



February 12, 2024

James Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Submitted via email to: Jim.Jones@fda.hhs.gov

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)

Dear Deputy Commissioner Jones,

The Center for Science in the Public Interest (CSPI) submits this letter requesting a meeting to discuss the status of the citizen petition we submitted to the Food and Drug Administration (FDA) on January 31, 2022,¹ as well as concerning draft Guidance recently issued by the Agency.

Our petition requested that FDA amend 21 C.F.R. § 101.11(b)(2)(ii) to include added sugars among the nutrients for which information is required to be available in written form on the premises of covered establishments and provided to the customer on request.

CSPI submitted this petition two years ago with co-petitioners Consumer Reports and Dr. Jason Block MD, MPH. In the petition, we identified the need to harmonize the nutrition information required by law for chain restaurants with the information required by the Food and Drug Administration (FDA) in the Nutrition Facts label² to enable consumers to make informed choices and maintain healthy dietary practices when ordering from restaurants.³ That need has only increased since we filed our petition, as two local jurisdictions (New York City, NY and Prince George's County, MD) have passed restaurant nutrition policies that hinge upon a change in federal rules on added sugars (discussed further below), and the White House has identified added sugar reduction as a federal priority.

¹ Regulations.gov. Petition to Update the Required Nutrition Information at Chain Restaurants to Include Added Sugars. Posted by the Food and Drug Administration. February 1, 2022. <https://www.regulations.gov/docket/FDA-2022-P-0110>. Accessed January 24, 2024.

² See Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule, 81 Fed. Reg. 33741 (May 27, 2016) [Hereinafter: Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule].

³ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 STAT. 119 § 4205, *codified as* 21 U.S.C. § 343(q)(5)(H)(ii)(III).

The 2020-2025 Dietary Guidelines for Americans recommend limiting added sugar intake to 10 percent of daily calories from age 2 onwards.⁴ Yet past and current consumption levels surpass this recommendation, with adults and children in every age group regularly exceeding the daily limit for added sugars.⁵ The average American consumes 17 teaspoons of added sugars per day (13% of total daily calories),⁶ which is over 30% more added sugars than recommended for a healthy diet.⁷ As our petition details, restaurant foods and beverages are a significant source of added sugars in the American diet, contributing 20% of total daily added sugars intake,⁸ Notably, the average default fast food combination meals in the U.S. contains 68 grams of total sugar, with a substantial portion coming from beverages sweetened with added sugars.⁹ *Sweet Excess*, a report published in 2021 by CSPI, compared added sugars in fountain drinks at the largest fast food chains and found that even most “small” drinks exceed the 50-gram daily recommended value (DRV) for added sugars.¹⁰ Overconsumption of foods and beverages high in added sugars is linked to increased risk of type 2 diabetes^{11,12,13} and cardiovascular disease,^{14,15,16} in part by increasing the risk of weight gain,¹⁷ and can contribute to dental decay.¹⁸ But consumers currently have no way of determining the added sugars content of these products.

⁴ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

⁵ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

⁶ U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS). Food Patterns Equivalents Intakes from Food: Mean Amounts Consumed per Individual, by Gender and Age, What We Eat in America, NHANES 2017-March 2020 Prepandemic. 2023.

https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/fped/Table_1_FPED_GEN_1720.pdf. Accessed January 24, 2024.

⁷ U.S. Department of Agriculture (USDA) and U.S. Department of Health and Human Services (USDHHS). Dietary Guidelines for Americans, 2020-2025. December 2020. https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf. Accessed January 24, 2024.

⁸ USDA ERS. Average daily intake of food group by food source and demographic characteristics, 2017-18. 2021. <https://www.ers.usda.gov/data-products/food-consumption-and-nutrient-intakes/>. Accessed January 24, 2024.

⁹ Vercammen, K. A., et al. (2019). Calorie and Nutrient Profile of Combination Meals at U.S. Fast Food and Fast Casual Restaurants. *American journal of preventive medicine*, 57(3), e77–e85.

¹⁰ As described *infra*, CSPI assumed all of the sugars in fountain drinks were from added sugars in order to create this report. Center for Science in the Public Interest, 2021.

¹¹ Drouin-Chartier JP, et al. Changes in consumption of sugary beverages and artificially sweetened beverages and subsequent risk of type 2 diabetes: Results from three large prospective U.S. cohorts of women and men. *Diabetes Care*. 2019;42(12):2181-2189.

¹² Imamura F, O’Connor L, Ye Z, Mursu J, Hayashino Y, Bhupathiraju SN, Forouhi NG. Consumption of sugar sweetened beverages, artificially sweetened beverages, and fruit juice and incidence of type 2 diabetes: Systematic review, meta-analysis, and estimation of population attributable fraction. *BMJ*. 2015;351:h3576.

