

February 12, 2024

Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Comment on Menu Labeling: Supplemental Guidance for Industry (Edition 2) re: (Docket No. FDA-2011-F-0172)

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on FDA's Draft Guidance for Industry: Menu Labeling Supplemental Guidance (Edition 2). This draft supplemental guidance covers two topics:

- 1) Whether Covered Establishments must include calorie disclosures for standard menu items when selling food through third-party platforms (TPPs), and
- 2) Whether Covered Establishments may declare added sugars as part of the additional nutrition information available upon request for standard menu items.

With respect to the first topic, calorie disclosures for food sold through TTPs, the draft guidance tells Covered Establishments that providing this information is voluntary and encourages voluntary disclosure. We are deeply disappointed that the draft guidance fails to clarify that existing FDA regulations already make calorie labeling (and the provision of additional nutrition information upon request) mandatory for menus posted on TPPs by Covered Establishments. Advising restaurants and similar retail food establishments that such disclosure is voluntary is therefore a step backwards. Today, CSPI, Consumer Federation of America, Consumer Reports, and the American Public Health Association submitted a petition requesting that FDA issue final guidance stating that calorie labeling is mandatory for menus posted on TPPs by Covered Establishments (see attached).

Regarding the second topic, added sugars declaration, the draft guidance states that including added sugars as part of the additional nutrition information for standard menu items available upon request is currently voluntary. This is an accurate depiction of the status quo. However, given that FDA has ample authority to require the availability of such information, we urge FDA to initiate a rulemaking so that the availability of added sugars information upon request is mandatory, not voluntary.

Indeed, in January 2022, CSPI, Consumer Reports, and Dr. Jason Block, MD, MPH filed a citizen petition requesting that FDA do exactly that: update its menu labeling rules to require chain restaurants to post added sugars information alongside other nutrition information that consumers can request.¹ When FDA initially clarified its thinking on such information, added sugars were not a mandatory part of the Nutrition Facts Label. Now that they are and given that FDA has the authority to extend the additional nutrition information requirements to all nutrients

that must be labeled under 21 U.S.C. § 343(q)(1)(D), it is only logical that FDA require such information, the way it does for all other nutrients on the Nutrition Facts Label. Today, February 12, 2024, we sent a letter to FDA requesting a response to our petition.² This item did not appear in the agency's Spring 2023 Unified Agenda.

Overconsumption of foods and beverages high in added sugars is linked to increased risk of type 2 diabetes^{3,4,5} and cardiovascular disease,^{6,7,8} in part by increasing the risk of weight gain,⁹ and can contribute to dental decay¹⁰The Dietary Guidelines for Americans recommends limiting added sugars to less than 10% of calories (about 12 teaspoons for the 2000-calorie reference diet).¹¹ However, data from the National Health and Nutrition Examination Survey (NHANES) show that from 2017-2020 U.S. consumers aged 2 and above consumed on average nearly 17 teaspoons of added sugars per day.¹²

States and localities are attempting to address overconsumption of added sugars with policies directed at restaurants, but these policies cannot be fully implemented without consistent added sugars disclosure. For example, in November 2023, New York City adopted the Sweet Truth Act, which will require warnings at chain restaurants on menu items that are high in added sugars.¹³ In Maryland, Prince George's County adopted a healthy kids' meals policy in which restaurants must serve at least one children's meal that meets nutrition standards, including a 15g limit on added sugars per meal.¹⁴ But neither policy can be fully implemented if restaurants are not consistently declaring added sugars content, likely the case if such disclosure is voluntary.

In a recent public meeting and series of listening sessions, FDA made a clear public commitment to investigating strategies to reduce added sugars consumption across the U.S.¹⁵ Many groups, including CSPI, submitted comments highlighting mandatory added sugars disclosure for chain restaurants as an important strategy that FDA should prioritize.^{16, 17} In the summary of the November 2023 public meetings about added sugars, FDA noted "General support for mandatory disclosure of added sugars on restaurant menus" and that "Participants stressed the need to align nutrition labeling on packaged foods with requirements on menus."¹⁸ Indeed, harmonizing the menu labeling rules with the Nutrition Facts label would be a simple, straightforward way for the agency to reinforce the importance of added sugars as a nutrient to consider.

For both calorie disclosures for food sold through TPPs and added sugars declarations upon request for standard menu items from Covered Establishments, voluntary guidance is insufficient as history shows there tends to be low uptake of voluntary nutrition labeling policies. For example, a recent study found that calorie disclosures for menus on TPPs, which are currently viewed as voluntary by many Covered Establishments, were present for at least one menu item on only 58% of chain restaurant menus on DoorDash, 51% on Uber Eats, and 12% on Grubhub.¹⁹ Similarly, a 2023 study found that voluntary "Serving Facts" labels for alcoholic beverages were present on only 28% of sampled beers and on no sampled wines.²⁰ There is no reason to expect high uptake of voluntary disclosure of calories on TPPs or voluntary disclosure of added sugars by Covered Establishments.

We look forward to receiving a response from FDA regarding our petition for a final guidance mandating calorie disclosure on menus from Covered Establishments posted to TPPs, and we hope FDA will promptly issue a proposed rulemaking regarding mandatory added sugars disclosure.

Sincerely,

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² Re: Inaction on Citizen Petition Seeking FDA Rulemaking to Update the Required Nutrition Information at Chain Restaurants to Include Added Sugars for Standard Menu Items, submitted January 31, 2022 (FDA-2022-P-0110). Center for Science in the Public Interest. Published February 12, 2024. Accessed February 12, 2024. <u>https://www.cspinet.org/sites/default/files/2024-</u>

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Appendix









February 12, 2024

Division of Dockets Management U.S. Food and Drug Administration 5630 Fishers Lane Room 1061, HFA-305 Rockville, MD 20852 *Submitted electronically via* Docket No. FDA 2013-S-0610

Re: Citizen petition for the U.S. Food and Drug Administration to issue final guidance requiring covered establishments that post and/or maintain menus on third-party platforms to include calories and additional nutrition labeling

To Whom It May Concern:

The undersigned organizations—Center for Science in the Public Interest (CSPI), the American Public Health Association, Consumer Federation of America, and Consumer Reports—submit this petition pursuant to 5 U.S.C. § 553(e), 21 U.S.C. § 343, 21 C.F.R § 101.11(a), and 10 C.F.R § 10.30 requesting that the U.S. Food and Drug Administration (FDA) issue final guidance for industry clarifying that FDA's existing menu labeling regulations apply to menus from covered establishments on third-party platforms (TPPs) such as DoorDash, Grubhub, and Uber Eats. As a consequence of such a guidance, calories would appear on all online menus controlled by covered establishments, the way they currently do for versions of those same menus in stores and on those restaurants'/merchants' websites, and all online menus would communicate that additional nutrition information, such as sodium and saturated fat, is available if requested by the customer.

