

January 4, 2024

James Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Deputy Commissioner Jones,

We write to request a meeting with you regarding the agency's recent release of draft Edition 2 of its Menu Labeling Supplemental Guidance for Industry. The guidance includes two requested voluntary actions related to chain restaurants: the posting of calorie information on menus by chain restaurants on third party platforms such as Grubhub, Uber Eats, and Doordash, and the inclusion of added sugars information as part of the nutrition information that is to be made available to consumers.

In a press statement on December 15th 2023,² and at the in-person FDA/Consumer Nutrition Stakeholder Meeting on December 18th, the Center for Science in the Public Interest (CSPI) communicated our disappointment that the draft guidance fails to clarify that existing FDA regulations already make calorie labeling mandatory for menus on the Internet, including menus that are posted by covered establishments on third-party platforms (TPPs). The draft guidance instead tells covered establishments that providing this information is voluntary, and also describes voluntary disclosure of added sugars information.

We are concerned that the agency is suggesting that industry take only voluntary action to provide important nutrition information to consumers, when the agency has authority under the Food, Drug, and Cosmetic Act (FDCA) to compel mandatory disclosures and has failed to exercise it.

CSPI first urged the agency to clarify its guidance for menus posted to TPPs in April 2021, when we, along with five other consumer and health advocacy organizations, sent a letter to FDA requesting that the agency clarify that covered establishments must comply with menu labeling requirements when posting their menus online via TPPs.³ Our letter highlighted how such information was needed because use of TPPs to order restaurant food has soared in recent years.

restaurant-industry-disclosing-calories-menus-delivery-platforms. Accessed December 21, 2023.

¹ U.S. Food and Drug Administration. Menu Labeling: Supplemental Guidance for Industry (Edition 2). Draft Guidance. December 2023. https://www.fda.gov/media/174528/download. Accessed December 21, 2023. https://www.spinet.org/statement/fda-flubs-guidance- Center for Science in the Public Interest. December 15, 2023. https://www.cspinet.org/statement/fda-flubs-guidance-

³ Center for Science in the Public Interest, American Heart Association, American Public Health Association, Center for Digital Democracy, Consumer Federation of America, Consumer Reports. Consumer Groups' letter to FDA re: menu labeling on third party platforms. April 1, 2021. https://www.cspinet.org/resource/consumer-groups-letter-fda-re-menu-labeling-third-party-platforms. Accessed December 21, 2023.

The FDCA, as amended by the Affordable Care Act of 2010, requires that calorie information be posted on the menus of certain chain restaurants, referred to as "covered establishments." While we agree with FDA⁵ that TPPs are not themselves covered entities subject to menu labeling requirements, our letter asked the agency to clarify that the chain restaurants that post menus on these platforms are nevertheless responsible for ensuring that such menus comply with the statute. FDA regulations define menus as "the primary writing of the covered establishment from which a customer makes an order selection, including, ... menus on the Internet." Menus posted by chain restaurants on TPPs are the primary writing from which customers make an order selection, and are the "writing of the covered establishment" because TPPs allow restaurants to post and modify the content of such menus themselves.

We note that, because FDA regulations define a menu as the "primary writing of the covered establishment," calorie labeling should only be required where it is the covered entity that posts its menu on the TPP. Because it is theoretically possible for covered entities menus to be posted on TPPs without the knowledge or consent of a covered entity, FDA will need to discern who posted the menu should it seek to enforce the requirement. That may raise enforcement challenges similar to other rules where compliance information is contained in private records, such as the declaration for "added sugars," which is calculated based on recipes that are not published. Nevertheless, such challenges should not preclude creation of an effective policy that clearly communicates to industry their legal obligations to disclose.

In addition, enforcement can be facilitated by publicly available evidence of the relationship between the covered entity and the TPP, such as public announcements, or public terms of service showing that covered entities have control over the menus they post. For example, researchers from CSPI recently relied on publicly available customer service information to document that DoorDash, Uber Eats, and Grubhub allow covered establishments to control their own menu information, including by posting calorie disclosures, in an analysis that was published in *Public Health Nutrition* in September 2023. These three platforms together account for 96 percent of meal delivery sales, meaning a policy covering menus posted on the platforms would have extensive impact.

⁴ 21 CFR § 101.11(a) ("Covered establishment means a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name [regardless of the type of ownership, e.g., individual franchises] and offering for sale substantially the same menu items…")

⁵ Reiley L. Food delivery apps are exempt from posting nutrition information. This loophole has added to our pandemic pounds, advocates say. *Washington Post*. April 1, 2021.

https://www.washingtonpost.com/business/2021/04/01/food-delivery-apps-calorie-labeling/. Accessed December 21, 2023. ("Third-party ordering websites were not covered in the ACA language, so they are not required to comply... an FDA spokeswoman said.")

⁶ 21 C.F.R. § 101.11(a) (emphasis added).

⁷ Lucas A. McDonald's adds GrubHub as its latest delivery partner in New York City area. *CNBC*. September 5, 2019. https://www.cnbc.com/2019/09/05/mcdonalds-adds-grubhub-as-its-latest-delivery-partner.html. Accessed December 21, 2023.

 ⁸ Greenthal E, et al. Availability of calorie information on online menus from chain restaurants in the USA: current prevalence and legal landscape. *Pub Health Nutr.* 2023;26(12):3239-3246.
 ⁹ Kaczmarski M. Which company is winning the restaurant food delivery war? *Bloomberg Second Measure*.