¹³ Neuenchwander M, Ballon A, Weber KS, Norat T, Aune D, Schwingshackl L, Schlesinger S. Role of diet in type 2 diabetes incidence: Umbrella review of meta-analyses of prospective observational studies. *BMJ*. 2019;365:12368.

¹⁴ Narain A, Kwok CS, Mamas MA. Soft drinks and sweetened beverages and the risk of cardiovascular disease and mortality: A systematic review and meta-analysis. *Int J Clin Pract*. 2016;70(10):791-805.

¹⁵ Bergwall S, Johansson A, Sonestedt E, Acosta S. High versus low-added sugar consumption for the primary prevention of cardiovascular disease. *Cochrane Database Syst Rev*. 2022;1(1):CD013320.

¹⁶ Yang Q, Zhang Z, Gregg EW, Flanders WD, Merritt R, Hu FB. Added sugar intake and cardiovascular diseases mortality among US adults. *JAMA Intern Med*. 2014;174(4):516.

¹⁷ Nguyen M, Jarvis SE, Tinajero MG, Yu J, Chiavaroli L, Mejia SB, Khan TA, Tobias DK, Willett WC, Hu FB, Hanley AJ. Sugar-sweetened beverage consumption and weight gain in children and adults: A systematic review and meta-analysis of prospective cohort studies and randomized controlled trials. *Am J Clin Nutr*. 2023;117(1):160-174.

¹⁸ Valenzuela MJ, Waterhouse B, Aggarwal VR, Bloor K, Doran T. Effect of sugar-sweetened beverages on oral health: A systematic review and meta-analysis. *Eur J Public Health*. 2020;31(1):122-129.

Clear and consistent federal requirements must be the goal. The FDA has established a way for consumers to distinguish between added and naturally occurring sugars, in the form of the Nutrition Facts Label. Such information is important for consumers, and the lack of comparable information on restaurant menus impedes consumers' ability to make informed choices. The agency can help address this gap by requiring chain restaurants to publish added sugars information, enabling consumers to access such vital information consistently, without relying on patchwork voluntary disclosures from restaurants.

The petition docket reflects broad and deep public support and conveys a clear message to the agency to take decisive action. Following receipt of the petition, the FDA received comments supporting the petition from 4,700 members of the public.¹⁹ On July 18, 2022, the New York City Department of Health and Mental Hygiene (DOHMH) and the Mayor's Office of Food Policy also submitted a comment supporting the petition,²⁰ and on May 11, 2022, the following organizations signed on to a group comment in support of our petition: Society of Behavioral Medicine, UConn Rudd Center for Food Policy & Health, Association of State Public Health Nutritionists, Jump IN for Healthy Kids, and Foodicine Health Inc.²¹ There were no comments indicating opposition to our petition.

The agency acknowledged receipt of the petition on February 1, 2022,²² and on July 18, 2022, provided an interim response advising that it had not reached a decision on the petition because of other agency priorities and limited resources.²³ To date, the agency has not responded substantively to our petition, and has not indicated it will undertake rulemaking in the most recent Spring 2023 Unified Agenda.²⁴

FDA has clear legal authority to grant our petition by requiring a declaration for added sugars upon request, providing Americans with access to added sugars information across all FDA-regulated foods. First, the FDA has authority under the Affordable Care Act (ACA) of 2010 to require restaurant or similar retail establishments that are part of a chain of 20 or more²⁵ to make nutrition information for standard menu items available to consumers upon request.²⁶ While added sugars are not specifically required to be made available under the ACA,²⁷ FDA has clear discretion to require such disclosure if it finds that added sugars "should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices."²⁸

¹⁹ Regulations.gov. Letter Comment from Center for Science in the Public Interest (multiple signatures) <https://www.regulations.gov/comment/FDA-2022-P-0110-0003>. Accessed January 24, 2024.

²⁰ Regulations.gov. Comment from New York City Department of Health and Mental Hygiene. <https://www.regulations.gov/comment/FDA-2022-P-0110-0006>. Accessed January 24, 2024.

²¹ Regulations.gov. Comment from Center for Science in the Public Interest et al. <https://www.regulations.gov/comment/FDA-2022-P-0110-0004>. Accessed January 24, 2024.

²² Regulations.gov. Acknowledgment Letter from FDA DMS to Center for Science in the Public Interest. February 1, 2022. <https://www.regulations.gov/document/FDA-2022-P-0110-0002>. Accessed January 24, 2024.

²³ Regulations.gov. 180 Day Interim Response Letter from FDA CFSAN to Center for Science in the Public Interest July 20, 2022. <https://www.regulations.gov/document/FDA-2022-P-0110-0005>. Accessed January 24, 2024.