CSPI, your food and health watchdog, is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept corporate donations and is supported by subscribers to its Nutrition Action magazine and grants from individuals and private foundations. CSPI has a long history of advocating for policies that leverage food labeling to support public health, including health warnings on alcoholic beverages, the mandatory Nutrition Facts panel, rules requiring the disclosure of allergens, calorie counts on chain restaurant menus, and more.

The American Public Health Association (APHA) champions the health of all people and all communities. APHA is the only organization that combines a 150-year perspective, a broad-based member community and the ability to influence policy to improve the public's health.

The Consumer Federation of America (CFA) is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, more than 250 of these groups participate in the federation and govern it through their representatives on the organization's Board of Directors. CFA has advocated for policies to provide consumers with transparent, accurate, and actionable information on food labels for decades.

Founded in 1936, Consumer Reports (CR) is an independent, nonprofit, and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, and provides free content and tools to 6 million members across the U.S. The Consumer Reports website and magazine regularly publishes articles providing its readers with advice based on the nutrition information published by food manufacturers and restaurants, and encourages consumers to use the Nutrition Facts panel information when shopping for food and when dining out.

While a core tenet of the 2020-2025 Dietary Guidelines for Americans (DGA) is the recommendation to "focus on meeting food group needs with nutrient-dense foods and beverages and stay within calorie limits," our diets diverge substantially from this advice.¹ Average calorie intake in the U.S. population increased by 286 calories per day (16%) from 1977 to 2018.² The DGA acknowledges that "the high percentage of the population with overweight or obesity suggests that many people in the United States consume foods and beverages that contribute to a calorie imbalance."³ Poor diet and excess weight are linked to diet-related chronic diseases such as type 2 diabetes⁴ and cardiovascular disease.⁵ Both heart disease and diabetes are among the top 10 leading causes of death in the United States, accounting for 210 and 31 deaths out of every 100,000 deaths, respectively.⁶

Given the high burden of diet-related chronic disease, it is important that Americans have access to tools to help them make informed, nutritious food choices, including while ordering food prepared away from home. Food prepared away from home, which includes restaurant food, restaurant-type food sold at convenience stores and cafeterias, and more, accounts for about one-third of average daily energy intake for people in the United States.⁷ Therefore, population-level interventions that help individuals monitor and regulate their calorie intake from restaurant-type foods are important for improving population health. In 2010, the Affordable Care Act (ACA) amended the Food, Drug, and Cosmetic Act (FDCA) to require that restaurants and similar retail food establishments with 20 or more locations ("Covered Establishments") provide calorie information for standard menu items to customers on a routine basis and that, upon request, Covered Establishments must provide additional, more detailed nutrition information.⁸ Studies evaluating the effects of calorie labeling on consumer behavior have found that calorie labeling on restaurant menus is associated with statistically significant reductions in calories ordered,^{9,10} which could lead to improved health outcomes and health care cost savings.¹¹

It is critical that FDA's food labeling requirements keep pace with changes in how Americans obtain their food. Overall, the number of calories Americans consume through food prepared away from home is increasing,¹² and consumers are ordering takeout and delivery more frequently.¹³ Food ordering is now often facilitated by TPPs.¹⁴ However, customers ordering restaurant-type food from chain restaurants or similar retail establishments via TPPs do not currently have access to the same nutrition information that is available when ordering from those same restaurants' and stores' physical locations or from the restaurants' and stores' own websites.¹⁵

As we describe further below, while TPPs themselves are not Covered Establishments under the ACA, menus from Covered Establishments that are posted and/or maintained on TPPs by the Covered Establishment are covered by the law and subsequent regulations. The majority of menus from Covered Establishments on TPPs are from restaurants that partner with TPPs and can control their own menus,¹⁶ therefore the majority of menus from Covered Establishments are covered by the law. Accordingly, such menus must contain both calorie information and a statement for consumers to request additional nutrition information, as required under the ACA and FDA's menu labeling rule.¹⁷

Unfortunately, FDA has to date failed to interpret its existing authority in this manner. Instead, in December 2023, FDA issued a draft guidance that, by resorting to a voluntary approach, implied that providing calorie disclosures and nutrition information on TPPs is not required.¹⁸ This reflects an underutilization of FDA's existing authority, and a failure to leverage existing FDA regulations to promote transparency and health in our evolving food environment. Given that voluntary labeling initiatives routinely face low uptake by industry, such voluntary guidance is insufficient.

For the menu labeling requirements established under the ACA to have their intended public health impact, consumers must have consistent, easy access to calorie information wherever they view menus from Covered Establishments. Similarly, consumers should be able to access additional nutrition information should they wish to request it when viewing menus from Covered Establishments on TPPs. There is simply no public health justification for a process where consumers do or do not receive critical nutrition information depending on where they happen to shop. We therefore ask FDA to remedy the gap in access to this information by issuing guidance stating that FDA's existing menu labelling requirements apply to menus that Covered Establishments post and/or maintain on TPPs.

A. Action Requested

The petitioners request that FDA issue final guidance for industry clarifying that FDA's existing menu labeling regulations at 21 C.F.R. 101.11 apply to menus from Covered Establishments that are posted and/or maintained by the Covered Establishment on TPPs. These regulations include the requirements that calorie labeling, the succinct statement about recommended daily calorie intake ("Succinct Statement"), and the statement about availability of additional nutrition information ("Statement of Availability") be present on menus, and that such additional nutrition information be made available to consumers upon request. The final guidance should also include guidance on where and how to provide required disclosures for all menus on the Internet.

