CITIZEN PETITION

Center for Science in the Public Interest
1250 I Street, NW
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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852
Submitted electronically via Docket No. FDA 2013-S-0610

Re: Citizen Petition Seeking to Facilitate State and Local Exemptions from Federal Food Labeling Laws

To Whom It May Concern:

The Center for Science in the Public Interest (CSPI)[1] and the Philadelphia Department of Public Health (Philadelphia DPH)[2] respectfully submit this petition pursuant to 5 U.S.C § 553(e), 21 U.S.C. § 343-1, 21 C.F.R. § 100.1, and 10 C.F.R. § 10.30, requesting that the Commissioner of Food and Drugs amend the regulation[3] governing State and local petitions for exemption from the preemptive effects of the Food, Drug, and Cosmetic Act's (FDCA) nutrition and menu labeling standards.[4] The proposed changes would provide a more efficient and fairer petitioning

[1] CSPI, America's Food and Health Watchdog, is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported primarily by subscribers to its *Nutrition Action* magazine, grants, and members.

CSPI was instrumental in passage of the Nutrition Labeling and Education Act (NLEA), which amended the Food, Drug, and Cosmetic Act (FDCA) to include uniform nutrition labeling, and the organization continues to advocate for improvements to nutrition and menu labeling at the local, state, and Federal level, including additions of the trans fat and added sugars lines on the Nutrition Facts label. Center for Science in the Public Interest. *Trans Fat Coming to Food Labels: New Regulation is Important Step in Right Direction, Says CSPI*. July 9, 2003. https://www.cspinet.org/new/200307091.html; Center for Science in the Public Interest. *New Nutrition Facts Label to Feature Added Sugars, with Daily Value: CSPI Praises FDA, First Lady, Administration for Revisions to the Labels*. May 20, 2016. https://cspinet.org/news/new-nutrition-facts-labels-feature-added-sugars-daily-value-20160520.

[2] Philadelphia DPH's mission is to protect and promote the health of all Philadelphians and provide a safety net for the city's most vulnerable. Philadelphia DPH not only provides medical services for Philadelphians, but enforces laws, creates policies, and supports numerous health and well-being programs across the city. Philadelphia DPH works to make Philadelphia a healthy place to live, work, and play.

[3] 21 C.F.R. § 100.1.

[4] 21 U.S.C § 343-1(a). The Nutrition Labeling and Education Act (P.L. 101-535) amended the FDCA to include national uniform nutrition labeling on packaged and prepared food and the Affordable Care Act (P.L. 111-148) amended the FDCA to include national uniform menu labeling at chain restaurants with 20 or more locations.

process. A more accessible and appropriate path to exemption would enable States and localities to pass innovative food labeling laws that advance public health.

National standards set an important regulatory "floor," but, as Food and Drug Administration (FDA) regulations provide, States and localities must have the chance to develop new, innovative labeling approaches. States and localities can then test novel approaches to nutrition and menu labeling and gather population-level evidence that can inform improvements to FDCA's uniform national requirements. As former Supreme Court Justice Louis Brandeis famously wrote, "It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[5]

To balance the interest in uniform national labeling with States' and localities' ability to innovate, it is essential that the process for seeking an exemption under the FDCA be efficient and fair. However, the current process is inefficient and biased toward the food industry, which in general would oppose many of the exemptions sought.

It is inefficient because there is no fixed end date for FDA to grant or deny an exemption request. Petitioners must invest considerable resources in passing legislation and then potentially wait years without receiving a decision from the agency about whether it will grant the exemption.

It is biased toward industry because, in considering a policy's effect on interstate commerce, the proper Constitutional test involves weighing a policy's burden on interstate commerce against its State or local benefit, but FDA erroneously gives no weight to State or local benefits. Such benefits may include assuring transparency in food labeling and enhancing residents' health.

Finally, the current regulation does not make clear that, in addition to addressing unique local needs, the FDCA permits exemptions for local policies that address the national need for evidence that could inform Federal policy reform. Together, these hurdles discourage preemption exemption petitions and make it overly difficult for States and localities to prevail in the petition process.