²⁴ U.S. Office of Information and Regulatory Affairs. Agency Rule List – Fall 2023. <https://www.reginfo.gov/public/do/eAgendaMain>. Accessed January 24, 2024. (15_Agency Rule List - Fall 2023, search for "added sugar" or "menu" reveals nothing)

²⁵ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 STAT. 119 § 4205, *codified as* 21 U.S.C. § 343(q)(5)(H)(iii).

²⁶ 21 U.S.C. § 343 (H)(ii)(iii).

²⁷ 21 U.S.C. § 343(5)(H)(vi).

²⁸ 21 U.S.C. 343 (q)(5)(H)(vi). (13_21 U.S. Code § 343_page 15)

FDA used that authority when it issued its proposed rule for menu labeling in 2011, requiring that restaurants disclose *trans*-fat upon request.²⁹

Second, added sugars clearly meet the standard for disclosure. FDA already determined that added sugars must be disclosed in the Nutrition Facts label, which relies on a separate statutory authority whose standard is identical (i.e., FDA may require disclosure upon finding that such disclosure “will assist consumers in maintaining healthy dietary practices”). This is why the agency required added sugars to be disclosed when it issued its final rule updating the Nutrition Facts label in 2016.³⁰ There is no question that the agency could similarly require the declaration for restaurants, harmonizing the two rules as the agency has previously done for *trans* fats.

Action on this petition is not only well within the agency’s authority, but also compatible with congressional and White House administration nutrition priorities. Language in the House Report for the FY2023 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill aligned with our request and called for FDA to “issue regulations updating its menu labeling rules to disclose added sugars in additional nutrition information.”³¹ Additionally, in September 2022, the White House/Biden-Harris Administration hosted a White House Conference on Hunger, Nutrition, and Health, while co-releasing the *White House Strategy on Hunger, Nutrition, and Health*, a comprehensive national strategy to end hunger and promote healthier eating. The strategy focuses on five pillars, the third of which addresses the need to, “*Empower All Consumers to Make and Have Access to Healthy Choices*”.³²

Requiring added sugars disclosure for standard menu items would help to meet specific goals within this pillar including empowering consumers with updated and more accessible food labeling, creating healthier food environments, and lowering added sugars consumption.³³

The White House Strategy also included specific directives to FDA, including holding a public meeting regarding future steps the federal government could take to reduce intake of added sugars.³⁴ In response, on November 6-8th, 2023, FDA held a virtual public meeting followed by virtual public listening sessions, where the agency made a clear public commitment to investigating strategies to reduce added sugars consumption across the U.S.³⁵ Many groups,

²⁹ Food Labeling; Nutrition Labeling of Standard Menu Items, Proposed Rule, 76 Fed. Reg. at 19212.

The FDA also declined to require that restaurants report complex carbohydrates, as this nutrient, while required under the statute, had been removed by the agency from Nutrition Facts regulations.

³⁰ 81 FR 33742. Food Labeling: Revision of the Nutrition and Supplement Facts Labels.

<https://www.govinfo.gov/content/pkg/FR-2016-05-27/pdf/2016-11867.pdf>

³¹ H.R. Rep. 117-392, at 93 (2023).

³² The White House, 2022. <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>. Accessed January 24, 2024.

³³ Ibid. Pg 22-23.

³⁴ Ibid. Pg 23.

³⁵ Virtual Public Meeting and Listening Sessions on Strategies to Reduce Added Sugars Consumption in the United States - 11/06/2023 | FDA. U.S. Food and Drug Administration. <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/virtual-public-meeting-and-listening-sessions-strategies-reduce-added-sugars-consumption-united>. Accessed January 24, 2024.

including CSPI, testified at the meeting and submitted comments highlighting mandatory added sugars disclosure for chain restaurants as an important strategy that FDA should prioritize.^{36,37}

Yet, in December 2023, only one month after the conference, FDA released draft Edition 2 of its Menu Labeling Supplemental Guidance for Industry, stating that including added sugars as part of the additional nutrition information for standard menu items available upon request is currently voluntary.³⁸ While the guidance accurately describes the status quo (namely, restaurants are permitted to voluntarily include added sugars information), it does not respond to our petition, which requested that FDA initiate a rulemaking so that added sugars declarations would be mandatory, not voluntary.

Offering guidance on voluntary added sugars labeling is unlikely to have an impact on disclosure, because chains are already aware they can voluntarily label for added sugars. This is demonstrated by the fact that a small number of large restaurant chains are already disclosing this information, including the following: Cold Stone Creamery,³⁹ Dominos,⁴⁰ Smoothie King,⁴¹ Dunkin Donuts,⁴² McDonalds,⁴³ KFC,⁴⁴ Taco Bell,⁴⁵ and Cinnabon.⁴⁶

Overall, however, voluntary labeling policies tend to lead to low uptake and are not sufficient for ensuring access to important nutrition information. For example, 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.⁴⁷

Stronger action is needed. 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

³⁶ Regulations.gov. Comment from Center for Science in the Public Interest

<https://www.regulations.gov/comment/FDA-2023-N-3849-0412>. Accessed January 24, 2024.

