

# FDA CITIZEN PETITION PROCESS & PUBLIC HEALTH ADVOCACY



The citizen petition process allows public health advocates to take initiative in shaping the regulatory agenda of the U.S. Food and Drug Administration.<sup>1</sup> By filing a citizen petition, advocates can influence agency action by petitioning the agency to issue, change, or cancel a regulation, or to take other action.<sup>2</sup>

A citizen petition is different from a general grassroots petition directed at a federal agency because under agency rules, the agency is required to respond.<sup>3</sup> Unfortunately, the agency's response is not always particularly timely, but it is important that the agency ultimately responds to the petition.



The U.S. Food and Drug Administration (FDA) receives approximately 150 to 200 petitions each year.<sup>4</sup> While many petitions come from regulated industry or consumer groups,<sup>5</sup> public health advocates have also increasingly used the citizen petition process to advance public health goals.

## **FDA Citizen Petition Advocacy in Practice**

### **Strengthening Commercial Tobacco Control**

Commercial tobacco control advocates can use the FDA's citizen petition process to encourage the FDA Center for Tobacco Products to fully exercise its authority under the Family Smoking Prevention and Tobacco Control Act to regulate the commercial tobacco industry.<sup>6</sup>

For example, advocates have filed citizen petitions asking the FDA to regulate all tobacco products,<sup>7</sup> prohibit menthol as a characterizing flavor in cigarettes,<sup>8</sup> and implement a track-and-trace program to monitor tobacco products.<sup>9</sup>

### **Advancing Nutrition Standards and Food Safety**

Public health and other public interest advocacy organizations can use the FDA's citizen petition process to advance nutrition standards and improve labeling to help consumers make healthy, informed choices about their food. Advocates can use citizen petitions to challenge FDA determinations of safe products, contact substances, and food prep processes; encourage administrative action to enforce existing regulations; and petition for improved standards in the interest of public health.

For example, in recent years, public interest organizations have filed citizen petitions asking the FDA to regulate toddler milks and transition formulas,<sup>10</sup> issue warning letters to diet soda companies that the term 'diet' is "false and misleading,"<sup>11</sup> ensure safe levels of added sugars in certain beverages and foods,<sup>12</sup> and protect the public from food color additives that pose a cancer risk.<sup>13</sup>

### **Before You Begin**

Before drafting your own petition, it may be useful to review submitted petitions related to the relevant topic to see what issues are already before the FDA. If the topic you are most interested in asking the FDA to address has already been raised in a citizen petition, you may choose to provide your input to the agency in the form of a comment on the previous petition rather than submitting a separate petition.

## How to Draft a Petition

Petitions require significant preparation, including very specific format and content requirements. According to the federal rules, petitions submitted to FDA must include the following information:<sup>14</sup>

- **Action requested.** Identify the rule, order, or other administrative action that the petitioner wants the FDA to issue, amend, or revoke and specify the specific action or relief requested.<sup>15</sup> If requesting the FDA issue, amend, or revoke an order, a petition must include the exact wording of the existing order and the petition's proposed wording.<sup>16</sup>
- **Statement of grounds.** Describe the factual and legal grounds for the petition, including all supporting material, as well as information known to the petitioner that may be unfavorable to the petitioner's position.<sup>17</sup>
- **Environmental impact.** Include an environmental assessment or a statement claiming a categorical exclusion from conducting an assessment.<sup>18</sup> An environmental assessment is generally required if the petition requests approval of food or color additives, biological products, or certain medical devices, or for a food to be categorized as GRAS (generally recognized as safe), unless otherwise categorically excluded.<sup>19</sup>
- **Certification statement.** Include the following language: "The undersigned certifies 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 petition which are unfavorable to the petition."<sup>20</sup>
- **Petitioner's identifying information.** The petition must be signed and include the petitioner's name, mailing address, and phone number.<sup>21</sup>

Some petitions may also need to include information on the economic impact of the requested action, but this information is required only if the FDA requests it after review of the petition.<sup>22</sup>

## How to File a Citizen Petition

The FDA provides instructions for electronic filing on [the agency's website](#).<sup>23</sup> In addition to the content requirements above, there are also procedural details to be aware of. For example, if filing a physical copy, the filing must include two copies of the complete petition and any attachments.<sup>24</sup> Any information referred to or relied upon by a petition must be submitted as well.<sup>25</sup> This means that if you reference an article or other document in your petition, you must attach it to the petition.<sup>26</sup>

For more information on submitting petitions, consult 21 C.F.R § 10.30. For sample formats, you can review citizen petitions filed with the FDA at [www.regulations.gov](http://www.regulations.gov).

## What's Next?

After a petition is submitted, the FDA will post the petition on [www.regulations.gov](http://www.regulations.gov) and create a docket folder where members of the public may submit a comment supporting or opposing the petition. For example, a petition that requests the FDA to regulate in an area provides the public with an opportunity to submit information and research that the agency may not have previously collected or considered. Both public comments and agency responses to the petition are filed in the petition's online docket, which is accessible to the public.

Once the petition is filed, it is evaluated by FDA staff, a process that may take several weeks to more than a year, depending on the issue's complexity. The FDA is required to rule upon each petition after considering agency resources, the priority of the petition topic, and statutory time requirements.<sup>27</sup> The evaluation of the petition may include: meetings, discussions, and correspondence;<sup>28</sup> a hearing;<sup>29</sup> a notice in the Federal Register requesting information and views;<sup>30</sup> and a proposal to issue, amend, or revoke a regulation.<sup>31</sup>

The FDA must respond within 180 days of receipt of the petition.<sup>32</sup> The agency's response must either: (1) grant the petition; (2) deny the petition; (3) dismiss the petition, if the Commissioner finds the issue has become moot since it was submitted; or (4) provide a tentative response, indicating why the agency has been unable to reach a decision on the petition.<sup>33</sup> If the FDA grants the petition, it must simultaneously take appropriate action to implement the approval.<sup>34</sup> If the FDA provides a tentative, or interim, response, it may also indicate the likely ultimate agency response, and may state when a final response may be furnished.<sup>35</sup>

After the FDA grants or denies the petition, the agency will notify the petitioner directly. Within 30 days of receiving an agency decision, an interested person may file a petition for reconsideration or for a stay of action.<sup>36</sup>

If not satisfied with the agency response, the petitioner can take the matter to court by filing suit under the Administrative Procedure Act,<sup>37</sup> FDA citizen petition regulations,<sup>38</sup> and the Food, Drug, and Cosmetics Act.<sup>39</sup> Public health advocates have filed suit against the FDA for both agency nonresponsiveness<sup>40</sup> and denial of citizen petitions.<sup>41</sup>

## