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Menu Labeling: Supplemental Guidance for Industry

Draft Guidance

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Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [insert docket number] listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

November 2017

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Menu Labeling: Supplemental Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

1. Introduction

This guidance document addresses concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in covered establishments,² including expanded and new interpretations of policy. It also clarifies that there are additional options for complying with the labeling requirements and identifies places where FDA intends to be more flexible in its approach. The guidance reflects input from stakeholders, including the public and industry, in response to an interim final rule (IFR) (82 FR 20825, May 4, 2017). The IFR also extended the compliance date for menu labeling, and invited comments to the docket.

In addition, given extensive further analysis by the FDA, we are withdrawing Questions and Answers 5.17 and 5.18 in our previous guidance entitled “A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance With FDA’s Food Labeling Regulations) effective November 7, 2017. We address the issue of distinguishing between menus and other information presented to the consumer in this draft guidance, and once finalized, this will represent our current thinking on this topic. This guidance also includes many graphical depictions in order to convey our thinking on various topics. The draft guidance covers several topic areas outlined in the IFR, including: calorie disclosure signage for self-service food, including buffets and grab-and-go food; various methods for providing calorie disclosure information, including those for pizza; criteria for distinguishing between menus and marketing material; compliance and enforcement;

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² 21 CFR 101.11(a) defines “covered establishment” as a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that voluntarily registers with FDA to be covered by the federal menu labeling requirements.

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reasonable basis, including the criteria for considering the natural variation of foods; criteria for covered establishments; and standard menu items.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

2. Background

On December 1, 2014, FDA (we) published a final rule in the Federal Register (79 FR 71156) on nutrition labeling of standard menu items in restaurants and similar retail food establishments to implement the menu labeling provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The menu labeling requirements are codified at Title 21 of the Code of Federal Regulations, section 101.11 (21 CFR 101.11). Before these requirements, consumers could find nutrition information on most packaged foods; however, this labeling was not generally available in restaurants and similar retail food establishments that serve ready-to-eat, prepared food. Providing calorie and other nutrition information for ready-to-eat prepared foods in restaurants and similar retail food establishments will enable consumers to make informed and healthy dietary choices.

The original compliance date for the menu labeling provisions was December 1, 2015. On July 10, 2015, we extended the compliance date to December 1, 2016 (80 FR 39675). On December 18, 2015, the Consolidated Appropriations Act (Pub. L. 114-113) was adopted. It contained a provision stating that none of the funds made available under the Consolidated Appropriations Act could be used to implement, administer, or enforce the menu labeling final rule until one year after FDA issued a final guidance document regarding the rule. We issued the final guidance document on May 5, 2016. In accordance with Congress's direction, we subsequently set the compliance date for the rule as May 5, 2017, one year from the date of the publication of the guidance (81 FR 96364). On May 4, 2017, we published an IFR (82 FR 20825) in the Federal Register extending the compliance date to May 7, 2018, in response to the diverse and complex set of stakeholders affected by the rule and questions they raised regarding the final rule and its implementation (Refs. 1, 2, 3, and 4). The IFR provided additional time to support industry innovation and to ensure consistency across establishments when delivering nutrition information to consumers. Our goals are to ensure that consumers are provided with consistent nutrition information they can use to make informed choices for themselves and their families, and to guide industry to clearly understand the flexible manner in which the requirements can be implemented. We intend to consider comments and finalize this guidance to provide clarity to the industry on these remaining questions ahead of the new compliance date of May 7, 2018.

3. Calorie Disclosure Signage for Self-Service Foods, Including Buffet Foods

3.1. We are a covered establishment that has a self-service buffet. Are we required to have individual signs (e.g., food tags) next to each buffet item with the calorie declaration?

Answer: No. You are not required to have individual signs next to each buffet item. While the menu labeling final rule requires calorie information for each buffet item that is a standard menu item, the menu labeling final rule is flexible, and allows the calories for self-service foods and foods on display to be declared in a variety of ways, as long as the consumer can view the name, calorie declaration, and serving or unit of a particular menu item while selecting that item. You could place a sign next to each item or on the sneeze guard over the item with the calorie declarations (21 CFR 101.11(b)(2)(iii)(A)). However, you could also comply with the requirements by using a sign or placard listing the calorie declaration for multiple food items, along with the names of those food items. Illustrations in Figures 1, 2, 3, 4, and 5 show examples of how this requirement could be implemented, including illustrating some examples that are currently in use by covered establishments.

3.2. What are the options for declaring calories for standard menu items on a self-service buffet?

Answer: You may place the calorie information on a sign adjacent to, and clearly associated with, the food for which the calories are provided, or on a sign attached to a sneeze guard (e.g., a gel cling or hanging placard attached to the glass), or on a single sign or placard listing the calorie declaration for multiple food items along with the names of the food items as long as the sign or placard is located where a consumer can view the name, calorie declaration, and serving or unit of a particular menu item while the consumer is selecting that item (21 CFR 101.11(b)(2)(iii)(A)). The illustration(s) in Figures 1, 2, 3, 4 and 5 show examples of how this requirement could be implemented.


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Figure 1: Example of declaring calories for multiple items on a self-service salad bar on a single sign attached to the sneeze guard.



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Figure 2: Close-up of a single sign attached to the sneeze guard used for declaring calories for multiple items on a self-service salad bar.



Salad Bar Item	Serving	Calories	Salad Bar Item	Serving	Calories
Baby spinach	1 cup	30	Mushrooms	2oz	15
Beets	½ cup	40	Peaches	½ cup	35
Black olives	2oz	35	Pineapple	½ cup	40
Boiled eggs	1 egg	80	Potato salad	1 scoop	180
Carrots	2oz	15	Radishes	2oz	10
Celery	2oz	10	Red onions	2oz	25
Chopped ham	2oz	100	Romaine Lettuce	1 cup	20
Chow mein noodles	½ cup	130	Season Lettuce Mix	1 cup	20
Cottage cheese	½ cup	110	Shredded Cheddar	¼ cup	110
Croutons	½ cup	140	Strawberries	½ cup	25
Cucumbers	2 oz	5	Vanilla pudding	½ cup	140
Feta Cheese	¼ cup	100	Watermelon	½ cup	25
Garbanzo beans	2 oz	40	Salad Dressings	Serving	Calories
Grapes	5 grapes	20	Lite Italian	2Tbl	40
Grilled Chicken	2oz	90	Italian	2Tbl	70
Green Peppers	2oz	5	French dressing	2Tbl	150
Iceburg Lettuce	1 cup	10	Greek Dressing	2Tbl	100
Low fat vanilla yogurt	½ cup	100	Lite Ranch dressing	2Tbl	50
Macaroni salad	1 scoop	180	Ranch dressing	2Tbl	130

2,000 calories a day is used for general nutrition advice, but calorie needs vary
Additional nutrition information available upon request

Figure 3: Example of declaring calories for self-service foods on individual signs that are interchangeable and are attached to the sneeze guard by permanent placard holders.



