



Advocacy Department

1150 Connecticut Ave., NW | Suite 300 | Washington, DC 20036

P 202-785-7900 | F 202-785-7950 | www.heart.org

Chairman of the Board
James J. Postl

President
John J. Warner, MD

Chairman-elect
Bertram L. Scott

President-elect
Ivor Benjamin, MD, FAHA

Immediate Past
Chairman of the Board
Alvin L. Royse, JD, CPA

Immediate Past President
Steven R. Houser, PhD, FAHA

Treasurer
Raymond P. Vara, Jr.

Directors
Mary Ann Bauman, MD
Emelia J. Benjamin, MD, ScM, FAHA
Douglas S. Boyle
Lloyd H. Dean
Mitchell S. V. Elkind, MD, MS, FAHA
J. Donald Fancher
Linda Gooden
Ron W. Haddock
Robert A. Harrington, MD, FAHA
Marsha Jones
Stacey E. Rosen, MD
Lee Shapiro
David A. Spina
Bernard J. Tyson
Thomas Pina Windsor
Joseph C. Wu, MD, PhD, FAHA

Chief Executive Officer
Nancy A. Brown

Chief Operating Officer
Suzie Upton

Chief Science & Medical Officer
Rose Marie Robertson, MD, FAHA

January 8, 2018

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2011-F-0172

Dear Sir or Madam:

The American Heart Association (AHA) appreciates the opportunity to provide comments on the draft Menu Labeling: Supplemental Guidance for Industry. As AHA has expressed in previous communications with the Food and Drug Administration (FDA), we strongly support menu labeling and would like to see it fully implemented as soon as possible. We are encouraged that many retail food establishments have already complied with the requirements, and we hope this additional guidance will help those who have not yet done so. We urge the FDA to finalize this guidance quickly to facilitate implementation by the May 7, 2018 deadline.

Overall, AHA supports the draft guidance document. The document largely reinforces clarifications that have already been made through the final regulations, previous guidances, and technical assistance. However, there are a few areas of the document where minor modifications are needed. We believe these revisions, as described below, will provide better clarity for the food industry.

1. Introduction

It is our understanding that the draft supplemental guidance, as evidenced by its name, is a supplement or addition to the existing April 2016 guidance document titled "A Labeling Guide for Restaurants and Retail Food Establishments Selling Away-From-Home Foods – Part II". In other words, the supplemental guidance adds to, but does not replace the older guidance document.

To ensure that covered food establishments understand that there are two guidance documents that address menu labeling, we recommend that the FDA add text to the introduction section that specifically refers to the April 2016 document. While there is currently language announcing that the FDA has decided to withdraw Questions and Answers 5.17 and 5.18 “in our previous guidance”, it does not clearly indicate that the April 2016 guidance document is still in effect and should be consulted by industry.

Without this language, we are concerned that covered establishments may mistakenly consult only the supplemental guidance when preparing to implement the menu labeling requirements. While the supplemental guidance addresses many topics of interest to industry, it is not as comprehensive as the 2016 guidance document. For example, the supplemental guidance contains one Question and Answer that addresses “menu items that can be combined for a special price”,¹ while the 2016 guidance contains multiple Questions and Answers on this topic and explains the distinction between an “opportunity for a consumer to combine standard menu items for a special price”² and a predetermined “combination meal”³. If a covered establishment only reviews the supplemental guidance, they may not understand that there are two different types of “combinations” and the requirements differ for each. We address this specific example in more detail in our comments on Question and Answer 5.3 below.

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

Question and Answer 3.3 states, “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?” The answer given is “No, menus and menu board are not required at each self-service location.” The answer continues to explain that establishments do not have to create a new menu or menu board and that the final rule provides flexibility in the options that can be used to declare calories.

While we understand why the Agency answered “no” to this question, we are concerned that covered establishments could misinterpret the response. Although covered establishments are not required to use a formal menu or menu board at a self-service display, they are required to provide calorie information at each self-service location in the establishment. We do not believe that is clear in the current response; covered establishments could incorrectly infer that posting calorie information in one location is sufficient. Therefore, we recommend that the FDA revise the first paragraph of Answer 3.3 to read:

Menus and menu boards are not required at each self-service location; however, the menu labeling final rule requires that calories be declared for self-service food or food on display

¹ Menu Labeling: Supplemental Guidance for Industry. Draft Guidance. Food and Drug Administration. November 2017. Q&A 5.3.

² A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11): Guidance for Industry. Food and Drug Administration. April 2016. Q&A 5.41.

³ Ibid. 3.10.

at each self-service location within the establishment. The menu labeling final rule is flexible in the options that can be used to declare the calories.

5. Methods for Providing Calorie Disclosure Information

Question and Answer 5.2 states, “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?” The answer given is “No.” FDA then explains that establishments are not required to use menu boards and that alternative means such as electronic devices, hand-held paper menus, or laminated menus on the counter can be used to meet the requirements.

AHA recommends that FDA add text to this response to clarify that establishments cannot rely on online menus alone. We are concerned that establishments could misinterpret this response and believe that an online menu is an acceptable alternative to providing calorie information within the establishment.

We suggest adding the underlined text to the response:

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 consumers 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. (Please note that calorie information must be made available within the establishment; providing calorie information on an online menu alone does not meet the requirements. See Question and Answer 5.4 for more information).