B. Statement of Grounds

a. General Statement of Grounds

The undersigned organizations first urged FDA to clarify the labeling requirements for menus on TPPs in April 2021, when we sent a letter to the agency requesting guidance clarifying that Covered Establishments must comply with menu labeling requirements when posting their

menus online via TPPs.¹⁹ We reiterated this request in comments at the agency's public meeting on ecommerce in November 2021.²⁰

Members of Congress likewise urged FDA to adopt a guidance clarifying this interpretation of the ACA. In June 2022, the House Report for the FY2023 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill called for FDA to "issue guidance for industry clarifying that restaurants are required to post calorie information at the online point of sale when using third-party platforms to post menus online...".²¹

In September 2023, researchers from CSPI, Tufts University, and New York University published research revealing that, given the lack of clarity on whether calorie disclosures are required for menus on TPPs, most chain restaurants frequently do not include calorie disclosures on those menus, though most do include calorie disclosures on online menus posted to their own websites.²² The study examined menus from 75 U.S. restaurant chains across four locations (1. The restaurants' own website or app, 2. Grubhub, 3. DoorDash, 4. Uber Eats). The authors found significant differences between the labeling of menus on restaurants' own platforms compared to labeling of menus from those same restaurants on TPPs, as well as differences among TPPs (see Figure 1). While 60% of menus posted on restaurants' own websites or apps had calorie information on all items, calories were present all the time on only 27% of menus on DoorDash, 19% of menus on Uber Eats, and 6% of menus on Grubhub. Similarly, 94% of menus on restaurants' own sites had calorie disclosures on at least one menu item, but at least one calorie disclosure was found on only 58% of menus on DoorDash, 51% of menus on Uber Eats, and 12% of menus on Grubhub. There were no instances of a restaurant disclosing calories on a TPP but not on its own website. CSPI shared a pre-print version of the study with FDA in August 2023, requesting that-- as the agency's temporary guidance halting its enforcement of menu labeling regulations during the COVID-19 emergency expires in November 2023-- it issue guidance alerting the industry that enforcement will resume and will apply to menus on TPPs.

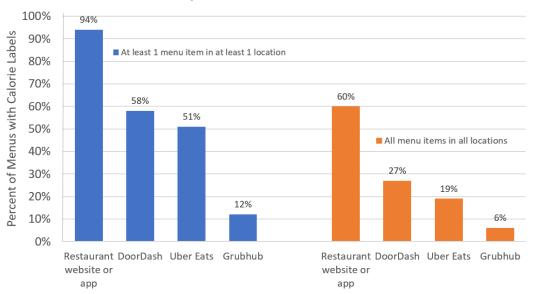


Figure 1: Prevalence of calorie disclosures on Internet menus from the top 75 U.S. chain restaurants, 2022

Source: Greenthal E, Sorscher S, Pomeranz JL, Cash SB. Availability of calorie information on online menus from chain restaurants in the USA: current prevalence and legal landscape. *Public Health Nutr.* 2023;26(12):3239-3246. doi:10.1017/S1368980023001799

However, in December 2023, FDA did the opposite of what CSPI and members of Congress had requested, and issued a draft guidance encouraging voluntary disclosure, implying that providing calorie disclosures, and other nutrition information if requested, on TPPs is not required.²³

b. Statement of Legal Grounds

In 2010, the ACA amended the FDCA to require that Covered Establishments provide consumers with nutrition information. Covered Establishments must (1) disclose on menus "the number of calories contained in"²⁴ standard menu items; (2) make "available on the premises of the restaurant...and to the consumer upon request"²⁵ more detailed nutrition information; and (3) display both "a succinct statement concerning suggested daily caloric intake"²⁶ (Succinct Statement) and "a prominent, clear, and conspicuous statement regarding the availability"²⁷ of the more detailed nutrition information (Statement of Availability) on menus.

These menu labeling requirements apply to all "standard menu item[s]...offered for sale"²⁸ "on the menu"²⁹ "of the"³⁰ Covered Establishment.³¹ Therefore, for the menu labeling requirements to apply, FDA needs only to determine that: (1) the restaurant/merchant is a Covered Establishment,³² (2) the food offered is a "standard menu item,"³³ (3) the writing offering standard menu items for sale meets the definition of "menu," as defined by the ACA and FDA regulations,³⁴ and (4) the menu is the writing "of the" Covered Establishment.³⁵

The first three prerequisites are easily disposed of. First, this Petition is limited to Covered Establishments, which are chain restaurants and "similar [chain] retail food establishments" offering "restaurant-type food," such as "bakeries...coffee shops, [and] convenience stores."³⁶

Second, the petition also addresses only those "standard menu items" subject to menu labeling requirements. These must be "a restaurant-type food," which is a food "[u]sually eaten on the premises, while walking away, or soon after arriving at another location."³⁷ Thus, while a Covered Establishment may list other items on a TPP platform, such as flowers, a bottle of aspirin, or a pack of gum, such items would fall outside the scope of both the menu labeling rule and our petition to the extent that they are not "restaurant-type food" under FDA's definition. Similar retail food establishments like convenience stores are already making decisions in-store and on their own websites and apps about which restaurant-type foods require menu labeling. For example, Image 1 in Appendix A is a screenshot from convenience store chain Casey's menu on its own website showing calorie labeling for pizza, a restaurant-type food. Image 2 in Appendix A is a screenshot from Casey's menu on its own website without calorie labeling for gum, which is not a restaurant-type food. Another convenience store, 7-Eleven, is voluntarily labeling non-restaurant-type foods on their own mobile phone application, as shown by Image 3 in Appendix A. Regardless of what approach restaurants use to determine when to post calories on their own menus, the analysis will be no different for the menus they choose to publish on TPPs.

Third, the FDA has made clear in both its regulations and its recent guidance, that a Covered Establishment's online ordering platform meets the definition of "menu," because it is "the primary writing of the covered establishment from which a customer makes an order

selection."³⁸ Per FDA's regulations, a writing is a "menu" if it "contains the name (or image) and price of a standard menu item, and [it] can be used by a consumer to make an order selection from the establishment at the time the consumer is viewing the writing."³⁹ As demonstrated by Images 4-6 in Appendix A (screenshots of menus from McDonald's on Uber Eats, DoorDash, and Grubhub), menus on TPPs meet this test, because they include the name (or image) and price of menu items, and a consumer can use this information to make an order selection from the establishment at the time the consumer is viewing the writing. Similar retail food establishments' writings on TPPs also meet the definition of "menu" for the same reasons. Image 7 in Appendix A is a screenshot of Casey's Pepperoni Pizza on Uber Eats; the ordering interface includes the pizza name, image, and price, and a button where the consumer can select the pizza while viewing those pieces of information.