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Figure 4: Example of declaring calories for multiple items at a self-service buffet on a single sign hanging below the sneeze guard.



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Figure 5: Example of declaring calories for self-service foods on individual signs using gel clings on the sneeze guard. Gel clings can be moved or removed as standard menu items change in the buffet.



3.3. We have several locations in our establishment where self-service food is offered. Are we required to post menus/menu boards at each self-service location?

Answer: No, menus and menu boards are not required at each self-service location. The menu labeling final rule requires that calories be declared for self-service food or food on display (21 CFR 101.11(b)(2)(iii)), but the rule does not require a covered establishment to create a new menu or menu board. The menu labeling final rule is flexible in the options that can be used to declare the calories.

For example, you may display the calories using individual placards or gel clings on the sneeze guard of a buffet or use one single sign on the buffet to list multiple items as discussed in Q&As 3.1 and 3.2. See Figures 6, 7, 8, and 9 for examples. If an establishment chooses to use a single sign option at each self-service location throughout a store or restaurant, that single sign could list only the calorie declarations for each standard menu item offered only at that particular self-service location in the store or restaurant, and would not be required to list calorie declarations for all standard menu items, because those declarations could be listed elsewhere in close proximity to selection of those standard menu items.

Additionally, if a packaged food, such as a sandwich prepared on site by the covered establishment bears a front-of-pack (FOP) calorie declaration (e.g., a sticker that reads “350 cal”) then the FOP labeling would meet the calorie declaration requirements in the menu labeling final rule and additional signage disclosing calorie information would not be required. See Figures 10 and 11. Additionally, if a packaged food bears a Nutrition Facts label or if an establishment voluntarily chooses to use a Nutrition Facts label that includes the nutrition information required by 21 CFR 101.11(b)(2)(i)(A), the Nutrition Facts label would meet the menu labeling requirements for calorie declaration, provided that the food, including its label, can be examined by a consumer before purchasing the food (21 CFR 101.11(b)(2)(iii)(C)).

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Figure 6: Example of declaring calories for multiple self-service items on a single sign.

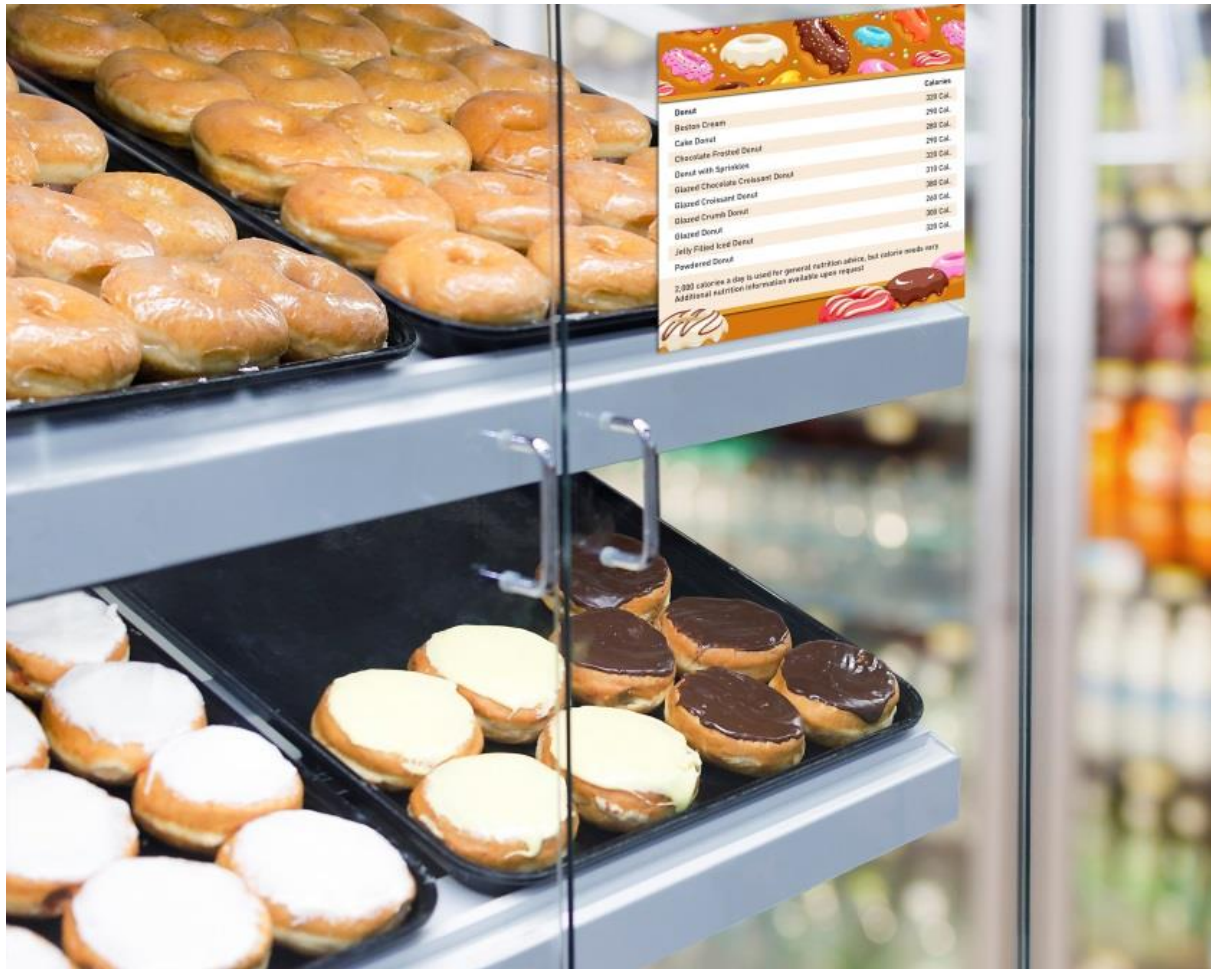


Figure 7: Close-up example of a single sign declaring calories for multiple self-service items.



Donut	Calories
Boston Cream	320 Cal.
Cake Donut	290 Cal.
Chocolate Frosted Donut	280 Cal.
Donut with Sprinkles	290 Cal.
Glazed Chocolate Croissant Donut	320 Cal.
Glazed Croissant Donut	310 Cal.
Glazed Crumb Donut	380 Cal.
Glazed Donut	260 Cal.
Jelly Filled Iced Donut	300 Cal.
Powdered Donut	320 Cal.

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Figure 8: Example of declaring calories at a self-service beverage station.



Figure 9: Close-up of a sign declaring calories for a self-service beverage station.

	Small 12 fl oz Calories	Medium 20 fl oz Calories	Large 36 fl oz Calories
Cola	140	240	420
Diet Cola with Lime	0	0	0
Cherry Cola	150	260	450
Orange	160	270	480

2,000 calories a day is used for general nutrition advice, but calorie needs vary.
Additional nutrition information available upon request.

Figure 10: Example of a grab-and-go food that meets the calorie declaration requirements using a front of pack calorie declaration (e.g., a sticker) that can be viewed by the consumer before purchase.



Figure 11: Example of a grab-and-go food that meets the calorie declaration requirements using a front-of-pack calorie declaration (e.g., a sticker) that can be viewed by the consumer before purchase.



3.4. Are the succinct statement providing context about calories in a daily diet and statement regarding the availability of additional written nutrition information required on every sign for self-service food?

Answer: No. For self-service foods and foods on display, these statements may be on an individual sign adjacent to the food itself; on a separate, larger sign in close proximity to the food that the customer can easily read as he or she is making his or her order selections; or on a large menu board that the consumer can easily read as he or she is ordering their food (21 CFR 101.11(b)(2)(iii)(B)).

4. Criteria for Distinguishing Between Menus and Marketing Materials

4.1. Is marketing material (e.g., coupons, posters in store windows, or signs on gas pumps) required to bear calorie information?³

Answer: Marketing material (e.g., pizza coupons, posters in store windows, signs on gas pumps, or paper inserts) generally would not be considered a menu or menu board and would not require calorie declarations. The applicability of the rule to marketing materials is intended to be flexible and not prescriptive. Written material of an establishment that does not satisfy the criteria of a primary writing from which a customer makes an order selection, such as a poster on a storefront, a coupon, or other promotional material, banners, billboards, and stanchions, would be considered a “secondary writing” of an establishment. If the primary purpose of these materials is to “entice” customers into the covered establishment, then we would not consider them to be a primary writing, and they would not require calorie declarations. See Figures 12 and 13 for examples of marketing materials that would not require calorie labeling.

Figure 12: Example of a poster or banner in a window or on a gas pump that would not require a calorie declaration.



³ This question, once finalized, will supersede Questions and Answers 5.17 and 5.18 in the April 2016 Guidance; accordingly, we are withdrawing these two questions from the April 2016 Guidance.

Figure 13: Example of a marketing board that would not require calorie declarations.



5. Methods for Providing Calorie Disclosure Information

5.1. I am concerned that adding the calories of each standard menu item adjacent to the name of the item will increase clutter on my menu board, or that I will have to reduce the type size to make all of the information fit, making the menu board more difficult for customers to read. How can I meet the requirements without reducing the readability of my menu board?

Answer: We understand that there is variability in the way menus are designed, and the rule provides flexibility to address this variability. We have provided covered establishments with the ability to list calorie declarations adjacent to either the name or the price of the associated standard menu item with the intention of providing greater flexibility to incorporate the calorie declarations within existing menu designs (21 CFR 101.11(b)(2)(i)(A)(I)). In considering what would be “adjacent and clearly associated” with the menu item, we expect that the name or price and the calorie declaration would be displayed such that the consumer can easily determine which calories are posted for each standard menu item. See Figures 14 and 15 for examples of menu boards that meet the requirements for listing calorie declarations adjacent and clearly associated with the menu item.

5.2. I am a quick-service/takeout establishment, and I don't have menu boards in my establishment. Do I have to create menu boards – in addition to my paper menus or online menus?

Answer: No. The menu labeling regulation does not mandate that establishments have menu boards; however, if establishments have menu boards, they must be labeled so consumers have access to the required nutrition information (21 CFR 101.11(b)(2)(i)(A)). However, in lieu of having a menu board, you may use other alternatives such as electronic devices for customers to place their order (e.g., an in-store tablet or electronic kiosk). Establishments may also use other options such as hand-held paper menus or laminated menus on the counter for ordering. Thus, there are both innovative and simple solutions that may be used to disclose the calorie and other nutrition information in lieu of having a menu board.

5.3. On my menu I have standard menu items that can be combined for a special price. If the calorie declarations for those standard menu items are declared elsewhere on the menu, do I have to include the calorie declarations for the combinations?

Answer: No. Where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (e.g., “Combine any soup with a sandwich for \$8.99”), you do not need to also declare the calories for the combinations, provided that the calories for each standard menu item, including calories for each relevant size option that may be combined are declared elsewhere on the menu or menu board (21 CFR 101.11(b)(2)(i)(A)(6)(iv)). See Figures 14 and 15 for examples.




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Figure 14: Example of a menu or menu board that describes an opportunity for the consumer to combine standard menu items for a special price (and the calories for each standard menu item that may be combined are declared elsewhere on the menu or menu board).

Sandwiches or Wrap			Chocolate Milkshakes		
	¼ lb Patty with Cheese	\$3.49 560 Cal.		Small	\$0.99 350 Cal.
	½ lb Patty with Cheese	\$4.29 820 Cal.		Medium	\$2.19 470 Cal.
	¾ lb Patty with Cheese	\$5.59 1070 Cal.		Large	\$2.49 590 Cal.
	½ lb Patty with Bacon	\$5.39 930 Cal.			
	Mini-Bacon Cheeseburger	\$1.39 370 Cal.			
	Chicken Wrap	\$1.69 260 Cal.			
Salads			Fries		
	Hummus & Chicken Salad	Full Size \$5.89 470 Cal. ½ Size \$3.89 240 Cal.		Small	\$1.59 310 Cal.
	Bacon & Chicken Salad	Full Size \$5.89 580 Cal. ½ Size \$3.89 300 Cal.		Medium	\$1.99 410 Cal.
	Chicken Caesar	Full Size \$5.89 710 Cal. ½ Size \$3.89 400 Cal.		Large	\$2.39 520 Cal.
			Chili		
				Small	\$0.99 160 Cal.
				Large	\$1.99 260 Cal.
			Sides		
				Sour Cream & Chive Baked Potato	\$0.99 300 Cal.
				Bacon & Cheddar Baked Potato	\$2.49 470 Cal.
Or Pair Two					
	Choose any ½ Size salad and ADD 1 of these options				\$5.59
	Chicken Wrap	Small Milkshake			
	Mini-Bacon cheese burger	Small Chili			
	Small Fries	Sour Cream & Chive Baked Potato			
	2,000 calories a day is used for general nutrition advice, but calorie needs vary. Additional nutrition information available upon request.				

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Figure 15: Example of a menu or menu board that describes an opportunity for the consumer to combine standard menu items for a special price (and the calories for each standard menu item that may be combined are declared elsewhere on the menu or menu board).

SANDWICH			Whole Serving	Pick 2
	Turkey Breast	\$5.89	560 Cal.	280 Cal.
	Tuna Salad	\$5.89	660 Cal.	330 Cal.
	Ham and Swiss	\$5.89	730 Cal.	370 Cal.
	Chicken Salad	\$6.89	700 Cal.	350 Cal.
SOUP		Bread Bowl	Bowl	Cup
	Broccoli Cheddar	\$5.39	\$4.39	\$3.69
	Chicken Noodle	900 Cal.	360 Cal.	230 Cal.
	New England Clam Chowder	780 Cal.	160 Cal.	110 Cal.
	Chicken and Rice	1040 Cal.	570 Cal.	370 Cal.
	Chicken and Rice	840 Cal.	260 Cal.	180 Cal.
SALAD				
	Caesar	\$5.49	320 Cal.	160 Cal.
	Greek	\$5.89	400 Cal.	200 Cal.
	Apple and Chicken	\$7.29	570 Cal.	280 Cal.
	Southwest with Chicken	\$7.49	650 Cal.	320 Cal.
Pick 2	½ Sandwich • ½ Salad • Cup of Soup			\$6.79
2,000 calories a day is used for general nutrition advice, but calorie needs vary. Additional nutrition information available upon request.				

5.4. I am a covered pizza parlor that uses both online menus and menu boards in our establishment. Do I have to provide calorie declarations on our menu boards within the establishment if we declare calories on our online menu?

Answer: Yes, even though you declare calories on your online menu, if you choose to use a menu board in your covered establishment you must provide calorie declarations for standard menu items listed on your menu board (section 403(q)(5)(H)(i) of the FD&C Act). This includes online menus if consumers can order online (21 CFR 101.11(b)(2)(i)(A)). However, in lieu of having a menu board, you may use other alternatives such as electronic devices for customers to place their order (e.g., an in-store tablet or electronic kiosk). Establishments may also use other options such as hand-held paper menus or laminated menus on the counter for ordering. Thus, there are both innovative and simple solutions that may be used to disclose the calorie and other nutrition information in lieu of having a menu board. We also note that establishments that do not have menu boards are not required to create menu boards. Furthermore, marketing boards or marketing materials can be used and would not require calorie declarations. See Figures 12 and 13.

5.5. I am a covered pizza parlor that sells build-your-own pizzas with a variety of options for crusts, sauces and toppings listed (i.e., the customer chooses from 4 crust options, 4 sauce options, and many topping options). How should I declare calories for each option of my build-your-own pizzas on my menu or menu board?

Answer: In the menu labeling final rule we provided options and examples for declaring calories for pizzas and pizza toppings listed on a menu or menu board. In the examples provided, we took the approach that there was a “basic preparation” of the pizza pie with a set amount of calories. In accordance with menu labeling requirements, calories for toppings listed on a menu board must be declared (21 CFR 101.11(b)(2)(i)(A)(5)). In the build-your-own pizzas scenario described in the question above, there does not appear to be a ‘basic preparation’ of the pizza pie prior to adding the toppings. Therefore, the calories for crust and sauce options may be declared in the same manner as the toppings in this scenario. A covered establishment may use a range for each crust or sauce option to represent the added calories across various sizes of the pizza. In addition, crust and sauce options that have the same number of calories after rounding may be grouped together (21 CFR 101.11(b)(2)(i)(A)(5)(ii)). This approach accommodates flexibility, while still providing the required calorie information for consumers to make informed dietary choices. See Figures 16, 17, and 18 for examples.

5.6. I am a covered pizza parlor that sells build-your-own pizzas. How should I declare calories for each option of my build-your-own pizzas if multiple sizes are offered and I want to provide calorie declarations per slice?

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Answer: The calories may be declared in multiple ways. The menu labeling final rule provides the flexibility to declare calories for the entire pizza or per slice, provided the number of slices per pie is included on the menu or menu board in a manner that clearly associates the calories per slice and the number of slices for each size of pie offered by the establishment (21 CFR 101.11(b)(2)(i)(A)).

Calories may be declared for each topping for each size of the pizza. However, they may also be declared using a slash between the two calorie declarations for each topping where only two sizes of the pizza are available (e.g., “adds 150/250 cal”) or as a range for each topping where more than two sizes of the pizza are available (e.g., “adds 100-250 cal”). Toppings that have the same number of calories after rounding may also be grouped together (21 CFR 101.11(b)(2)(i)(A)(5)(ii)). These options can provide greater flexibility for creating readable menus/menu boards. See Figures 16 – 22 for examples.

Figure 16: Example of declaring calories per slice for a build-your-own pizza using a column format.

