U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

September 2, 2022

Peter Lurie
President
Center for Science in the Public Interest
1250 I Street, NW
Washington, DC 20005

Sent via email to: plurie@cspinet.org

Dear Mr. Lurie:

This letter is in response to your citizen petition (FDA-2022-P-0256) dated February 28, 2022, requesting the Food and Drug Administration "amend 21 C.F.R. § 100.1 in the following three ways:"

1. Amend 21 C.F.R. § 100.1(f)(5) to provide a fixed end date for the FDA to grant or deny a petition with the option for a mutually agreed upon extension. The agency should retain the current 90-day time period within which to issue a tentative grant, denial, or tentative response stating that it has been unable to reach a decision, and add a requirement to grant or deny the exemption within a 90-day extension period if the agency initially issues a tentative response. If the agency cannot reach a decision within 180 days, the Secretary of Health and Human Services (Secretary) and the petitioner may mutually agree upon an extension with a firm end date. The current regulation provides no fixed end date for a grant or denial.

2. Amend 21 C.F.R. § 100.1(d)(3)(C)(3) to adopt the Pike balancing test for analyzing a policy's effect on interstate commerce. The statute underlying FDA's current regulation requires that exempt policies "not unduly burden interstate commerce." However, the current regulation applies the incorrect test and improperly skews the analysis toward industry by focusing on economic impact on industry without balancing State or local benefit, a consideration required under the Pike balancing test.

3. Amend 21 C.F.R. § 100.1(d)(3)(C)(4) or issue a guidance to clarify that a "particular need for information," another statutory requirement for obtaining an exemption, can relate to a national interest, in addition to a State or local interest. Clarification would allow States and localities to develop evidence on innovative nutrition and menu labeling approaches that could inform national policy changes. Although FDA acknowledged in its 1993 rulemaking that a "particular need for information" can relate to a national interest, the regulation does not include this information. Instead, the regulation indicates that FDA will grant an exemption only when unique local circumstances call for a policy that differs from the national standard.

In accordance with Title 21 Code of Federal Regulations, section 10.30(e)(2), this letter is to advise you that we were not able to reach a decision on your petition within the first 180 days of its receipt, nor as of the date of this letter, because of other agency priorities and the limited availability of resources. When we complete our review of your petition, we will notify you of our decision. If you have any questions, please contact us.

Sincerely yours,

Claudine J. Kavanaugh -S

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Director
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