FDA regulations promulgated under the ACA also state that this definition of "menu" extends beyond physical menus and includes "menus on the Internet."⁴⁰ And FDA's December 2023 draft guidance acknowledges that "Covered establishments offering online ordering directly through their websites are subject to our menu labeling requirements."⁴¹

FDA has also made clear that "primary writing" is interpreted from the vantage point of a consumer engaged in ordering, regardless of whether a different writing also displays the calorie information.⁴² Thus, when a consumer orders off a McDonald's menu posted on Grubhub, that menu is the "primary writing" from the perspective of the consumer engaged in that transaction, even if they could alternatively view calories and place an order via the McDonald's mobile phone application.

Thus, the only question in dispute is whether the menu a Covered Establishment displays on a TPP is a menu "of the" Covered Establishment.⁴³ In other words, is there a legal distinction between a menu a company posts on its own website and one it posts and/or maintains on the TPP? There is not.

A menu posted and/or maintained by a Covered Establishment on a TPP is that Covered Establishment's menu or, in the ACA's terms, it is the menu "of the" Covered Establishment. After all, no one would call a McDonald's menu that McDonald's posted and/or updated on Uber Eats an "Uber Eats menu." Just as restaurants develop and control menus on their own website and applications, they typically do the same for their menus that consumers view on TPPs. Greenthal et al (2023) found that all three major TPPs allow restaurants/merchants to post and update their own menus, and one TPP (Uber Eats) even provided guidance about how restaurants can include calorie information when posting their menus to the platform.⁴⁴ Appendix B contains screenshots of instructions that Uber Eats, DoorDash, and Grubhub provide to restaurants/ merchants related to the tools and portals restaurants/merchants can use to post and maintain their own menus, and add descriptions that may include calories for those items. Appendix B also includes examples of menu items with calorie information displayed on each of these TPPs, demonstrating that the posting of calories is feasible. Indeed, there is evidence on TPPs that Covered Establishments regularly update their own menus, for example, by showing when items are temporarily out of stock. Although formatting may be different, the menus that companies post on their own websites and apps and the menus that they post and/or maintain on TPPs typically display the same items, images and descriptions. Thus, when a Covered Establishment

uses a TPP to post its menu, there is no factual distinction and, therefore, no legal distinction between a menu on a Covered Establishment's own website, which FDA has already acknowledged requires nutrition labeling, and a menu a Cover Establishment posts and/or maintains on a TPP.

We acknowledge that, in some instances, TPPs or unrelated third parties may upload menus from restaurant websites and enable ordering without a restaurant's permission. In those circumstances, such a menu is at least arguably not a menu "of the" Covered Establishment and fairness favors not applying the menu labeling requirements where labeling decisions are out of the restaurant's control. Accordingly, we are not asking FDA to determine that menu labeling requirements apply to menus on TPPs that are not controlled by the Covered Establishment. However, TPPs Grubhub and DoorDash have stated that the majority of orders on their platforms come from partnered restaurants (*i.e.*, restaurants that have agreed to partner with the TPP by posting and updating their menus using a merchant portal).⁴⁵

As described below, the practice of TPPs uploading menus from non-partnered restaurants should not prevent FDA from issuing the requested guidance, which would cover the majority of Covered Establishment menus on TPPs.

c. Statement of Factual Grounds

I. Nutrition Labeling on TPP Menus Provides Important Public Health Benefits

Despite ongoing public health efforts to improve the American diet, people in the United States generally have poor diet quality^{46,47} and average calorie intake has increased over recent decades.⁴⁸ Data from the National Health and Nutrition Examination Survey (NHANES), 2017-2018, show the average Healthy Eating Index score for Americans aged 2 and older was only 58 out of 100, indicating that the general population is not consistently eating in line with the DGA, which are designed to promote optimal health.⁴⁹ From 1977-2018, average calorie intake increased by about 16%, from 1,807 to 2,093 calories per day.⁵⁰ The United States is also facing unprecedented rates of chronic diseases such as cardiovascular disease and type 2 diabetes, for which obesity is a top risk factor. According to NHANES, 42% of U.S. adults have obesity,⁵¹ which results in part from excess calorie intake.

Restaurant and restaurant-type food plays an important role in the diets of most Americans. A 2023 analysis of 2018 NHANES data found that intake of food prepared away from the home accounted for nearly 32% of daily calorie intake for people in the United States aged 2 and older.⁵² Average calorie intake from food prepared away from the home rose substantially from 345 calories per day in 1977 to 691 calories per day in 2018.⁵³ NHANES data also show that more frequent consumption of food prepared away from home (intake of two or more times per week compared to less than 2 times per week) is associated with poorer diet quality, including lower intake of beans, whole grains, and fruits, and higher intake of saturated fat and added sugars.⁵⁴

Nutrition labeling requirements for menus, established under the ACA, facilitate transparency and are essential to allow consumers to make informed decisions about their health. Since the

menu labeling policy went into effect, FDA has used it to educate consumers about how to make informed and healthful decisions via online educational resources. FDA encourages the use of calories on menus as part of its nutrition education efforts for consumers.⁵⁵⁵⁶ For menu labeling requirements and FDA's nutrition education efforts to have their intended public health impact, consumers must have consistent access to menu labeling information in all locations where they are likely to encounter those menus.

Menu labeling is modestly but significantly associated with a reduction in calories ordered from restaurants,^{57, 58, 59} which could have an impact on obesity and related chronic diseases.⁶⁰ A 2023 quasi-experimental study found that customers exposed to menu labeling purchased an average of 25 fewer calories per transaction when exposed to menu labeling.⁶¹ A meta-analysis that included three randomized controlled trials evaluating calorie labeling found that calorie counts on menus reduced calories purchased by about 8% (47 calories per meal).⁶² Additionally, a quasi-experimental longitudinal study found a decrease of 60 calories per transaction immediately after the menu labeling policy was first implemented, though this was partially attenuated by a small subsequent increase in calories per transaction over the next year.⁶³ Even a small reduction in calories consumed as a result of menu labeling over time could have an important impact on individual and public health.⁶⁴

Data from the 2019 FDA Food Safety and Nutrition Survey show that consumers pay attention to calorie information on menus. About 19% of respondents reported counting calories on a daily basis. When asked if they "ever use calorie information on menus or menu boards to decide what to order," 53% of respondents answered yes. The most frequent self-reported ordering changes made in response to calorie information included "avoid ordering high-calorie menu items" and "decide on a smaller serving size."⁶⁵

There was massive growth in the food delivery sector during the COVID-19 pandemic, with the food delivery market more than tripling between 2017 and 2021.⁶⁶ Research from the U.S. Department of Agriculture (USDA) Economic Research Service (ERS) found that the amount spent per month at full-service restaurants on delivery doubled from \$0.3 billion in December 2019 to \$0.6 billion in June 2022. And a 2023 report published by DoorDash found that 77% of consumers surveyed had ordered delivery in the past month.

