U.S. FOOD & DRUG ADMINISTRATION

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Devin Watkins, Attorney
Devin.watkins@cei.org
Dan Greenberg, General Counsel
Dan.greenberg@cei.org
Competitive Enterprise Institute
1310 L Street NW, 7th Floor
Washington, DC 20005

Dear Mr. Watkins and Mr. Greenberg,

This letter is in response to the Competitive Enterprise Institute's (CEI or you) Request for Reconsideration, regarding the U.S. Food and Drug Administration's (FDA) 2021 guidance for industry titled, "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods" (Sodium Reduction Guidance).[1] See Request for Reconsideration from Devin Watkins and Sam Kazman, Competitive Enterprise Institute, submitted to the Office of the Ombudsman, FDA, dated October 10, 2023 ("RFR"). Your RFR requests that we reconsider our denial of your Request for Correction. See Request for Correction from Devin Watkins and Sam Kazman, Competitive Enterprise Institute, submitted to the Office of the Commissioner, FDA, dated November 9, 2021 ("RFC"). Your RFC requested that FDA withdraw its Sodium Reduction Guidance until "a peer review process is validly completed," as the Sodium Reduction Guidance "does not meet the requirements of the Information Quality Act" (IQA). See RFC at pp. 2 and 7.

We have reviewed and considered your RFR pursuant to the Office of Management and Budget's (OMB) Information Quality – Implementation Memoranda (https://www.whitehouse.gov/omb/information-regulatory-affairs/information-policy/#IQIM), and the Department of Health and Human Services (HHS) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, which include FDA's Responsibilities and Guidelines (https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information) ("FDA Guidelines"). The FDA Guidelines outline administrative mechanisms for FDA's pre-dissemination review of information products and describes mechanisms to enable affected persons to seek and obtain corrections from FDA regarding disseminated information that they believe does not comply with the FDA Guidelines or OMB guidelines (i.e., OMB Information Quality Guidelines and

[1] U.S. Food and Drug Administration. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. October 14, 2021. Available at https://www.fda.gov/media/98264/download.

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5001 Campus Drive, College Park, MD 20740
www.fda.gov

Memorandum M-19-15).[2] FDA is committed to applying these guidelines, including each of the updates outlined in M-19-15, to the FDA Guidelines. The RFC process under the FDA Guidelines is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality standards. As such, we have reviewed: (1) your RFC and RFR; (2) the September 12, 2023, denial from FDA (see RFC response from Kristi Muldoon Jacobs, FDA, dated September 12, 2023); and (3) the Sodium Reduction Guidance in relation to your appeal.

In the RFR, you challenge both Dr. Muldoon Jacobs' response and the Sodium Reduction Guidance. I am responding to this RFR, as Dr. Muldoon Jacobs' immediate supervisor and the Deputy Center Director for Scientific Operations, at FDA's Center for Food Safety and Applied Nutrition (CFSAN). See 21 CFR 10.75 and FDA Guidelines VI.

In accordance with HHS's Information Quality Guidelines and upon review of the relevant documents and consideration of all the issues and arguments raised, I affirm FDA's denial of your RFC. I respond to each of your claims below.

1. **"The 3,000 mg/day Recommendation is Not Included in Any NASEM Report"**

You state that "[t]he first problem is that 3,000 [milligrams per day (mg/d)] was never mentioned in any NASEM report; this recommendation therefore cannot be used by HHS without additional peer review. You also claim that FDA is "inventing its own analysis concerning sodium…As such, the Data Quality Act requires further peer review before these statements are published by HHS." See RFC at p. 2.

We disagree with these assertions. The voluntary targets in the Sodium Reduction Guidance are intended to help support a reduction in average sodium intake to 3,000 mg/d to support the NASEM Chronic Disease Risk Reduction (CDRR) recommendations of limiting sodium intake to 2,300 mg/d.[3] As we state in the Sodium Reduction Guidance, "[t]his guidance aims to help Americans reduce average sodium intake to 3,000 mg/day by encouraging food manufacturers, restaurants, and food service operations to gradually reduce sodium in foods over time. Although we recognize that a reduction to 3,000 mg/day still would be higher than the recommended sodium limit of 2,300 mg/day, the 2.5-year goals are intended to balance the need for broad and gradual reductions in sodium and what is publicly known about technical and market constraints on sodium reduction and reformulation." See Sodium Reduction Guidance at p. 4. We relied on the current evidence, best intake estimates, and NASEM CDRR recommendation of limiting sodium intake to 2,300 mg/d and chose a short-term voluntary target level of 3,000 mg/d to support the lower CDRR recommendation. Further peer review is not necessary, as the use of a measurable, voluntary short-term target level of 3,000 mg/d was a policy decision made after considering the evidence provided in the NASEM report.

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[2] U.S. Office of Management and Budget, Executive Office of the President. OMB Memorandum M-19-15, Improving Implementation of the Information Quality Act (2019). Available at https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

[3] *See* National Academies of Science, Engineering and Medicine. Dietary Reference Intakes for Sodium and Potassium (March 2019). Washington, DC: The National Academies Press. Available at http://www.nationalacademies.org/hmd/Reports/2019/dietary-reference-intakes-sodium-potassium.aspx.

2. **"The Response Relies Upon Older Tolerable Upper Intake Level Since Repudiated by NASEM"**

You express concern that our RFC response "appears to rely upon older data, which the more modern NASEM reports repudiate." See RFR at p. 2. You state that we relied upon the 2005 NASEM report and failed to consider the 2019 NASEM report which you claim repudiated earlier findings. You said that "what the 2005 [NASEM] Report was describing as a Tolerable Upper Intake Level should instead be characterized as a Chronic Disease Risk Reduction level" and that "[Dietary Reference Intake (DRI)] standards for adequacy and toxicity are fundamentally different than DRI standards based on chronic disease." See RFR at pp. 2 through 3.

We disagree with this characterization. Our RFC response notes that the Sodium Reduction Guidance is based on the DRI levels set by NASEM and supports recommendations of the *Dietary Guidelines for Americans*. See RFC at p. 2. The RFC response then notes both the 2005 and the 2019 NASEM reports recommend limiting daily sodium intake to 2,300 mg/d for those aged 14 years and older. See RFC at p. 2. In the 2005 NASEM report, that level was a Tolerable Upper Intake Level,[4] and in the 2019 NASEM report it is a CDRR level.[5]

3. **"The Response Fails to Address the Guidance's New Findings About the Risk of Low Sodium Recognized by NASEM"**

You state that the 2019 NASEM report acknowledged observational studies that suggest the possibility that lower intakes of sodium may increase the risk of harmful health outcomes and, therefore, the Sodium Reduction Guidance should mention risks of low sodium. See RFR at p. 3.

We disagree. The 2019 NASEM DRI committee reviewed the evidence of low sodium intake and health effects, and the final report concluded, "[t]here is insufficient evidence that low sodium intakes are associated with potential harmful health effects. The paradoxical J- and U-shaped relationships of sodium intake and cardiovascular disease and mortality are likely observed because of methodological limitations of the individual observational studies, particularly their sodium intake assessment methods." See 2019 NASEM report at pp. 232 through 233.

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[4] *See* Institute of Medicine. Dietary Reference Intakes for Water, Potassium, Sodium Chloride and Sulfate (2005). Washington, DC: The National Academies Press. Available at https://nap.nationalacademies.org/catalog/10925/dietary-reference-intakes-for-water-potassium-sodium-chlorideand-sulfate.

[5] *See* National Academies of Sciences, Engineering and Medicine, *supra* note 3.

4. "The Response Fails to Address Scientific Studies In the Guidance Outside of the NASEM Reports"

You state that, in the Sodium Reduction Guidance, we "directly analyze a variety of scientific studies to derive conclusions outside of the NASEM report" and that these studies are inappropriate for us to use without additional peer review. See RFR at p. 3 through 4.

We disagree. The various references cited to in the Sodium Reduction Guidance provide corroborating data to further support the actions we took, but they do not provide the underlying data that support our policy decision. Under OMB's Improving Implementation of the Information Quality Act,[6] "a particular piece of information supporting [a decision] may or may not be 'influential,' depending on whether the decision could be reached in the information's absence." See Improving Implementation of the Information Quality Act at p. 3. Since the Sodium Reduction Guidance could have been published without these various studies cited, they were not deemed influential, and they did not need to be separately peer reviewed under the IQA.[7]

5. "The Response Is from an Individual Who is Not an Officer of the United States Able to Act on Behalf of HHS"

You claim that the Director of the Office of Food Additive Safety does not have "the authority to act on behalf of HHS or FDA in providing the response issued" for two reasons. See RFR at p. 4. First, you assert that the Director of the Office of Food Additive Safety cannot be an officer under the Appointments Clause because Congress did not specifically create that office.