CREATE YOUR OWN PIZZA CALORIES ARE LISTED PER SLICE

CHOOSE YOUR SIZE & CRUST		6 SLICES S \$9.99	8 SLICES M \$11.99	10 SLICES L \$13.99	12 SLICES XL \$15.99																																		
 <p style="font-size: small;">THIN & CRISPY</p>	 <p style="font-size: small;">ORIGINAL</p>	<p>CHEESE PIZZA</p> <table style="width: 100%; font-size: small;"> <tr><td>ORIGINAL</td><td>200-240 Cal.</td></tr> <tr><td>THIN & CRISPY</td><td>150-190 Cal.</td></tr> <tr><td>PAN</td><td>260-300 Cal.</td></tr> <tr><td>GLUTEN FREE - SMALL ONLY</td><td>140 Cal.</td></tr> </table>				ORIGINAL	200-240 Cal.	THIN & CRISPY	150-190 Cal.	PAN	260-300 Cal.	GLUTEN FREE - SMALL ONLY	140 Cal.																										
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BBQ	10-20 Cal.																																						
CHOOSE YOUR TOPPINGS*		S \$1.00	M \$1.50	L \$2.00	XL \$2.25																																		
<p style="font-size: x-small;">2,000 CALORIES A DAY IS USED FOR GENERAL NUTRITION ADVICE, BUT CALORIE NEEDS VARY</p> <p style="font-size: x-small;">ADDITIONAL NUTRITION INFORMATION AVAILABLE UPON REQUEST</p>	<p>MEATS</p> <table style="width: 100%; font-size: small;"> <tr><td>BACON</td><td>45-60 Cal.</td></tr> <tr><td>BEEF</td><td>40-45 Cal.</td></tr> <tr><td>CHICKEN</td><td>15-20 Cal.</td></tr> <tr><td>HAM</td><td>10-15 Cal.</td></tr> <tr><td>PEPPERONI</td><td>25-35 Cal.</td></tr> <tr><td>SALAMI</td><td>25-30 Cal.</td></tr> <tr><td>SAUSAGE, ITALIAN</td><td>40-50 Cal.</td></tr> </table>	BACON	45-60 Cal.	BEEF	40-45 Cal.	CHICKEN	15-20 Cal.	HAM	10-15 Cal.	PEPPERONI	25-35 Cal.	SALAMI	25-30 Cal.	SAUSAGE, ITALIAN	40-50 Cal.	<p>VEGGIES</p> <table style="width: 100%; font-size: small;"> <tr><td>BANANA PEPPERS</td><td>0-5 Cal.</td></tr> <tr><td>GREEN PEPPERS</td><td>0 Cal.</td></tr> <tr><td>JALAPENOS</td><td>0-5 Cal.</td></tr> <tr><td>FRESH MUSHROOMS</td><td>5 Cal.</td></tr> <tr><td>OLIVES, BLACK</td><td>10-15 Cal.</td></tr> <tr><td>FRESH ONIONS</td><td>0-5 Cal.</td></tr> <tr><td>PINEAPPLE</td><td>10 Cal.</td></tr> <tr><td>RED PEPPERS, ROASTED</td><td>0 Cal.</td></tr> <tr><td>FRESH BABY SPINACH</td><td>0 Cal.</td></tr> <tr><td>TOMATOES</td><td>5 Cal.</td></tr> </table>	BANANA PEPPERS	0-5 Cal.	GREEN PEPPERS	0 Cal.	JALAPENOS	0-5 Cal.	FRESH MUSHROOMS	5 Cal.	OLIVES, BLACK	10-15 Cal.	FRESH ONIONS	0-5 Cal.	PINEAPPLE	10 Cal.	RED PEPPERS, ROASTED	0 Cal.	FRESH BABY SPINACH	0 Cal.	TOMATOES	5 Cal.			
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CHICKEN	15-20 Cal.																																						
HAM	10-15 Cal.																																						
PEPPERONI	25-35 Cal.																																						
SALAMI	25-30 Cal.																																						
SAUSAGE, ITALIAN	40-50 Cal.																																						
BANANA PEPPERS	0-5 Cal.																																						
GREEN PEPPERS	0 Cal.																																						
JALAPENOS	0-5 Cal.																																						
FRESH MUSHROOMS	5 Cal.																																						
OLIVES, BLACK	10-15 Cal.																																						
FRESH ONIONS	0-5 Cal.																																						
PINEAPPLE	10 Cal.																																						
RED PEPPERS, ROASTED	0 Cal.																																						
FRESH BABY SPINACH	0 Cal.																																						
TOMATOES	5 Cal.																																						
*ADDED CALORIES FOR 1 TOPPING PIZZA																																							

Figure 17: Example of declaring calories per slice for a build-your-own pizza using a string format.

CREATE YOUR OWN PIZZA CALORIES ARE LISTED PER SLICE

CHOOSE YOUR SIZE & CRUST

6 SLICES

S \$9.99

8 SLICES

M \$11.99

10 SLICES

L \$13.99

12 SLICES

XL \$15.99



THIN & CRISPY
PAN



ORIGINAL

CHEESE PIZZA
ORIGINAL (200-240 Cal.), THIN & CRISPY (150-190 Cal.),
PAN (260-300 Cal.), GLUTEN FREE† (140 Cal.)
†ONLY AVAILABLE IN SMALL

CHOOSE YOUR SAUCE*



TOMATO SAUCE (10 Cal.), SPICY MARINARA (10 Cal.), WHITE GARLIC SAUCE (30-50 CAL.), BBQ (10-20 Cal.)

CHOOSE YOUR TOPPINGS*

S \$1.00

M \$1.50

L \$2.00

XL \$2.25



MEATS
BACON (45-60 Cal.), BEEF (40-45 Cal.),
CHICKEN (15-20 Cal.), HAM (10-15 Cal.),
PEPPERONI (25-35 Cal.), SALAMI (25-30 Cal.),
ITALIAN SAUSAGE (40-50 Cal.)

VEGGIES
BANANA PEPPERS (0-5 Cal.), GREEN PEPPERS (0 Cal.),
JALAPENOS (0-5 Cal.), FRESH MUSHROOMS (5 Cal.),
BLACK OLIVES (10-15 Cal.), FRESH ONIONS (0-5 Cal.),
PINEAPPLE (10 Cal.), ROASTED RED PEPPERS (0 Cal.),
FRESH BABY SPINACH (0 Cal.), TOMATOES (5 Cal.)

2,000 CALORIES A DAY IS USED FOR GENERAL NUTRITION ADVICE, BUT CALORIE NEEDS VARY
ADDITIONAL NUTRITION INFORMATION AVAILABLE UPON REQUEST

*ADDED CALORIES FOR 1 TOPPING PIZZA

Figure 18: Additional example declaring calories for a build-your-own pizza using a string format.

CREATE YOUR OWN PIZZA
CALORIES ARE LISTED PER SLICE

CHOOSE YOUR SIZE & CRUST

6 SLICES **S** \$9.99 8 SLICES **M** \$11.99 10 SLICES **L** \$13.99 12 SLICES **XL** \$15.99

 THIN & CRISPY

 PAN

 ORIGINAL

CHEESE PIZZA
ORIGINAL (200-240 Cal.),
THIN & CRISPY (150-190 Cal.),
PAN (260-300 Cal.),
GLUTEN FREE† (140 Cal.)
†ONLY AVAILABLE IN SMALL

CHOOSE YOUR SAUCE*

 TOMATO SAUCE (10 Cal.), SPICY MARINARA (10 Cal.),
WHITE GARLIC SAUCE (30-50 CAL.), BBQ (10-20 Cal.)

CHOOSE YOUR TOPPINGS*

S \$1.00 **M** \$1.50 **L** \$2.00 **XL** \$2.25

 **MEATS**
BACON (45-60 Cal.), BEEF (40-45 Cal.),
CHICKEN (15-20 Cal.), HAM (10-15 Cal.),
PEPPERONI (25-35 Cal.), SALAMI (25-30 Cal.),
ITALIAN SAUSAGE (40-50 Cal.)

 **VEGGIES**
BANANA PEPPERS (0-5 Cal.), GREEN PEPPERS (0 Cal.),
JALAPENOS (0-5 Cal.), FRESH MUSHROOMS (5 Cal.),
BLACK OLIVES (10-15 Cal.), FRESH ONIONS (0-5 Cal.),
PINEAPPLE (10 Cal.), ROASTED RED PEPPERS (0 Cal.),
FRESH BABY SPINACH (0 Cal.), TOMATOES (5 Cal.)

2,000 CALORIES A DAY IS USED FOR GENERAL NUTRITION ADVICE, BUT CALORIE NEEDS VARY
ADDITIONAL NUTRITION INFORMATION AVAILABLE UPON REQUEST

*ADDED CALORIES FOR 1 TOPPING PIZZA

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Figure 19: Example of declaring calories per slice for a “basic preparation” pizza offered for sale in different sizes, with the option of adding toppings listed on the menu or menu board, using a column format.

Plain pizza pie (Calories per slice): Small (6 slices) 150 cal. Medium (8 slices) 160 cal.
Large (10 slices) 170 cal.

Toppings	Added Cal (per slice)		
	Small	Med	Large
Pepperoni	30	40	40
Sausage	40	40	45
Green Peppers, Red Peppers, or Onions	0	0	5

Figure 20: Example of declaring calories per pie for a “basic preparation” pizza offered for sale in different sizes, with the option of adding toppings listed on the menu or menu board, using a column format.

Plain pizza pie: Small (12”) 500 cal. Medium (14”) 750 cal. Large (16”) 1,000 cal.

Toppings	Added Cal		
	Small	Med	Large
Pepperoni	200	300	400
Sausage	250	350	450
Green Peppers, Red Peppers, or Onions	15	20	25

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Figure 21: Example of declaring calories per slice for a “basic preparation” pizza offered for sale in different sizes, with the option of adding toppings listed on the menu or menu board, using a column format.

Plain pizza pie (Calories per slice): Small (6 slices) 150 cal. Medium (8 slices) 160 cal.
Large (10 slices) 170 cal.

Toppings	Added Cal (per slice) (S/M/L pie)
Pepperoni	30-40
Sausage	40-45
Green Peppers, Red Peppers, or Onions	0-5

Figure 22: Example 2 of declaring calories per pie for a “basic preparation” pizza offered for sale in different sizes, with the option of adding toppings listed on the menu or menu board, using a column format (below, calories listed for the entire standard menu item.

Plain pizza pie: Small (12”) 500 cal. Medium (14”) 750 cal. Large (16”) 1,000 cal.

Toppings	Added Cal (S/M/L pie)
Pepperoni	200-400
Sausage	250-450
Green Peppers, Red Peppers, or Onions	15-25

5.7. I am a covered establishment that serves family-style dishes, such as salads and pasta bowls that serve multiple people. If I were to list the total calories on our menu, the calorie declaration would be very large. Since these standard menu items are not divided into discrete units, may I declare the calories based only on a recommended serving?

Answer: In the case of multiple-serving standard menu items that are not offered for sale divided in discrete units (e.g., slices of pizza), the calories declared must be for the entire standard menu item listed on the menu or menu board as usually prepared and offered for sale (e.g., “family-style salad: 1,000 Cal”) (21 CFR 101.11(b)(2)(i)(A)). However, you may, in addition to declaring the calories for the entire standard menu item, declare the number of suggested servings and the calories per suggested serving, but this must be in addition to declaring the calories for the entire standard menu item. For example: Family-Style Salad: 1,200 Cal: 150 Cal/serving, 8 servings; or Family-Style Lasagna: 625 Cal/serving, 8 servings; 5,000 Cal (21 CFR 101.11(b)(2)(i)(A)).

6. Compliance and Enforcement

6.1. I am a covered establishment working to comply with menu labeling requirements. Will FDA work cooperatively with me to help me come into compliance?

Answer: We plan to work cooperatively with covered establishments to come into compliance with the menu labeling requirements. Specifically, we plan to continue with education and outreach, especially in the first year, to help covered establishments achieve compliance.

6.2. How does FDA intend to approach enforcement of the menu labeling rule?

Answer: As stated in question and answer 6.1, our goal is to ensure compliance among covered establishments in a cooperative manner, and we do not intend to penalize or recommend the use of criminal penalties for minor violations. For example, we would consider examples such as the following to be minor violations:

- Inadvertently missing a calorie declaration for a standard menu item on a buffet when other items are labeled;
- Minor discrepancies in the type size/color contrast of calorie declarations, provided that they are readable;

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- Minimal variations or inadvertent error that would only minimally impact the calorie declaration or other nutrition information, such as adding extra slices of pepperoni on a pizza or adding an extra dollop of ketchup on a hamburger when not typically added; or
- Not rounding your calorie declaration correctly in accordance with the menu labeling rule

Our goal is to seek compliance and to work flexibly with establishments to achieve compliance with menu labeling requirements. For example, our typical approach following an inspection would be to raise any compliance concerns with the most responsible person (e.g., the manager or owner) at a covered establishment during a close-out inspection meeting or in regulatory meetings with that establishment. If post-inspection issues remain, we may send a letter to the establishment asking for the firm to come into compliance. Any enforcement activities we pursue will be consistent with our public health priorities. We note that the range of potential enforcement tools for menu labeling is the same as for other misbranding actions under the FD&C Act; we did not receive any new enforcement tools specifically for menu labeling.

6.3. If a covered establishment misunderstands the requirements and needs to make a correction, is there a grace period in which to make the correction (e.g., 90 days or our next menu printing)?

Answer: The menu labeling final rule does not specify a grace period for covered establishments to make corrections to menus or menu boards. If or when we become aware of menus or menu boards that are not in compliance, we will work flexibly and cooperatively with individual establishments making a good-faith effort to comply with the law, and will work with an establishment on an appropriate time-frame in which to make the correction. Additionally, as discussed in Q&A 6.2, our typical enforcement strategy for labeling violations is to raise any compliance concerns with the most responsible person (e.g., the manager or owner) at a covered establishment during a close-out inspection meeting or in regulatory meetings with that establishment.

7. Determining Nutrient Content for Standard Menu Items

7.1. We are a covered establishment that sells hot rotisserie chicken and prepared vegetables. We have two different suppliers and the nutrition information is slightly different for the items from each supplier due to natural variation of the food. How should we determine the calorie and nutrient information for our standard menu items?

Answer: The menu labeling rule requires a covered establishment to have reasonable basis for its nutrient declarations (21 CFR 101.11(c)(1)), which provides flexibility for a covered establishment to take such natural variation into account when determining the calorie content and calorie declaration for a standard menu item. You should take reasonable steps to determine calorie and nutrition information for standard menu items that may slightly vary due to natural variation. We understand that the calorie content of non-uniform menu items, such as pieces of chicken or prepared vegetables vary depending on the size and, in some cases, composition of the items (e.g., chicken breast, thigh, or drumstick or different sizes of baked potatoes). This natural variation can be taken into account as a part of your reasonable basis when determining your calorie counts and other nutrition information for your standard menu items as they are usually offered and prepared in your establishment. For example, the calorie and other nutrient declarations could be based on the average values obtained when comparing the nutrient values of the food from different suppliers or from the same supplier when variations are known.

7.2. Am I required to conduct laboratory analysis to determine the nutritional content of my standard menu items? If not, what are examples of a “reasonable basis” to determine the nutritional content of my standard menu items?

Answer: No. You are not required to conduct laboratory analysis to determine the nutritional content of your standard menu items. While laboratory analysis of standard menu items would be considered a reasonable basis for determining calorie and other nutrient information for your standard menu items, this is not the only reasonable basis permitted. You may use any one of a number of means to arrive at these values, including:

- Calculations based on nutrient databases such as the USDA National Nutrient Database for Standard Reference (<http://ndb.nal.usda.gov/ndb/foods>), or valid and appropriate trade association or industry databases (with or without computer software programs);
- Calculations based on the Alcohol and Tobacco Tax and Trade Bureau’s (TTB’s) methods for determining values for the voluntary Statements of Average Analysis and voluntary Serving Facts statements;
- Values listed in a cookbook;
- Laboratory analysis of your menu items; or
- Other reasonable means such as:
 - Use of Nutrition Facts on the labels of packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and 21 CFR 101.9;
 - FDA’s nutrient values for raw fruits and vegetables (Appendix C of 21 CFR part 101; or
 - FDA’s nutrient values for cooked fish (Appendix D of 21 CFR part 101).

7.3. Am I required to store the information on the reasonable basis on the premises of my covered establishment?

Answer: No. The reasonable basis information is not required to be stored on your premises. You may choose to maintain these records at the covered establishment or you may maintain the information at your corporate headquarters (if you have one) or some other location, for the duration of the time that the standard menu items are offered for sale at the covered establishment. Upon request and within a reasonable period of time, you must supply to FDA the information used to substantiate the required calorie and nutrient values that you use for your standard menu items listed on your menus, menu boards or on display, and for your written nutrition information (21 CFR 101.11(c)(3)). This information must include both the data and the method you used to derive these nutrient values, as specified in 21 CFR 101.11(c)(3). We consider a reasonable period of time to be about 4-6 weeks after the request is made.

7.4. How often does a covered establishment have to recalculate their nutrition information for standard menu items?

Answer: A covered establishment should not need to recalculate nutrition information for menu items that stay the same (for example, a classic menu item such as a staple fried chicken recipe). In this instance, the establishment could rely on a one-time calculation, as long as that nutrition information remains accurate and consistent with the specific basis used to determine nutrient values (21 CFR 101.11(c)(2)). Recalculation of the nutrition information would only be necessary if there are changes to the recipe or preparation of a standard menu item that would result in a change in the calorie declaration or other nutrition information. In addition, Q&A 7.1 provides additional information on how to calculate the calorie and nutrient information if you have multiple ingredient suppliers that have slightly different nutrition information due to natural variation.

8. Covered Establishments

8.1. If establishments, which may be independently franchised, are doing business under the same name, selling restaurant-type food, and participate together in a marketing alliance (for example, independent grocery stores that participate in a marketing alliance, such as Bob’s Co-op Grocery and Sally’s Co-op Grocery), but do not sell substantially the same menu items from location to location, are they covered by the menu labeling requirements?

Answer: No. If establishments do not sell substantially the same menu items from location to location, then those establishments would not be covered by the menu labeling final rule because they do not meet the definition of a “covered establishment” (21 CFR 101.11(a)). To be covered under the menu labeling requirements, an establishment must meet all 4 criteria of a covered

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establishment (as defined in the menu labeling final rule (21 CFR 101.11(a))) or voluntarily register with FDA. The menu labeling final rule defines a “covered establishment” as a restaurant or similar retail food establishment that meets the 4 criteria below:

- Have 20 or more locations (with the term location referring to a fixed position or site);
- Be doing business under the same name (**regardless of the type of ownership, such as individual franchises**). When the term “name” refers to the name of the establishment presented to the public, the term “same” includes names that are slight variations of each other, due to things such as the region, location, or size (e.g., “ABC” and “ABC Express”);
- Sell substantially the same menu items; and
- Sell restaurant-type foods (defined, in part, as food that is usually eaten on the premises, while walking away, or soon after arriving at another location).

While the establishments may meet some of these requirements, where these types of marketing alliances do not offer for sale substantially the same menu items, they are not covered by the menu labeling final rule unless they choose to voluntarily register with FDA.

8.2. I am a convenience store that sells gas under a brand name; however my convenience store operates under a different name (e.g., “Bob’s Corner Market”). Am I a covered establishment because I am selling gas under a brand name that has more than 20 locations?

Answer: No. As discussed in Q&A 8.1, in order to be covered under the menu labeling requirements, an establishment must meet all 4 criteria of a covered establishment (as defined in the menu labeling final rule (21 CFR 101.11(a))) or voluntarily register with FDA. In this situation, we would consider the convenience store to be doing business under the name “Bob’s Corner Market.” If there are less than 20 “Bob’s Corner Markets,” then this convenience store would not be covered under the menu labeling requirements in this example because it does not meet all 4 criteria of a covered establishment (e.g., does not have 20 or more locations). If “Bob’s Corner Market” does have 20 or more locations doing business under the same name, but does not offer substantially the same menu items from location to location, then this convenience store would also not be covered under the menu labeling requirements because it does not meet all 4 criteria of a covered establishment (i.e., not selling essentially the same menu items).