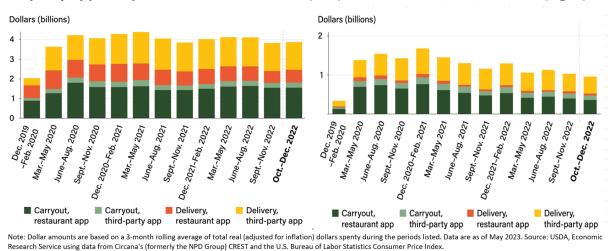


Figure 2. Consumer spending on carryout and delivery via restaurant apps and third party apps at quick-service restaurants (left) and full-service restaurants (right)

Source: Marchesi K. USDA ERS - Pandemic-Related Increase in Consumer Restaurant Spending Using Mobile Apps Continued Through 2022. USDA Economic Research Service. Accessed January 29, 2024. https://www.ers.usda.gov/amber-waves/2024/january/pandemic-related-increase-in-consumer-restaurant-

spending-using-mobile-apps-continued-through-2022/

TPPs play a large and growing role in how Americans order food. Even prior to the start of the pandemic, 41% of adults (including 63% of young adults aged 18-29) used TPPs for food ordering.⁶⁷ As seen above in Figure 2, between December 2019 and June 2022, spending on delivery via TPPs at quick-service restaurants more than tripled, and spending on delivery via TPPs at full-service restaurants quadrupled.⁶⁸. While the initial increase in spending on delivery via TPPs at both full and quick-service restaurants happened in the first few months of the pandemic, TPP spending at quick-service restaurants is holding steady at this increased level.⁶⁹

II. Voluntary guidance is insufficient

As consumer purchasing practices change and online/TPP ordering behaviors increase, consumers will increasingly not have consistent access to calorie disclosures and additional nutrition information until FDA makes disclosure on TPPs mandatory, not voluntary. Voluntary disclosure policies tend to be plagued by low compliance. For example, in 2013, the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau published a voluntary policy allowing manufacturers of beers, wines, and spirits to apply a voluntary "Serving Facts" label. A recent study found that after several years since introduction, the voluntary label was present on only 28% of beers sampled and no wines.⁷⁰

The same pattern is already playing out for voluntary menu labeling on TPPs. Figure 1 shows that in its current voluntary state, uptake of calorie disclosures for menus on TPPs is very low. FDA's draft guidance will likely do little to change the status quo. A mandatory policy is needed to ensure consumers have consistent access to calorie and additional nutrition information on TPPs.

III. Enforcement concerns should not prevent the FDA from issuing clear guidance

The relationship between Covered Establishments and TPPs presents nuanced but surmountable enforcement considerations. As noted above, the FDCA's nutrition labeling requirements and this petition only apply to menus of a Covered Establishment. It is possible for a TPP to post a Covered Establishment's menu without that establishment's knowledge or consent. Therefore, should FDA seek to prosecute a Covered Establishment for introducing misbranded food into commerce by failing to provide calorie information (an act implicating criminal penalties), the agency would need to discern which entity posted or updated the menu. This inquiry may benefit from access to contractual and other records that are not public. Nonetheless, these enforcement considerations should not prevent FDA from taking the requested actions.

The lack of legal distinction between menus that Covered Establishments post on their own websites and those that they post or maintain on TPPs means that Covered Establishments must, by law, comply with the ACA's menu labeling requirements whenever they post or maintain their menus online. In these circumstances, enforcement concerns are not relevant.

However, even for discretionary rulemakings (*i.e.*, those not required by statute), a lack of public information to aid enforcement has generally not prevented FDA from acting in the past. FDA has promulgated numerous rules that are not mandated by statute and hinge on private information, including rules describing the amount of nutrients in a product necessary to make nutrient content claims,⁷¹ and requiring disclosure of added sugar content.⁷²

Moreover, the food industry generally attempts to comply with FDA labeling and other requirements even without the prospect of swift and effective criminal enforcement. For example, a 2020 study found that 94% of the 197 highest grossing Covered Establishments had implemented calorie labeling on their printed menus by May 2018,⁷³ and Greenthal et al (2023)⁷⁴ documented that 94% of restaurant websites and apps posted at least some calorie information as required under FDA rules in 2022, despite FDA never having criminally prosecuted a Covered Establishment for failing to post calories or issuing a warning letter threatening to do so. Furthermore, Greenthal et al (2023) conducted their study when FDA had expressly stated that it would not enforce menu labeling requirements due to the COVID-19 emergency. Yet, restaurants generally complied with the underlying clear regulatory obligation to post such information, meaning fear of prosecution was not a determinative factor in the decision to comply.

Were FDA to enhance compliance with the policy through enforcement action, we expect the agency would be able to initially identify cases to investigate based on publicly available information. For example, some restaurants have public partnerships with TPPs, as evidenced by public announcements⁷⁵ or TPP partners' stickers displayed in restaurants' physical locations (*see* Figure 3). As previously discussed, all major TPPs allow restaurants to post and update their own menus, and Grubhub and DoorDash have stated that the majority of orders on their platforms come from partnered restaurants.⁷⁶ If FDA suspects a compliance issue, before undertaking a more intensive investigation it could contact a Covered Establishment and afford it the opportunity to voluntarily indicate whether a third party controls its menu appearing on a TPP. Regardless, that FDA might need to undertake some investigations to enforce a mandatory

policy, based on publicly available or other information, is not a justification for taking the voluntary route.



Figure 3. Example of stickers at a restaurant's physical location demonstrating their partnerships with TPPs

Photo Source: Tada Images/stock.adobe.com.