We disagree. The Appointments Clause allows for flexibility in the appointments of inferior officers, and there is no requirement that Congress specifically identify each office or position before that position may hold an inferior officer. *See Edmond v. United States*, 520 U.S. 651, 656 (1997); *In re Grand Jury Investigation*, 916 F.3d 1047, 1053 (D.C. Cir. 2019); *Pennsylvania Dep't of Pub. Welfare v. HHS*, 80 F.3d 796, 804-05 (3d Cir. 1996). Congress has granted the Secretary of HHS broad authority to make appointments to carry out their duties, and the Secretary has the "discretion to fashion inferior officer appointments to fit [their] needs." *Pennsylvania Dep't of Pub. Welfare*, 80 F.3d at 805. *See also* U.S. Const. art. II, § 2, cl. 2 (permitting Congress to vest appointments "as [it] think[s] proper").

Second, you assert that the current Director of the Office of Food Additive Safety is not an Officer of the United States because she "has not been commissioned for any office." See RFR at p. 4.

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[6] *See* U.S. Office of Management and Budget, *supra* note 2.

[7] *See* U.S. Office of Management and Budget, Executive Office of the President. OMB Memorandum M-05-03, Issuance of OMB's "Final Information Quality Bulletin for Peer Review" (2004). Available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf.

Again, we disagree. The Secretary of HHS properly appointed Dr. Muldoon-Jacobs, then the Acting Director, now the Director of the Office of Food Additive Safety, pursuant to the Appointments Clause, as she was identified as an inferior officer and the Secretary ratified her appointment. Receiving a commission is "incidental rather than essential" to being an Officer of the United States. Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. O.L.C. 73, 122 (2007).

6. **"The Response Fails to Follow HHS Regulations 21 CFR 10.75 and Information Quality Guidelines That Require an Initial Decision by the Supervisor of the HHS Employee"**

You state that we have not acted in accordance with the HHS Information Quality Guidelines, as the "HHS Information Quality Guidelines require the supervisor of the employee who disseminated the decision to respond to the initial request for correction." See RFR at p. 5. You claim that, as Lauren K. Roth signed the *Federal Register* notice, her direct supervisor should have provided the initial response, not the Director of the Office of Food Additive Safety.

You also assert that FDA failed to comply with HHS guidelines, referencing 21 CFR 10.75, because the response was issued by an official in CFSAN, rather than the direct supervisor of Lauren K. Roth, Associate Commissioner for Policy, who signed the *Federal Register* notice.

You are correct that 21 CFR 10.75 provides a mechanism for requesting review of a decision of an FDA employee by an employee's supervisor. However, the HHS guidelines in question do not mandate strict adherence to one particular process, such as the process outlined in 21 CFR 10.75. Indeed, your November 2021 RFC was directed to Ms. Roth, but it did not invoke 21 CFR 10.75 except in reference to a possible future appeal. Accordingly, nothing required FDA to strictly adhere to the process outlined in 21 CFR 10.75 in issuing its response. Instead, FDA had the flexibility to determine the most appropriate official to send the response based on the substance of your arguments.

We also do not agree with your claim that Ms. Roth's supervisor is the person who was required to provide the initial RFC response. While Ms. Roth signed the *Federal Register* notice, it is the Office of Food Additive Safety within the Center for Food Safety and Applied Nutrition that was responsible for disseminating the Sodium Reduction Guidance. Therefore, Dr. Muldoon-Jacobs was appropriately the proper person to provide the initial RFC response, as the direct supervisor of her staff.

FDA remains committed to the guidelines established by the OMB for maximizing the quality, integrity, objectivity, and reproducibility of information we disseminate to the public.

We are similarly committed to the guidelines established by HHS, as well as the FDA responsibilities and guidelines, to ensure the quality of the information we disseminate to the public.

Thank you for your interest in FDA's information quality.

Sincerely,

Steven M. Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition