



June 14, 2017

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Comments regarding the Request for Comments on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Docket ID: FDA-2011-F-0172 ([82 Fed. Reg. 20825](#))

The National Federation of Independent Business (NFIB) submits these comments for the record to the U.S. Food and Drug Administration (FDA) regarding the request for comment on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments published in the May 4, 2017, edition of the *Federal Register*.

NFIB is the nation's leading small business advocacy association, representing small and independent businesses in Washington, DC, and all 50 state capitals. A nonprofit, nonpartisan organization founded in 1943, NFIB's mission is to promote and protect the right of its members to own, operate, and grow their businesses. The membership of NFIB includes small and independent businesses directly impacted by the menu labeling rule.

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I. Background

In the *Federal Register* notice referenced above, FDA extended the compliance date for its menu labeling rule to May 7, 2018. FDA requested comments from the public regarding how the agency “might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies.”

The rule in question is authorized by the Patient Protection and Affordable Care Act (ACA) of 2010.¹ Section 4205 of the ACA amends section 403(q) of the Federal Food, Drug, and Cosmetic (FD&C) Act, which governs nutrition labeling requirements, and section 403A of the FD&C Act, which governs Federal preemption of State and local food labeling requirements. As amended, Section 403(q)(5)(H) of the FD&C Act requires chain retail food establishments with 20 or more locations to provide calorie information for standard menu items, including food on display and self-service food, and to provide, upon consumer request, additional written nutrition information for standard menu items.²

On December 1, 2014, FDA published a final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments with 20 or more locations.³ The final rule had an effective date of December 1, 2015, which also served as the compliance date.

On July 10, 2015, FDA published an extension of the compliance date to December 1, 2016.⁴ Later that year, on December 18, President Obama signed the Consolidated Appropriations Act.⁵ That law included the following language at Section 747 of Division A:

¹ Pub. L. 111-148

² 21 U.S.C. 343(q)(5)(H)(i) to (iii)

³ [79 Fed. Reg. 71156](#)

⁴ [80 Fed. Reg. 39675](#)

⁵ Pub. L. 114-113

None of the funds made available by this Act may be used to implement, administer, or enforce the final rule entitled “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” published by the Food and Drug Administration in the Federal Register on December 1, 2014 (79 Fed. Reg. 71156 et seq.) until the later of--

(1) December 1, 2016; or

(2) the date that is one year after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments in accordance with paragraphs (g)(1)(i), (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of section 10.115 of title 21, Code of Federal Regulations.

FDA did not publish the notice of availability of the Level 1 guidance until May 5, 2016.⁶ By the law referenced above, FDA pushed back the compliance date one year from that date to May 5, 2017, in the same notice. As noted above, the compliance date has been extended once again to May 7, 2018.

The preamble of the 2014 final rule states that the rule contains ten major provisions impacting covered establishments. The most significant of these include requiring that calories for standard menu items be declared prominently on menus and menu boards, prescribing that menus and menu boards include a statement regarding recommended daily calorie intake, and establishing the foods in an establishment that would be covered by the rule.

II. Issues and Challenges Raised by Small and Independent Businesses

Small and independent business owners directly affected by the rule have raised issues and challenges that FDA should address. This section explains those issues briefly, while Section III provides specific recommendations, including regulatory language, that would improve the rule for covered establishments.

A. The Definition of Menu is Too Broad

The definition of a menu or menu board was written so broadly by FDA that it includes items few would consider “menus.” The definition in the final rule is as follows:

⁶ [81 Fed. Reg. 27067](#)

Menu or menu board means the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children’s menus; other specialty menus; electronic menus; and menus on the Internet. Determining whether a writing is or is part of the primary writing of the covered establishment from which a customer makes an order selection depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing. The menus may be in different forms, e.g., booklets, pamphlets, or single sheets of paper. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments.

A broad, but logical, reading of this definition would require that any piece of information produced by the establishment from which a customer may order would be considered a menu. Included in this reading are: advertisements, coupons, flyers, window displays, packaging, and social media posts. The inclusion of this information renders these items less effective and is not necessary given requirements for nutrition information to be on hand at request at the establishment location and on menus on its website. Consumers could easily see a coupon or advertisement for a restaurant and then check nutrition information on a website before ordering via phone or the internet.