IV. Covered Establishments should receive similar guidance regarding where and how to provide menu labeling information on their own websites and applications and on TPPs

Although FDA has made clear that Covered Establishments must comply with menu labeling requirements on their own websites, it has provided little guidance about how and where they should do so. A Covered Establishment must provide three pieces of information on menus themselves (calories, the Succinct Statement, and the Statement of Availability),⁷⁷ and make the required additional nutrition information available upon request.⁷⁸ To date, regarding calories for Internet menus, FDA has only stated that:

If electronic menus or menus on the Internet meet the definition of a menu in the menu labeling final rule...then they must meet the requirements of the menu labeling final rule including listing the number of calories adjacent to the name or price of the associated standard menu item. Calories may not be listed on a webpage or screen that is separate from the associated menu item listed on the electronic or Internet menu.⁷⁹

FDA has not given guidance about where to post the Succinct Statement and the Statement of Availability for online menus. And for the additional nutrition information available upon request, FDA has only stated that this information needs to appear "on the premises"⁸⁰ of a Covered Establishment, and not on the menu itself, and noted: "if a consumer orders from an Internet menu, a covered establishment could provide the written nutrition information on its Web site or include a link directing the consumer to a Web site providing the written nutrition information."⁸¹

Likely as a result of the lack of clarity surrounding how and where to provide the Succinct Statement and Statement of Availability, compliance with requirements to include these statements is substantially lower than compliance with calorie labeling requirements. In Greenthal et al (2023), nearly all chains included calories for at least some items on menus on their own websites or apps (94%), but only 72% included the Succinct Statement and 57% included the Statement of Availability (*see* Figure 4). For TPPs, these statements were rarely provided.

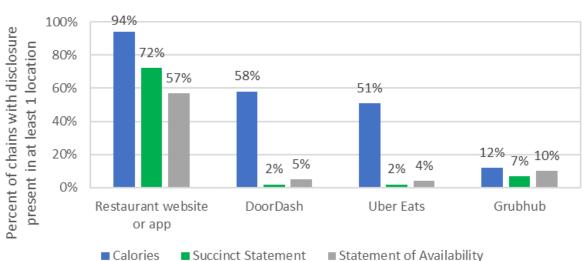


Figure 4. Prevalence of three mandatory disclosures on Internet menus from the top 75 U.S. chain restaurants, 2022

Source: Greenthal E, Sorscher S, Pomeranz JL, Cash SB. Availability of calorie information on online menus from chain restaurants in the USA: current prevalence and legal landscape. *Public Health Nutr.* 2023;26(12):3239-3246. doi:10.1017/S1368980023001799

There is also a need for additional guidance about where to post calories, conveying that they should be visible to the consumer at or prior to the point of selection. Greenthal et al (2023) found that at least one Covered Establishment—Domino's—is only providing calories alongside a menu item in the checkout "Cart" after a customer has already selected that item. FDA should craft additional guidance regarding how and where mandatory menu labeling disclosures should be provided on online menus, and this guidance should apply to Covered Establishments' menus on their own websites and applications, and menus that they control on TPPs.

C. Environmental Impact

Under 21 C.F.R § 10.30(3), petitioners must provide an environmental impact assessment or claim a categorical exclusion from such requirement. The action requested herein is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 (h) and 25.30(k), and therefore does not require the preparation of an environmental assessment. Further, the undersigned believe that the actions requested in this petition would have no environmental impact.

D. Economic Impact

Under 21 C.F.R § 10.30(3), upon request by the Commissioner following review of the petition, petitioners must submit "a statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand."

The Commissioner has not requested a statement of the economic impact of the requested action in this instance. However, the petitioners are providing a brief analysis of the cost to industry. There will be a moderate cost to Covered Establishments associated with updating menus that they control and post and/or maintain on TPPs and that are not currently in compliance with nutrition labeling requirements. However, the benefits will outweigh the costs. In FDA's 2014 Final Rule implementing the ACA labeling requirements, the agency estimated that the benefits of menu labeling would outweigh the costs on both a total and annualized basis over 20 years.⁸² While it is not clear whether this estimate included online labeling in addition to labeling in the physical restaurant environment, the definition of "menu" including "menus on the Internet" implies that it did.⁸³ Even if the cost-benefit analysis did not include online menus, the 2014 Final Rule notes elsewhere that menus on Internet websites are "less expensive menus."⁸⁴ Therefore, a cost-benefit analysis covering only Internet-based menus would presumably be even more favorable. Covered Establishments would not need to undertake new nutrition calculations because they must already post and make available the required nutrition information at their physical locations and on their own websites and applications.

E. Certification

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition. Correspondence related to the petition should be directed to Christina LiPuma at <u>clipuma@cspinet.org.</u>

Signed,

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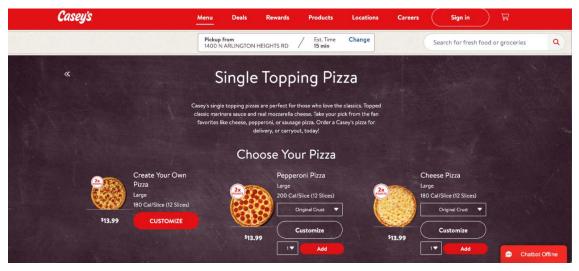
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Appendix A

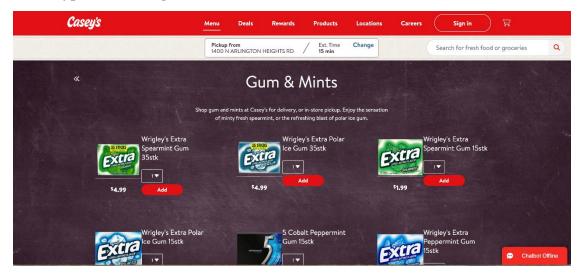
Covered establishments must post calories for restaurant-type foods for menus published on their own platforms, and employ various approaches to determining when such disclosures are made (*see* Images 1-3).

Image 1. Screenshot from convenience store chain Casey's menu on its own website. Calorie labeling is included for pizza, a restaurant-type food.



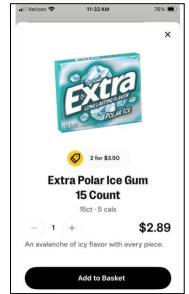
Source: https://www.caseys.com/menu/c/pizza. Accessed February 10, 2024.

Image 2. Screenshot from convenience store chain Casey's menu on its own website. Unlike for restaurant-type foods like pizza, Casey's excludes menu labeling disclosures on non-restaurant-type foods like gum.