⁹ Kaczmarski M. Which company is winning the restaurant food delivery war? *Bloomberg Second Measure*. December 11, 2023. https://secondmeasure.com/datapoints/food-delivery-services-grubhub-uber-eats-doordash-postmates/. Accessed January 2, 2024.

Unfortunately, rather than clarify that labeling requirements for menus on the internet extend to menus posted by chain restaurants on TPPs, FDA has done the opposite, stating in draft guidance that providing nutrition information through TPPs is a voluntary option rather than a mandatory requirement.

We also have concerns with the agency's failure to initiate mandatory rulemaking to require disclosure of added sugars information for restaurant menu items, the second topic of the recent draft guidance. In January of 2022, CSPI, along with others, petitioned FDA to update its menu labeling rules to require restaurants to post added sugars information alongside other nutrition information that consumers can request. ¹⁰ The original menu labeling rule was finalized in 2014 and included only disclosures for total sugars. ¹¹ It was not until 2 years later that FDA updated its regulations for the Nutrition Facts Panel to require added sugars information to be disclosed for packaged foods in addition to total sugars. ¹² However, the agency has not similarly updated its menu labeling regulations, leaving a discrepancy.

Added sugars information is needed to assist consumers in maintaining healthy dietary practices because the U.S. Dietary Guidelines advise to limit consumption of this nutrient. ¹³ It is also important for state and local policymakers and researchers to develop and assess policies designed to reduce added sugars in restaurant meals. For example, in November of this year, New York City adopted the Sweet Truth Act, which will require warnings on menu items that are high in added sugars. ¹⁴ However, until FDA requires restaurants to disclose added sugars information, most restaurant items will not be subject to the New York City law. ¹⁵

Under the FDCA, FDA has clear authority to require restaurants to publish added sugars information if the agency determines that it "should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices." FDA already leveraged nearly identical authority to require added sugars disclosure in the Nutrition Facts label, so there is no question that it could similarly require the declaration for restaurants. Harmonizing the menu labeling rules with the Nutrition Facts label is also a simple, straightforward way for the agency to reinforce the importance of added sugars as a nutrient to consider, thus facilitating reductions in added sugars consumption. Unfortunately, the agency has to date not responded to our petition by indicating it will engage in rulemaking to correct the

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¹⁰ Lurie P, et al. Citizen petition seeking FDA rulemaking to update the required nutrition information at chain restaurants to include added sugars for standard menu items. Center for Science in the Public Interest. January 31, 2022. https://www.cspinet.org/sites/default/files/2022-02/Petition_Menu_Labeling_Added_Sugars.pdf. Accessed December 21, 2023.)

¹¹ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Final Rule, 79 Fed. Reg. 71156, 71212 (December 1, 2014).

¹² Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule, 81 Fed. Reg. 33744 (May 27, 2016).

¹³ U.S. Department of Health and Human Services, U.S. Department of Agriculture. *Dietary Guidelines for Americans*, 2020 – 2025. 9th Ed. Dec. 2020. https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary Guidelines for Americans 2020-2025.pdf. Accessed December 21, 2023.

¹⁴ The New York City Council. File # Int 0687-2022. Law no. 2023/150.

¹⁵ Center for Science in the Public Interest. *NYC Mayor Eric Adams signs Sweet Truth Act*. November 17, 2023. https://www.cspinet.org/press-release/nyc-mayor-eric-adams-signs-sweet-truth-act. Accessed December 21, 2023. ¹⁶ 21 U.S.C. 343 (q)(5)(H)(vi).

¹⁷ 21 U.S.C. 343 (q)(2)(allowing additional nutrients "for the purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices").

discrepancy in the menu labeling rule, and this item does not appear in the Current Unified Agenda. 18

Given that FDA has clear authority to require disclosure of both calories in menus posted on TPPs and added sugars in restaurant nutrition information, it is unacceptable that the agency has chosen not to initiate such actions.

Last year, the Reagan-Udall Foundation issued a report on FDA's human foods program calling out the agency for an "aversion to risk that undercuts its ability to meet its public health mandate" and calling on the agency to be bolder in exercising its authority. ¹⁹ Unfortunately, the recent guidance reflects a "business as usual" approach to agency decision-making, in that the agency fails to use its full authority to protect consumer health, falling back instead on voluntary action by industry.

We appreciate that you are seeking to foster robust dialogue and partnership with stakeholders. To that end, we would like to request a meeting with you and the FDA staff involved in drafting the guidance, as well as any legal counsel who advised the agency on this set of issues, to discuss the agency's approach. Please direct responses to Sarah Sorscher, ssorscher@cspinet.org, 202-777-8397.

Sincerely,

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Dr. Claudine Kavanaugh, Director, Office of Nutrition & Food Labeling, CFSAN

¹⁸ U.S. Office of Information and Regulatory Affairs. *Agency Rule List – Fall 2023*. https://www.reginfo.gov/public/do/eAgendaMain. Accessed December 21, 2023.

¹⁹ Henney JE, et al. *Operational Evaluation of the FDA Human Foods Program*. Reagan-Udall Foundation for the FDA. December 6, 2022. https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf. Last Accessed December 21, 2023.