Question and Answer 5.3 states, “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?” The answer given is “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 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.”

AHA agrees with this response. Covered establishments should not be required to provide a calorie declaration for combinations where the consumer selects the food items that will be combined, such as selecting any two sandwiches, salads, and soups on the menu. However, as

we noted above, the 2016 guidance distinguishes between consumer-selected combinations and “combination meals”, which are defined as:

A standard menu item that consists of more than one food item, such as a meal that includes a sandwich, a side dish, and a drink. A combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item. For example, the side dish may vary among several options (such as fries, salad, or onion rings) or the drinks may vary (such as soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal. (21 CFR 101.11(a))

According to Questions and Answers 5.39 and 5.40 in the 2016 guidance, the combined calorie count for combination meals must be declared on the menu. For example, a restaurant that offers a “cheeseburger meal deal” consisting of a cheeseburger, medium fries, and a medium soft drink, that is marketed as a single menu item, has to provide the combined calorie declaration. Again, we agree with the Agency; covered establishments should be required to provide a total calorie declaration (or range when multiple sizes or choices are offered) for combination meals. Combination meals are offered by many fast food and quick service restaurants, and photos of these meals often dominate the menu or menu board.

However, as described previously, we are concerned that a covered establishment that only reviews the supplemental guidance may not understand that there are different requirements for a consumer-selected combination and a predetermined “combination meal”. If that occurs, the establishment may mistakenly believe that they do not have to provide a total calorie declaration for a combination meal.

To avoid this situation, we recommend that FDA add text to Question and Answer 5.3 to clarify that a different requirement applies to combination meals. We suggest the following text:

Please note that different requirements apply to “combination meals” (21 CFR 101.11(a)) such as a sandwich and side that are listed as a single menu item. Covered establishments must declare the total calories or calorie range for the combination on the menu or menu board. See Questions and Answers 5.39 and 5.40 in the April 2016 guidance document for more information.

Question and Answer 5.4 states, “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 board within the establishment if we declare calories on our online menu?” The answer given is “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.” The response continues to explain that establishments may use alternatives to a menu board such as electronic devices, hand-held paper menus, or laminated counter menus for ordering.”

AHA agrees with this response; online menus alone are not enough. Pizza chains and other establishments that offer takeout or delivery service must also post calories on an in-store menu just like other chain restaurants, to accommodate those consumers who place their orders in the store.

We do, however, recommend that FDA strengthen this answer by explicitly stating that pizza parlors must provide menu labeling in the store regardless of whether or not they use a menu board. We are concerned that the way the response is currently worded, which also states that “establishments that do not have menu boards are not required to create menu boards,” could be misinterpreted to mean that pizza parlors without a menu board do not have to provide menu labeling.

We recommend revising the response to read:

Yes, even though you declare calories on your online menu, you must provide calorie declarations in your covered establishment. If you have a menu board in your covered establishment, you must provide calorie declarations for standard menu items listed on your menu board; however, establishments that do not have menu boards are not required to create menu boards. 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), 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. Furthermore, marketing boards or marketing materials can be used and would not require calorie declarations. See Figures 12 and 13.

8. Covered Establishments

Question and Answer 8.2 states, “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?” The answer given is “No.” FDA then explains that it “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’ than the convenience store would not be covered under the menu labeling requirements.”

AHA is concerned with this response. It could allow convenience stores that otherwise meet all of the requirements for a covered establishment to alter their name simply to avoid having to comply with the rule. The FDA should revise this answer to indicate that a convenience store which is operated by and sells gas under a brand name, such as Exxon or Shell, which has 20 or more locations that do business under that brand name, sells restaurant-type foods, and offers for sale substantially the same menu items as other locations, is considered a covered establishment even if, as in this example, the convenience store has less than 20 locations that use that name.

That is because there is no difference between the restaurant-type food offered for sale at an Exxon or Shell gas station or an Exxon or Shell-owned, -operated, or -franchised venue operated as Bob's Corner Market. The FDA should consider Bob's Corner Market a variation of the name of the business. Should the Agency fail to clarify this aspect of the guidance document, it leaves open the possibility that businesses will rename subsidiaries merely to evade compliance.

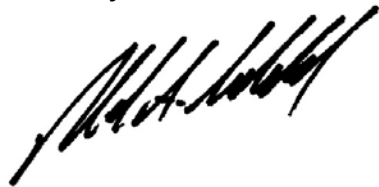
In addition, we recommend that FDA remind convenience stores and other potential covered establishments that doing business under the same name "includes names that are slight variations of each other, due to things such as the region, location, or size (for example, 'New York Ave. Burgers' and 'Pennsylvania Ave. Burgers' or 'ABC' and 'ABC Express')." ⁴ While this issue is addressed briefly in Question and Answer 8.1, again, we think it would be helpful to refer industry to the more comprehensive description contained in the April 2016 guidance document.

In closing, AHA reiterates our general support for the draft guidance, but believes the modifications described above will provide better clarity for industry. We encourage the FDA to make these revisions and release the final guidance document as soon as possible.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Thank you for your consideration of our comments.

Sincerely,



Mark A. Schoeberl
Executive Vice President
Advocacy and Health Quality

⁴ Ibid. 3.6.