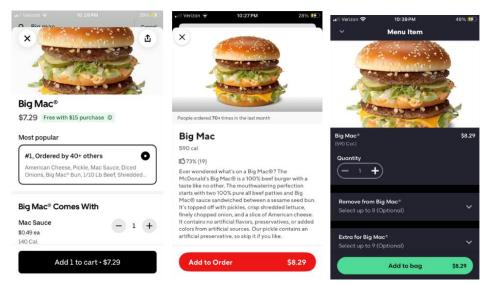
Source: <u>https://www.caseys.com/menu/sweet-treats/c/gummy-chewy-candy</u>. Accessed February 12, 2024.

Image 3. Screenshot from convenience store chain 7-Eleven's web app. 7-Eleven voluntarily posts calories for non-restaurant-type foods like gum, even though such disclosures are only required for restaurant-type foods.



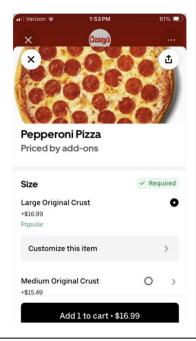
Source: 7-11 mobile phone application. Accessed February 12, 2024.

Images 4, 5, and 6 (from left to right). Screenshots of McDonald's Big Mac on Uber Eats, DoorDash, and Grubhub. Each of these writings is a "menu" of McDonald's meeting the "primary writing" test because each lists (1) the Big Mac's name and image; (2) the Big Mac's price, and (3) a consumer can make an order selection to buy a Big Mac while viewing the name/image and price by clicking the "Add 1 to cart" button on Uber Eats, the "Add to Order" button on DoorDash, or the "Add to bag" button on Grubhub.



Sources: McDonald's menu on Uber Eats mobile application; McDonald's menu on DoorDash application; and McDonald's menu on Grubhub application. All accessed February 11, 2024.

Image 7. Screenshot of convenience store Casey's Pepperoni Pizza on Uber Eats. This writing is a "menu" meeting the "primary writing" test because it (1) lists the name and image of the pizza, (2) the price of the pizza, and (3) a consumer can make an order selection to buy the pizza while viewing the name/image and price by clicking the "Add 1 to cart" button.



Source: Casey's menu on Uber Eats mobile application. Accessed February 9, 2024.

Appendix B

Image 1. The guide that Uber Eats provides to restaurants and similar retail food establishments for posting and maintaining their menus via Uber Eats' Menu Maker tool.



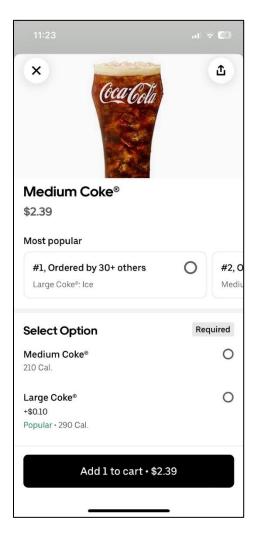
Source: https://uber.app.box.com/s/3qie4bhj7fmhpz4dqkzt5pgxc3x6nuby?uclick_id=e914d182-2760-40d9-88a6-4dfbbcc73df7 via <u>https://www.uber.com/en-GB/blog/your-guide-to-designing-your-menu-with-menu-maker/</u>. Accessed February 9, 2024.

Image 2. Page from Uber Eats' Menu Make guide (the guide that Uber Eats provides to restaurants/merchants for posting and maintaining their menus using Uber Eats' Menu Maker tool) describing how restaurants and similar retail food establishments can add calorie counts to menu items.

Uber Eats	Item details Add calorie counts to an item		
Edit an existing menu The basics	You can easily offer customers calorie information to help them make informed	1 Derrow Mena Molfer Sena	Help E* Log out See chances View online About
Hours Out-of-stock status Photos	choices by following these simple steps:	Deverview Menus Modifier Groups Lunch ~ Menus - Hold Per Ker	See changes View online About
Item details Pricing	 Navigate to the Overview tab of Menu Maker. 	Q Search Jörkams X A + Add Save Pizzas	Note (enjy visible to you) 0 / 400
Modifier group details	2 Click the Item to which you would like to add calorie information. The Edit Item side panel will open.	House Pizza 2 5 11.00 Object of fills: Challes of Fillues 2 5 11.00 State of fills: Challes of Fillues 5 11.00 11.00	Dietary attributes Ø Vegan Ø Végetarian & Gluten-free Energy values
	Olick the Details tab of the side panel.	Fungh Fizza s 1100 Deces ef Sele Conces Fize s 1250	cal kJ When is this item sold? Based on hours of Lunch
	 Scroll to the Energy Values section. Input calories or kilojoules in the gray boxes. 	Garden Pizza Onice efficie 8 13.50 Broccoli Pizza	Temperature () Heated Unheated Cold
	Glick the black Save button.	Contract filling South of filling Add Item	is this correct? V X External ID External data
Related topics		Salads Strawberry Spinach Salad 8 1350	
> Change item pricing		Kale Cansar Salid S 1350	

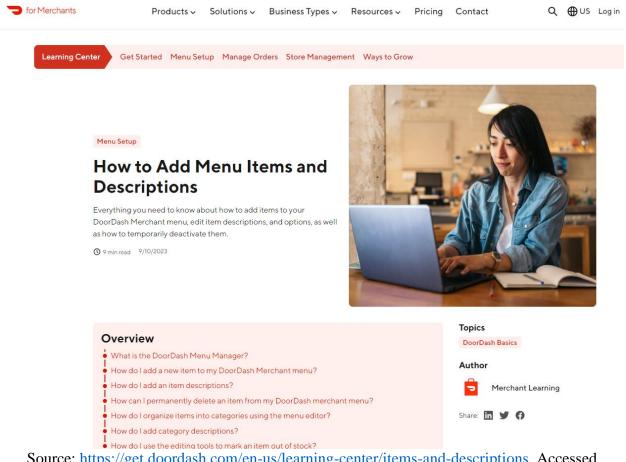
Source: <u>https://uber.app.box.com/s/3qie4bhj7fmhpz4dqkzt5pgxc3x6nuby?uclick_id=0bb6f5d5-</u>9b51-4e27-93da-b3dd98410ea9 via <u>https://www.uber.com/en-GB/blog/your-guide-to-designing-your-menu-with-menu-maker/</u>. Accessed February 9, 2024.

Image 3. Screenshot of Medium Coke with calorie disclosure on McDonald's menu on Uber Eats mobile application.



Source: McDonald's menu on Uber Eats mobile application. Accessed February 12, 2024.

Image 4. Screenshot from DoorDash's Learning Center for merchants explaining how merchants can add menu items and descriptions to their menus on DoorDash.