³⁷ Regulations.gov. Comment from SSB Reduction Workgroup (coalition of U.S. non-government organizations, public health advocates, and academics) <https://www.regulations.gov/comment/FDA-2023-N-3849-0410>. Accessed January 24, 2024.

³⁸ 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 January 24, 2024.

³⁹ Ice Cream, Sorbet and Frozen Dessert Nutritional Information (n.d). https://www.coldstonecreamery.com/nutrition/pdf/CSC_Nutrition%20Info-Ice%20Cream_Sorbet.pdf. Accessed January 24, 2024.

⁴⁰ Domino’s Nutrition Guide. August 2023. https://cache.dominos.com/olo/6_124_2/assets/build/market/US/_en/pdf/DominosNutritionGuide.pdf. Accessed January 24, 2024.

⁴¹ Nutrition Information. Smoothie King. (n.d.). <https://www.smoothieking.com/menu/smoothies/nutrition/smoothie-bowls>. Accessed January 24, 2024.

⁴² Nutrition Guide. Dunkin Donuts. December 13, 2023.

<https://www.dunkindonuts.com/content/dam/dd/pdf/nutrition.pdf>. Accessed January 24, 2024.

⁴³ Nutrition calculator. McDonalds. (n.d). <https://www.mcdonalds.com/us/en-us/about-our-food/nutrition-calculator.html>. Accessed January 24, 2024.

⁴⁴ Interactive Nutrition Menu. KFC. April 3, 2023. <https://www.kfc.com/full-nutrition-guide>. Accessed January 24, 2024.

⁴⁵ Full Nutrition Info. Taco Bell. February 8, 2024. <https://www.tacobell.com/nutrition/info>. Accessed February 8, 2024.

⁴⁶ Cinnabon Nutrition Guide. (n.d). <https://www.cinnabon.com/-/media/cinnabon/nutrition/cinnabonnutritionalguide.pdf>. Accessed January 24, 2024.

⁴⁷ Greenthal E, Sorscher S. P21-004-23 Implementation of Voluntary Nutrition Labeling Policies on Wine and Beer Sold in the United States. *Current Developments in Nutrition*. 2023;7:101654. doi:[10.1016/j.cdnut.2023.101654](https://doi.org/10.1016/j.cdnut.2023.101654)

authority.⁴⁸ Unfortunately, the recent guidance seems consistent with the Foundation's concern; it fails to use the agency's full authority to protect consumer health, falling back instead on voluntary action by industry.

Further delay on the petition also undermines opportunities for progress on added sugar reduction in restaurant foods at the state and local levels. For example, our petition cited the Sweet Truth Act, a bill then pending before the New York City Council requiring warnings on restaurant menu items that are high in added sugars. That bill was passed into law in November of 2023.⁴⁹ However, under the new law's provisions, until FDA requires restaurants to disclose added sugars information, most restaurant items will not be subject to the warning requirement.

In addition, Prince George's County, MD passed a healthy kids' meals policy in 2020, and in 2025, the entire policy will be enforceable, and restaurants must offer at least one children's meal that meets expert nutrition standards, including a limit on 15g of added sugars per meal.⁵⁰

But until the FDA requires restaurants to disclose added sugars information, Prince George's County will have difficulty enforcing this landmark policy. Moreover, other jurisdictions are unlikely to undertake restaurant menu reform if they see these local efforts stymied by FDA inaction.

Now is the time for the FDA to implement the recommendations of our petition. Information about added sugars is critical for individual consumers to be able to follow the DGA guidance on added sugars and will support efforts to design policies that promote transparency and improve the health of Americans. Accordingly, we request a meeting with you to review the evidence supporting our requests and to receive an update on our petition's status.

Sincerely,

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⁴⁸ 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 January 24, 2024. (16_Human Foods Program Independent Expert Panel Final Report 120622, page 15)

⁴⁹ New York, N.Y., Int. 0687-2022 (Nov 17, 2023). <https://legistar.council.nyc.gov/LegislationDetail.aspx?ID=5839410&GUID=C669DFA8-AB8D-4DB1-B75B-D0F233C03CD0&Options=&Search=>

⁵⁰Prince George's County, MD., Code §§ 12-215 – 12-218 (2020), https://library.municode.com/md/prince_george's_county/codes/code_of_ordinances?nodeId=PTIITI17PULOLAPRGECOMA_SUBTITLE_12HE_DIV12HECHMERE.

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