March 1, 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 Petitioner:

Your submission requesting that the Commissioner of Food and Drug take the following actions:

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 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.

This petition was received and processed under CFR 10.30 by this office on 02/28/2022 and it was assigned docket number FDA-2022-P-0256. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.01 14:06:56 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)