Source: https://get.doordash.com/en-us/learning-center/items-and-descriptions. Accessed

February 12, 2024.

Image 5. Screenshot of presentation by DoorDash describing how restaurants and other merchants can use DoorDash's Menu Manager tools to post and maintain their menus. Calories may be added as part of the item description.

	iood Delivery Self x rtalmage (1312x704) x rtalmage (1312x704) x rosty Bear of Lo h.com/merchant/menu/v2/2258263?store_id=1837176	s Angeles Deli × + ① ☆ 〇 〇 🏻 🇰 ጵ 🔲 (
	n.com/merchanymenu/vz/zz56265?store_iu=1657176	
	< Dashboard	Item
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	-	O You can edit the availability of this item after saving.
	Overview Modifiers	
		Name Red
Hello Los Angeles 🗸	Hello Los Angeles 🗸	E.g. "Nachos"
	Appetizers Oitems	Phice
	Hidden from customers until at least 1 item is added.	s
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	+ Add Item	%
	+ Add Category	
	Category	Description
	Salads 2 items	Add a mouthwatering description to help customers decide what to order. Include things like preparation methods, ingredients and anything that
	Caesar Salad	makes the item unique.
	● 3:2726:1Qt kat	🗌 This item contains alcomer 💿 🚥 💠 🔳 🔚
	r: Small Menu Changes for Big Impact	

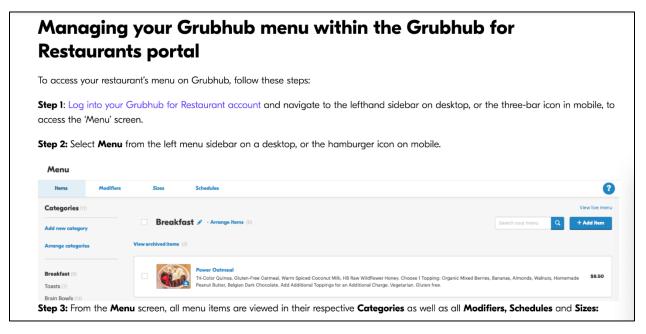
Source: <u>https://www.youtube.com/watch?v=jqPiLf5dWMU&t=536s</u>. Accessed February 12, 2024.

Image 6. Screenshot of Coke with calorie disclosure on McDonald's menu on DoorDash mobile application. The merchant apparently included calorie disclosures by entering them into the Description field.

11:38	al 🗟 41
×	
Coke®	
210 - 290 cal	
Select Size A Required • Select 1 O Medium 210 cal	
O Large 290 cal	
O Small 150 cal	
Pomovo from Caka®	
Make 1 required selection	\$1.85

Source: McDonald's menu on DoorDash mobile application. Accessed February 12, 2024.

Image 7. Screenshot from the Grubhub for Restaurants portal help center showing that restaurants can post and maintain their own menus on Grubhub.



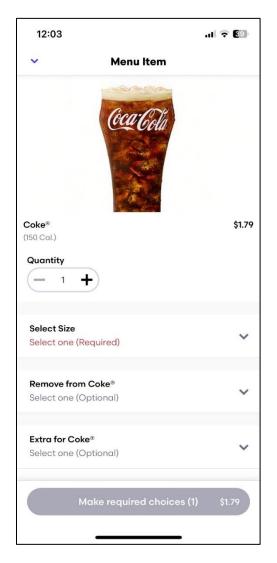
Source: <u>https://get.grubhub.com/help-center/grubhub-menu-overview/.</u> Accessed February 10, 2024.

Image 8. Screenshot from the Grubhub for Restaurants portal help center showing how restaurants and other merchants can use the portal to add and update menu items. Calories may be added as part of the item descriptions.

* Name		
Market Berry Bowl		
Description		
Mixed Organic Berries, HB Raw Wildflower	Honey, Mint. Vegetarian & Gluten-free	
Base price	* Menu category	
One size Multiple sizes	Healthful Snacks	v
	Healthful Shacks	-
\$8.50		
om Info and Modifiers tab, you can updo	ate:	
Item name		
Description		
Menu section		
Menu section Base price		
Base price		

Source: <u>https://get.grubhub.com/help-center/grubhub-menu-overview/.</u> Accessed February 12, 2024.

Image 9. Screenshot of Coke with calorie disclosure on McDonald's menu on Grubhub mobile application. The merchant apparently included calorie disclosures by entering them into the Description field.



Source: McDonald's menu on Grubhub mobile application. Accessed February 12, 2024.

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⁸ See Menu Labeling Requirements, U.S. Food and Drug Administration ("FDA") (January 11, 2024), https://www.fda.gov/food/food-labeling-nutrition/menu-labeling-requirements; see also 21 U.S.C. § 343(q)(5)(H)(ii) (setting forth the nutrition labeling requirements).

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²¹ H.R. Rep. 117-392, at 93 (2023).

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2?utm_medium=email&utm_source=govdelivery

²⁴ 21 U.S.C. § 343(q)(5)(H)(ii)(I)(aa).

²⁵ 21 U.S.C. § 343 (H)(ii)(III).

²⁶ 21 U.S.C. § 343(q)(5)(H)(ii)(I)(bb).

²⁷ 21 U.S.C. § 343(q)(5)(H)(ii)(IV).

²⁸ 21 U.S.C. § 343(q)(5)(H)(i).

²⁹ 21 U.S.C. § 343(q)(5)(H)(ii)(I)(aa), (bb); 21 U.S.C. § 343(q)(5)(H)(ii)(IV).

³⁰ 21 U.S.C. § 343(q)(5)(H)(xi).

³¹ 21 U.S.C. § 343(q)(5)(H)(i).

³² 21 U.S.C. § 343(q)(5)(H)(i)

³³ 21 U.S.C. § 343(q)(5)(H)(i).

³⁴ 21 U.S.C. § 343(q)(5)(H)(xi); 21 C.F.R. § 101.11(a).

³⁵ 21 U.S.C. § 343(q)(5)(H)(xi).

³⁶ 79 Fed. Reg. 71157.

³⁷ 21 C.F.R. § 101.11(a). "Restaurant-type food means food that is (i) Usually eaten on the premises, while walking away, or soon after arriving at another location; and (ii) Either: (A) Served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or (B) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in paragraph (ii)(A) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale.

38 21 C.F.R. § 101.11(a).

³⁹ 21 C.F.R 101.11(a).

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