Our requested actions would make the process more efficient and fairer by providing a fixed end date for the FDA to grant or deny a petition with the option for a mutually agreed upon extension, adopting the Constitutionally correct test for assessing a policy's effect on interstate commerce, and ensuring that States and localities can develop evidence to inform potential changes to national nutrition and menu labeling policies.

I. REQUESTED ACTION

The petitioners request that FDA 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

[5] *New State Ice Co. v. Liebmann*, 285 U.S. 262 (1932).

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."[6] 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,[7] 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,[8] 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.

II. STATEMENT OF GROUNDS

A. FDA's Current Process for Allowing States and Localities to Seek an Exemption from Federal Preemption Is Inefficient, Overly Burdensome, and Skewed Toward Industry, Hindering Innovation.

The Nutrition Labeling and Education Act of 1990 (NLEA), which amended the FDCA to include nutritional labeling, seeks to provide consumers with nutrition information on packaged and prepared foods in a coherent and understandable manner.[9] The Affordable Care Act (ACA) similarly amended the FDCA to include menu labeling requirements that help people patronizing chain restaurants to be "better informed consumers."[10]

To ensure national uniformity, both the NLEA and ACA contain several preemption provisions, limiting State and local ability to impose nutrition and menu labeling requirements different from

[6] 21 U.S.C. § 343-1(b)(2).
[7] 21 U.S.C. § 343-1(b)(3).
[8] 58 Fed. Reg. 2462, 2465.
[9] 136 Cong. Rec. S33427 (daily ed. Oct. 24, 1990) (statement of Sen. Mitchell).
[10] 155 Cong. Rec. S13765 (daily ed. Dec. 22, 2009) (statement of Sen. Carper).

those of the federal government.[11] However, there was clear legislative intent at the time of NLEA's passage to create a path for exemptions to federal food labeling standards; the statute noted the need for "a careful balance of firm regulation and enough flexibility to…accommodate the various needs of our consumers,"[12] by "preserving State regulatory authority where it is appropriate."[13]

For this reason, Congress created two exemptions to these preemption provisions, which apply to both NLEA nutrition labeling and ACA menu labeling requirements. First, States and localities can pass safety warnings—policies that require labeling regarding a food or food component's safety.[14] Second, Congress created a process for States and localities, under certain conditions, to petition the FDA for an exemption to Federal preemption.

The second exemption, which is the subject of this Petition, provides FDA with the authority to exempt from preemption a State or local policy that:

> (1) would not cause any food to be in violation of any applicable requirement under Federal law,
> (2) would not unduly burden interstate commerce, and
> (3) is designed to address a particular need for information which need is not met by the [national nutrition and menu labeling requirements].[15]

States and localities have successfully used the first of these exemptions, which does not require a petition to FDA, to pass safety warnings. For example, New York City and Philadelphia passed sodium warning rules[16] that require chain restaurants to include warning icons or labels on menu items containing 2,300 or more milligrams of sodium. Yet, States and localities cannot provide more comprehensive nutrition information, as opposed to safety information, either on packaging or menus, without an exemption via petition.

The process for seeking an exemption is broken. It results in States and localities investing considerable time and effort into policies that subsequently languish under federal review. For example, in 2011, the city of Philadelphia submitted a petition to allow enforcement of its menu labeling ordinance requiring declaration of calories, sodium, saturated fat, trans fat, and carbohydrates on restaurant menu items,[17] but the FDA never rendered a decision on that petition. The agency issued an interim response in 2011, stating that it could not reach a decision on the petition because it had not yet completed its rulemaking on FDCA's menu labeling requirements as required by the ACA.[18] FDA completed that rulemaking in 2014.[19] In 2015,

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[11] 21 U.S.C §§ 343-1(a)(4), (a)(5).
[12] 136 Cong. Rec. S33427 (daily ed. Oct. 24, 1990) (statement of Sen. Mitchell).
[13] 136 Cong. Rec. S33427 (daily ed. Oct. 24, 1990) (statement of Sen. Mitchell).
[14] 21 U.S.C. § 343-1 note (Construction of Pub. L. No. 101-535).
[15] 21 U.S.C. § 343-1(b).
[16] New York, N.Y., Code § 81.49 (2015); Philadelphia, Pa., Code § 6-310 (2018).
[17] City of Philadelphia Department of Public Health, Petition Requesting Exemption from Preemption for State Requirement (August 25, 2011), https://www.regulations.gov/document/FDA-2011-P-0646-0001.
[18] United States Food & Drug Administration, Interim Response to City of Philadelphia Department of Public Health, 2011.
[19] 79 Fed. Reg. 71156.

Philadelphia amended its petition to request exemption for narrower enforcement of the menu labeling ordinance regarding only declaration of milligrams of sodium.[20] In reply, the agency issued another interim response stating that it had not reached a decision due to other competing priorities, and has not responded further.[21] In 2018, Philadelphia passed its Sodium Safety Warning, which is allowed under the FDCA's exemption for safety warnings and so requires no petition.[22] Arguably, with this new sodium warning rule in place, Philadelphia no longer requires an answer on its 2015 amended petition. Nevertheless, FDA went at least seven years without substantively responding to the 2011 petition.

B. An Efficient and Fair Process for Allowing States and Localities to Seek an Exemption from Uniform National Nutrition and Menu Labeling Will Serve Public Health and Realize the FDCA's Statutory Purpose.

Diet-related disease is widespread in the United States. According to the 2020-2025 Dietary Guidelines for Americans (DGA), 60 percent of adults have one or more diet-related chronic diseases.[23] For example, 46 percent of adults have high blood pressure and 29 percent have high LDL ("bad") cholesterol, both of which increase the risk of heart disease and stroke.[24] Thirty-five percent of adults have prediabetes, and 13 percent have diabetes.[25] Poor diet is linked to increased healthcare costs; it is estimated that diet-related cardiometabolic disease is associated with $50.4 billion in U.S. healthcare costs annually.[26]

Nutritional labeling helps consumers improve their health by helping them to choose what to eat, aligning their diets more closely with the DGA. However, reading the Nutrition Facts label requires time and effort as well as numeracy and nutrition literacy, and people with lower incomes as well as people with less education are less likely to regularly use the Nutrition Facts label compared with people with higher incomes and more education.[27] People with lower incomes and people with less education tend to have lower diet quality,[28] and could therefore benefit from more accessible nutrition information.

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[20] City of Philadelphia Department of Public Health, Amended Petition Requesting Exemption from Preemption for State Requirement, 2015.
[21] United States Food & Drug Administration, Interim Response to City of Philadelphia Department of Public Health, 2015.
[22] 21 U.S.C. § 343-1 note (Construction of Pub. L. 101-535).
[23] United States Department of Agriculture, Department of Health & Human Services. Dietary Guidelines for Americans 2020 – 2025. December 2020. https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.
[24] Virani S, et al. Heart Disease and Stroke Statistics—2020 Update: A Report from the American Heart Association. *Circulation* 2020; 141:e139-e596.
[25] United States Department of Health & Human Services. National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States. 2020. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
[26] Jardim TV, et al. Cardiometabolic disease costs associated with suboptimal diet in the United States: A cost analysis based on a microsimulation model. *PLOS Medicine*. 2019;16(12): e1002981.
[27] Christoph MJ, et al. Nutrition Facts Panels: Who Uses Them, What Do They Use, and How Does Use Relate to Dietary Intake? *J Acad Nutr Diet*. 2018;118(2):217-228.
[28] Rehm CD, et al. Dietary intakes among US adults, 1999 - 2012. *JAMA.* 2016; 315(23): 2542–2553.

States and localities can test whether novel labeling approaches improve rates of label use. If successful, these policies can inform changes at the national level. Possible new labeling approaches include:

- Sodium and other nutrient disclosures
- "High in" disclosures for unhealthy nutrients
- Stop light nutrition information on food packages or menus indicating high or low levels of particular nutrients
- Points or star systems to indicate healthier choices
- Specialized disclosures and nutrition information for food marketed to children.

Many countries have recently adopted some form of these new labeling approaches. For example, some front-of-package labeling schemes lead to healthier food purchases; a meta-analysis based on experimental studies found that people who viewed products with "High in calories/sugar/saturated fat/sodium" warnings purchased fewer calories (-4 kcal/100 g of food), total sugar (-0.7 g/100 g), and sodium (-34 mg/100 g), on average, than people who viewed products without warnings ($p<0.05$).[29] While useful in illuminating front-of-package labeling's impact on consumer behavior, experimental studies cannot capture the real-world impact of labeling policies, including potential impacts on industry behavior through product reformulation. The U.S. could understand these innovative approaches' real-world impacts if U.S. States and localities could more easily implement them, collect data, and drive improvement to our national food labeling regimes.

There is ample precedent for local and State-level policies informing broader reforms in both consumer protection and public health contexts. As just one example, after New York City and other localities adopted laws requiring calorie disclosure on restaurant menus, Congress included calorie disclosure by certain restaurants in the ACA.[30] But the ACA requirement need not be the final word. While the ACA requirement set a regulatory "floor" for States and localities that may not have ever regulated in this space, it also set a "ceiling" that cannot be exceeded without exemption. It is important that this preemption exemption process work so that States and localities can keep driving improvements at the national level.

C. FDA Must Amend the Petition Process to Facilitate Efficient and Fair Consideration of Requests.

To provide petitioners with a more efficient and fairer process, we urge FDA to engage in a rulemaking to amend 21 C.F.R. § 100.1(f) and 21 C.F.R. § 100.1(d)(3) in the following ways:

i. Set a Fixed End Date for the FDA to Grant or Deny Petitions.

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[29] Crocker H, et al. Front of Pack Nutritional Labelling Schemes: A Systematic Review and Meta-Analysis of Recent Evidence Relating to Objectively Measured Consumption and Purchasing. *J Hum Nutr Diet*. 2020;33:518-537. Traffic light labels had similar significant effects on purchases of sodium; none of the label formats other than warning labels (including traffic light, Nutriscore, health star rating, and Daily Intake Guide) had significant effects on purchases of energy and sugar.

[30] Hodge JG Jr. and and Corbett A. Legal Preemption and the Prevention of Chronic Conditions. *Prev Chronic Dis* 2016; 13:160121.

When States and localities undertake the time-consuming processes of passing a law and petitioning for an exemption to accommodate that law's enforcement, it should produce a timely response from the FDA.

The existing preemption petition process requires the FDA to respond within 90 days with either a tentative grant of the exemption, a denial, or a tentative response indicating that the agency is unable to reach a decision.[31] If the agency issues a tentative response indicating that it cannot reach a decision, there is then no further end date imposed for doing so. This current scenario is problematic because it creates an indefinite extension: the FDA can satisfy its obligation to respond without actually granting or denying the exemption request.

FDA should engage in a rulemaking to amend 21 C.F.R. § 100.1(f)(5) to set a fixed end date for agency response. We propose that the agency retain the existing 90-day time period within which to issue a grant, denial, or tentative response, and add a requirement to grant or deny the exemption within a 90-day extension period. Further, we propose that if the agency cannot reach a decision within 180 days, the Secretary and the petitioner may mutually agree upon an extension, provided that the agency sets a firm end date and indicates why it has not yet reached a decision on the petition.[32] This change is reasonable because in other circumstances the FDA must grant or deny a petition within 180 days with the possibility of a mutually agreed upon extension, including for food allergy petitions[33] This change would make the petition process more efficient, accessible, and transparent, and is warranted because a State or locality will have invested considerable time and effort in the policy and will not be able to enforce it until the FDA renders a decision. Such a requirement is unlikely to burden FDA, as the number of petitions submitted by States and localities is likely to be exceedingly small. In 2020, as part of its information collection report to the Office of Management and Budget, the agency estimated that it will receive one petition per year[34] Philadelphia's petition is the only one from the last decade documented on Regulations.gov[35]

ii. Adopt the *Pike* Balancing Test to Assess a State or Local Policy's Effect on Interstate Commerce to Make the Petition Process Fairer for States and Localities.

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[31] 21 U.S.C. § 100.1(f)(5).

[32] The current regulation already requires the FDA to indicate "why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information." 21 C.F.R. § 100.1(f)(5)(iii).

[33] 21 U.S.C. § 343(w)(6).

[34] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption. 85 Fed. Reg. 54385 (Sept. 1, 2020).

[35] In its 2020 proposed collection of information submitted to the Office of Management and Budget Review, FDA noted that it had received one petition between 2017 and 2020. Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption. 85 Fed. Reg. 54385 (Sept. 1, 2020). However, such a petition is not documented on Regulations.gov and we have not been able to find further evidence of it. We are aware that California filed a petition in 1990 seeking exemption through January 1, 1992 for its fluid milk standards but have been unable to determine if FDA granted or denied this petition. Center for Science in the Public Interest. *Federal Preemption of State and Local Regulation of Food Labeling: A Guide for State and Local Agencies to the Nutrition Labeling and Education Act of 1990*. Feb. 1991.

The FDCA requires that an exempted policy "not unduly burden interstate commerce."[36] The Constitution's Commerce Clause gives Congress the power to regulate interstate commerce.[37] From this clause, courts infer a "dormant commerce clause" prohibiting States from discriminating against or excessively burdening interstate commerce.[38] The Supreme Court articulated its test of validity for State or local policies that do not discriminate against out-of-state commerce in the 1970 case *Pike v. Bruce Church, Inc.*[39] Known as the "*Pike* balancing test," courts uphold such policies "unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."[40] The *Pike* test is "paradigmatic" regarding movement-of-goods (for example, food products which are the subject of nutrition and menu labeling laws) dormant commerce clause cases.[41]

The FDCA's "not unduly burden interstate commerce" provision is a clear reference to the U.S. Supreme Court's "dormant commerce clause" jurisprudence and therefore necessitates uses of the balancing test. The term "unduly," as used in the FDCA, and the term "excessive," as used in the *Pike* balancing test, of course, are synonymous.[42] Indeed, before the NLEA amended the FDCA in 1990, and since then, the Supreme Court has repeatedly used the two terms interchangeably when applying the *Pike* balancing test.[43] This leaves little doubt that Congress intended FDA to use the *Pike* balancing test when analyzing petitions for preemption exemption.

Despite the clear intent of Congress to employ a balancing test, in its 1993 rulemaking, the FDA rejected a balancing test based on its own unique, strained, and woefully inaccurate interpretation of the term "unduly burden." Instead of relying on ample Supreme Court precedent requiring a balancing test using terminology nearly identical to the FDCA's language, FDA cited a Fifth Circuit case, *Mid-South Bottling Co. v. NLRB*, relying on that case to equate the terms "unduly burden" with "unfairness," and concluded that, based on this "unfairness standard," the agency did "not believe that the test for whether a State requirement does, in fact, 'unduly burden' interstate commerce is one of balancing burden versus need."[44] Remarkably, the case that FDA

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[36] 21 U.S.C. § 343-1(b)(2).
[37] U.S. Const. art. I, § 8, cl. 3.
[38] Gillian E. Metzger, *Congress, Article IV, and Interstate Relations*, 120 Harv. L. Rev. 1468, 1472 (2007).
[39] *Pike v. Bruce Church, Inc.* 397 U.S. 137 (1970).
[40] *Pike*, 397 U.S. at 142.
[41] Donald H. Regan. *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause,* 84 Mich. L. Rev. 1091, 1092 (1986).
[42] *Merriam-Webster Online*, s.v. "Undue," accessed Jan. 14, 2022, https://www.merriam-webster.com/dictionary/undue.
[43] *GMC v. Tracy*, 519 U.S. 278, n. 12 (1997) ("Our cases have indicated that even nondiscriminatory state legislation may be invalid under the dormant Commerce Clause, when, in the words of the so-called *Pike* undue burden test, "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits."); *Maine v. Taylor*, 477 U.S. 131, 138 (1986) ("In determining whether a State has overstepped its role in regulating interstate commerce, this Court has distinguished between state statutes that burden interstate transactions only incidentally, and those that affirmatively discriminate against such transactions...statutes in the first group violate the Commerce Clause only if the burdens they impose on interstate trade are "clearly excessive in relation to the putative local benefits."); *Great Atlantic & Pacific Tea Co. v. Cottrell*, 424 U.S. 366, 371-72 (1976) ("Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.")
[44] 58 Fed. Reg. 2462, 2464.