9. Standard Menu Items

9.1. Are menu items that are not sold in more than 20 locations of a chain, but are standard menu items at one or more locations of that particular chain, covered under the menu labeling requirements?

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Answer: Yes. If a covered establishment is offering for sale a restaurant-type food that is routinely included on their menu or menu board or routinely offered as a self-service food or food on display at only one location, that item is covered under the menu labeling requirements because it meets the definition of a standard menu item, and thus calorie and other nutrition information is required (21 CFR 101.11(b)(2)(i)(A)). For example, if one Tennessee location of a covered chain routinely offers a “Memphis BBQ Sandwich” on its menu or menu board or as a self-serve food or food on display, it meets the definition of a standard menu item at that location, even though it is not offered in any other location. Thus, the sandwich would be covered under 21 CFR 101.11 and calorie and other nutrition information would be required. However, the menu labeling requirements do build in flexibility by exempting items that are daily specials, temporary/seasonal food, and food that is part of a customary market test, such that these items are not required to have calorie labeling (21 CFR 101.11(b)(1)(ii)(A)(I)).

9.2. I am a covered establishment and I offer several unique items on my menu that are not offered in any of the other establishments within my chain. For example, if I routinely sell crab cakes at only 15 of my 30 establishments, do I have to provide nutrition information on the crab cakes?

Answer: Yes. See response to Q&A 9.1.

9.3. I am a covered establishment, and as part of my unique business model I offer “Chef Creations” that use extra produce as it becomes available from our produce department, so the ingredients routinely change and often on a daily basis. Am I required to declare calories for these menu items?

Answer: No, so long as the item is not routinely offered. The menu labeling final rule has built-in flexibility to accommodate these specific situations by exempting items that are daily specials, temporary/seasonal food, and food that is part of a customary market test, such that these items are not required to have calorie labeling. Thus, if the ingredients of a prepared food item vary depending on what ingredients a covered establishment happens to have available, the item may not meet the definition of a standard menu item. For example, if a grocery store with a hot soup bar offers a different vegetable soup every day based on whatever vegetables the store happens to have in surplus, for example, cabbage and tomato soup one day, carrots and leeks the next, spinach and squash on a third day, and if none of these vegetable soups is offered for sale routinely, then none of the vegetable soups would meet the definition of a standard menu item. Even if the grocery store names each version of the soup as “vegetable soup,” the item would not be considered a standard menu item because the soup’s ingredients differ daily. This example could be applied to other examples like chicken salad. If grapes are added to the chicken salad one day because of a surplus in the produce department, and grapes are not normally part of this standard menu item, then the chicken salad with added grapes would not meet the definition of a

standard menu item on that day. However, as noted above, if the establishment begins to routinely offer chicken salad with grapes, then that item would likely meet the definition of a standard menu item and would have to declare calorie and other nutrition information.

10. Alcohol

10.1. I am a covered establishment. I list various beers on my menu or menu board, some of which I rotate regularly to feature local or seasonal beer throughout the year (e.g., pumpkin beer in the fall). Am I required to declare calories for the beers listed on my menu or menu board that I offer at my establishment?

Answer: It depends. For beers that are listed on your menu or menu board and meet the definition of a standard menu item, you must declare the calories and other nutrition information for these standard menu items (21 CFR 101.11(b)(2)(i)(A)). This requirement also applies to beers that are on tap if they are also listed on your menu or menu board. Depending on how these beer selections are listed on your menu or menu board, declaring the calories in a range may be appropriate.

However, for beer that is served on tap and is not listed on your menu or menu board, these beers are considered foods on display. Alcoholic beverages that are foods on display and are not self-serve are exempt from the menu labeling requirements (21 CFR 101.11(b)(1)(ii)(B)). For example, beers that are served on tap, including local craft brews and regular offerings that are served by a bartender, would not require calorie and other nutrition labeling.

In addition, beers that are listed on your menu or menu board for less than a total of 60 days per calendar year (e.g., pumpkin beer offered in the fall) meet the definition of a temporary menu item and therefore, are exempt from menu labeling requirements (21 CFR 101.11(b)(1)(ii)(A)).

10.2. I am a covered establishment that lists on my menu or menu board alcoholic beverages supplied by small breweries, wineries, and distilleries that do not supply the nutritional information for their beverages. In this situation, is laboratory testing my only option for figuring out nutrition information for these beverages?

Answer: The final rule requires an establishment to have a reasonable basis for its nutrient content declarations. The final rule does not require an establishment to use a particular method or approach to determine nutritional content. For example, the reasonable basis you use to determine the nutrient content of your standard menu items that are alcoholic beverages could include calculations based on nutrient databases (e.g., industry generated databases or the USDA National Nutrient Database for Standard Reference); calculations based on the ingredients and processing of the products; calculations based on TTB's methods for determining nutrient values for voluntary Statements of Average Analysis and voluntary Serving Facts statements; or other

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reasonable basis. You could also use laboratory analysis as your reasonable basis; however, laboratory analysis is simply one of many methods – rather than the *only* method – that could be used.

Further, as part of your reasonable basis, if you do not expect that a nutrient would be present in your food based on the ingredients and processing techniques used (e.g., many beers will not have fat or cholesterol) then this may be considered as part of your reasonable basis in determining nutrient values and laboratory analysis would not be required.

Additionally, for items like alcoholic beverages where 6 or more of the required nutrients will be declared as zero, you have additional flexibility in how you present the additional written nutrition information, such as using the simplified format. The simplified format must be presented in a column, list, or table, and in accordance with 21 CFR 101.11(b)(2)(ii)(B).

11. References

1. Letter from National Grocers Association to Commissioner Ostroff, dated March 28, 2017.
2. Letter from National Association of Convenience Stores to Secretary Tom Price, dated February 24, 2017.
3. Letter from Food Marketing Institute (FMI), National Association of Convenience Stores (NACS), National Association of Truck Stop Operators (NATSO), Society of Independent Gasoline Marketers of America (SIGMA) to Dominic J. Mancini, dated February 10, 2017.
4. Letter from Members of Congress to Secretary Tom Price, dated April 7, 2017.