B. Menu Readability and Functionality

NFIB members have indicated that the requirements of the rule will impact the readability and functionality of menus and menu boards. The requirement that the calories of each standard menu item be adjacent to the name of the item and the recommended daily caloric intake statement increases word clutter and has led to some establishments reducing the font size of all text on the menu to make all the required information fit. This reduced readability makes it more difficult for customers to order or to understand the various options for specific meals and dishes.

C. Costs Associated with Compliance

The costs associated with compliance also fall disproportionately on small businesses impacted by the rule. Though proponents of the rule say that the 20-establishment threshold mitigates costs on franchised locations – typically small and independent

businesses – these companies face substantial costs on their own. As an example, paying for the new menus and boards falls on the franchised establishment, even if the chain headquarters supplies the necessary nutrition information. Franchised locations often produce their own advertisements and coupons, which will now need to be reconfigured to meet the rule’s requirements. These restaurants often have slim margins. An analysis by the Heritage Foundation found that the typical fast food restaurant has pre-tax profits of just three percent.⁷ Small and independent businesses, even those that operate multiple locations of a franchise, are not flush with extra resources to continually be printing out new menus or posting new menu boards.

D. Severity of Penalties

The final rule states that a standard menu item shall be deemed misbranded under the FD&C Act if its label or labeling fails to comply with the requirements for nutrition labeling for food sold in covered establishments or has an inaccurate determination of nutrition content. First-time violators are subject to up to one year in prison and fined up to \$1,000.⁸ The requirements of the rule are complex and some parts, including the term “adjacent,” lack certainty. Calculating the nutritional value may seem straightforward, but variation based on customization of the order or the person preparing the food may occur. The harsh penalties associated with a misbranded food violation are excessive for many of the circumstances in which a small business would fail to achieve compliance.

E. Food Sold only in Certain Locations of a Chain Establishment

In some restaurant chains and franchises, establishments can sell food developed entirely in-house or can sell local food products. For example, a chain sandwich establishment may be allowed to make desserts from recipes developed entirely by the establishment’s operator and not sold chain-wide. Similarly, a small or independent business franchisee who owns a handful of stores in a certain location may seek to support other small businesses in that area by stocking, in her stores only, goods made by a local company. These goods may qualify for an exemption from nutrition labeling requirements if the producer is below certain gross sales revenue thresholds.⁹ However, since these items remain on the menu longer than the market testing or seasonal menu item exemptions allow, the items would meet the definition of standard menu item for these particular establishments. Small and independent establishments are likely to drop these items from their restaurants rather than enduring the cost and complexity of

⁷ Sherk, James. [Higher Fast-Food Wages: Higher Fast-Food Prices](#). Heritage Foundation. September 4, 2014.

⁸ 21 U.S.C. 333(a)(1)

⁹ 21 CFR 101.9(j)

determining nutrient content for house-developed items or applying pressure on local producers to develop and re-label the product with nutrition information. Application of the rule to the situation described above appears to be inconsistent with the statute (21 U.S.C. 343(q)(5)(H)) that recognized that exempted companies with fewer than 20 establishments, because they would face disproportionate compliance costs associated with menu labeling.

III. Recommended Regulatory Changes to Improve Flexibility

FDA can improve flexibility in the rule's requirements – and alleviate some of the concerns raised above – while continuing to achieve its regulatory objectives. These recommendations will help FDA achieve its regulatory costs savings goals required by Executive Order 13771 of January 30, 2017.¹⁰ NFIB recommends FDA adopt the changes below.

A. Tighten the Definition of Menu

The current definition inappropriately requires establishments to put calorie information and the recommended daily caloric intake statement on all types of promotional materials if a standard menu item is named or shown. This requirement negatively impacts the effectiveness of items such as advertisements, coupons, and flyers. The requirement also demonstrates that FDA did not appropriately consider the impact of such a definition on small businesses that derive much of their business from the use of coupons, such as pizza restaurants. Further, the authorizing statute does not require the definition to be unnecessarily broad.

Accordingly, NFIB suggests FDA amend the definition of *menu or menu board* at 21 CFR 101.11(A) to read:

Menu or menu board means the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children's menus; other specialty menus; electronic menus; and menus on the Internet. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments. The ability to order from an advertisement, coupon, flyer, window display, packaging, social media posting, or other similar writing does not make the writing a menu or menu board.

¹⁰ Available at <https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-02451.pdf>

B. Improve Menu Readability and Functionality and Reduce Costs of Compliance

The authorizing statute requires covered establishments to include the number of calories in the item “adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item.” It also requires the recommended daily caloric intake statement to be “posted prominently on the menu.”

The final rule stringently applies this requirement in a manner that reduces menu and menu board readability and functionality beyond what the statute requires. The final rule requires the calorie statement to be “in a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item, and with the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.”¹¹

Similarly, the recommended daily caloric intake statement is to be in a typeface no smaller than the one above, with the same standards of conspicuousness. It also must be listed on the bottom of each page of a menu and the menu board.

These requirements unnecessarily go beyond what the statute requires in a way that makes it difficult for small businesses to make their menus and menu boards usable and that offers additional chances of compliance errors made in good faith.

NFIB recommends the following changes be made to the calorie statement requirement. Strike 21 CFR 101.11(b)(2)(i)(A)(1) and replace with the following:

(1) The number of calories must be listed adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu or menu board, including a drive through menu board, listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale.

Strike 21 CFR 101.11(b)(2)(i)(A)(3), and redesignate paragraphs (4)-(9) as (3)-(8).

¹¹ 21 CFR 101.11(b)(2)(i)(A)(1)

NFIB recommends the following changes be made to the recommended daily caloric intake requirement. Strike 21 CFR 101.11(b)(2)(i)(B)(1)-(3) and replace with the following:

(1) This statement must be posted prominently on the menu or menu board, including a drive through menu board.

NFIB recommends the following changes be made to the availability of additional nutrition information requirement. Strike 21 CFR 101.11(b)(2)(i)(C)(1)-(3) and replace with the following:

(1) This statement must be posted prominently on the menu or menu board, including a drive through menu board.

C. Allow for a Grace Period to Address Violations

FDA could further provide flexibility for small and independent businesses by allowing for a grace period to correct mistakes made in good faith. Despite best efforts, it is possible that establishments may not be able to meet every one of the many requirements in the final rule. It is important that FDA reflects Administration policies established in E.O. 13771, which sought to reduce unnecessary regulatory burdens.

Issuing a penalty of possible prison time or up to \$1,000 for compliance errors made in good faith is not consistent with the goals of E.O. 13771. Many minor mistakes are possible. One example is a covered establishment with a salad bar not having the calorie information adjacent enough to the particular item at the bar. The establishment might believe it is close enough to the item, but perhaps a customer or regulator would disagree. A second example is a restaurant that offers a coupon for a free pizza that has not specified the calorie possibilities for all of the 15 varieties of pies it offers, which may run afoul of the rule. In such situations, it is clear that the establishment is trying to comply, but may not perfectly meet all of the rule's requirements.

NFIB recommends FDA add a new paragraph, (g), to 21 CFR 101.11 as follows:

(g) Any restaurant or similar retail food establishment that is an unknowing or unwilling violator of this section shall have 90 days after receiving notification of the violation to correct the violation. No enforcement action, including the issuance of any public letter or other public communication, shall be taken for violations that are corrected within such 90-day period.

D. Exempt Food Sold Only in Certain Locations of a Chain Establishment

FDA should provide relief for small and independent businesses that make or sell food entirely independent of the chain that brings them under the final rule's coverage. Small and independent establishments should be exempt from the requirements of the menu labeling rule by allowing establishments to sell items developed entirely in-house or items from local food producers that meet the qualifications under 21 CFR 101.9(j) without corresponding nutrition information. Allowing these businesses relief in this situation is consistent with Congressional intent in the ACA that the burden of complying with the menu labeling rule should not fall on businesses with fewer than 20 establishments. Since the menu items in question are developed or sold entirely independent of a larger chain, there is no larger company to provide some of the compliance assistance on these items.

NFIB recommends FDA add the following language at 21 CFR 101.11(b)(1)(ii)(A):

(3) Items made in a covered establishment developed and produced independently of a chain that are not available for sale in 20 or more establishments of the chain.

(4) Items resold independently of a chain that are not sold in 20 or more establishments of the chain that meet the exemption for nutrition labeling standards under Section 101.9(j).

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NFIB urges FDA to adopt the recommendations above to increase flexibility for small and independent businesses while ensuring the agency meets its regulatory objectives. Thank you for the opportunity to comment on FDA's rule on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.

Sincerely,



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