25%	10mcg 50%	
Calcium	200mg 15%	400mg 30%	
Iron	1mg 6%	2mg 10%	
Potassium	470mg 10%	940mg 20%	
* 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.			

According to these new Dietary Guidelines, the percent daily values for nutrients including Sodium, Dietary Fiber, Potassium and Vitamin D would have to change. For example, the percent daily maximum value of Sodium would be reduced from 2,400 to 2,300 mg, which would affect the percent daily value for a food or beverage serving containing Sodium. Another example: the current recommendation for Fiber would be raised from 25 to 28 grams per day, which also impacts the percent daily value for this nutrient. Potassium and Vitamin D would need to be shown in grams as well as a percent daily value, to address the concern that people are not consuming enough of these nutrients. By the same token, the FDA has decided that due to supplementation, Vitamin C and A deficiencies are now so uncommon that it is no longer necessary to list their presence.

"Calories from Fat" would also be eliminated; the FDA has decided that the type of fat in a food is more important than the amount. Other fat categories, however, including "Total Fat," to include "Saturated Fat" and "Trans Fat," would need to remain. Product labels showing less than 0.5 fat grams would need to round up the amount to 0.5. In addition, the percent daily value, based on a 2000 calorie diet, would still need to appear, but in a more simplified format.

7. Qualified Health Claims, e.g., Low Fat, Low Cholesterol, Gluten Free or Genetically Modified Organism, would now be qualified only through a set of strict FDA guidelines. SixB Labels could offer assistance with the format, but not the content, of such claims.¹⁰

8. Exceptions: These proposed alterations were intended to cover all packaged food and beverage products, with the exception of the products regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service. These include certain meat, poultry and processed egg products, raw fruits, vegetables and fish; and such foods as coffee beans, tea leaves, spices, flavor extracts and food colors, which would not be affected by these new label requirements.¹¹



Under the Regulatory Flexibility Act, the FDA is required to analyze various regulatory options to help minimize any significant impact of regulations on small entities. This analysis has led to the conclusion that the additional costs of compliance to new FDA nutritional labeling guidelines would be far from minimal—the proposed rules would have a significant impact, especially on small businesses.

The new regulations could potentially increase costs or present potential business losses in multiple areas:

- 1. New record keeping requirements:** Under certain circumstances, food and beverage manufacturers would be required to make and keep records that would verify label declarations for amounts of added Sugars, Fibers (including dietary, soluble, and insoluble,) Vitamin E, and Folate/Folic acid. These records would need to be provided upon request of the FDA, during inspection, for official review and photocopying or other types of reproduction.
- 2. Product reformulations,** both to come into compliance with new regulations and to reformulate those products made to appear less attractive to consumers under the provisions of the new rules.
- 3. Label changes,** to include:
 - a. Minor label changes** (a one-color printing plate change, not a full label redesign) could include net quantity statement, minimal changes to an ingredient list, or the addition of a toll-free number.
 - b. Major label changes,** which could be anything from a product name change, to the addition of a Nutrition or Supplement Facts panel, to substantially changing or even entirely eliminating a health claim.

**For any further questions on the above information or general inquiries about the proposed FDA Nutrition Label changes, refer to the www.fda.gov/Food/GuidanceRegulation website.¹²*

SixB Labels excels in producing effective FDA Labels, so let us put our resources to work for you. If you are planning to change your current FDA Labels or create new ones, call us for a consultation!

- ✓ [Complimentary Phone Consultation + Project Quote](#)
- ✓ [Various Labels, Printers and Software Bundling Options](#)
- ✓ [Comparable Product Label Samples](#)

Appendix

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*SixB Labels Corporation provides this quick reference for our clients and is not responsible for any errors. Please direct all questions to www.FDA.gov