cited for this proposition was a labor practices case entirely unrelated to the dormant commerce clause and which analyzed the terms "undue *or unfair* burden" (emphasis added) in a non-analogous labor context. *Mid-South Bottling Co.* does not even mention "interstate commerce."[45] As a result, the agency requires significant information from petitioners only about a policy's economic feasibility without weighing it against local benefits.[46] Although FDA noted in its rulemaking that local interests would be considered under the "particular need for information" prong (see below),[47] the correct *Pike* test provides for consideration of State and local benefits beyond the "particular need for information." The FDA's current interstate commerce analysis, by constraining the use of a balancing test, therefore skews the analysis toward industry, making it difficult for petitioners to prevail.

iii. Clarify the Scope of "Particular Need for Information" to Advance Public Health.

As previously noted, the statute requires that an exempted policy must be designed to address a "particular need for information that is not met" by Federal labeling laws. Based on FDA's own interpretation in its rulemaking, an exempted policy's "particular need for information" can be national, in addition to local, in scope, but the agency did not include this position in the regulation. In its rulemaking, FDA noted that:

> The comments stated that a petition for exemption cannot be denied simply because the need for information is also national [in addition to State or local] in scope. *While the agency agrees with the comments' interpretation of the statute*, an agency decision to grant an exemption from preemption is likely to be based largely on the agency's evaluation of the situation within the requesting State. If the need for an exemption is not only local, the agency is likely to consider whether it would not in fact be more appropriate to amend the relevant Federal regulation.[48] [Emphasis added]

The current regulation does not convey that a "particular need for information" can be national in addition to State or local. It requires petitioners to "describe the conditions that require the State to petition for an exemption."[49] This language may be construed to imply that States and localities cannot cite a national need to augment their argument for granting an exemption. FDA noted in its rulemaking that a national need might indicate that it is more appropriate to amend national nutrition labeling policies than to grant a preemption exemption. However, Federal policy changes are best informed by robust evidence, gathered at the State and local level. Failure to incorporate the need for national information seems to leave little middle ground between petition denial and national regulation.

Importantly, the nutrition and menu labeling landscape has changed since 1993, when the FDA wrote the preemption exemption regulation. Many other countries have implemented novel

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[45] *Mid-South Bottling Co. v. NLRB*, 876 F.2d 458 (5th Cir. 1989).
[46] 21 C.F.R. § 100.1(d)(3)(C)(3).
[47] 58 Fed. Reg. 2462, 2464.
[48] 58 Fed. Reg. 2462, 2465.
[49] 21 U.S.C. § 100.1(d)(3)(C)(4).

labeling approaches of the kind mentioned above in Section II(B). Large amounts of research studying these approaches now exist, but little real-world research has been undertaken in the U.S., where the FDCA constrains most novel labeling policies. A national interest in informing this body of evidence in the U.S. context by studying it at the State and local level could be a "particular need for information."

The FDA should clarify that a "particular need for information" can be national in addition to State or local. This would not be a reversal of the agency's 1993 position, but rather would formalize a position that the agency already holds. The FDA could make this clarification by amending the regulation or issuing a guidance.

III. CONCLUSION

The current process to petition for an exemption to national nutrition and menu labeling requirements is not efficient or fair to States and localities and tilted toward industry. While nationally uniform laws are important, non-Federal governments also play an important role in regulating and innovating. This balance is especially crucial in the public health context, where it is often useful to gather population-level evidence before making sweeping Federal policy changes. The petition process for seeking an exemption from FDCA preemption should allow States and localities to more easily play this role.

IV. ENVIRONMENTAL IMPACT

The action requested herein is subject to a categorical exclusion under 21 C.F.R. §§ 25.30(h) and 25.30(k), and therefore does not require the preparation of an environmental assessment. Further, the undersigned believe that the actions required in this petition would have no environmental impact.

V. CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

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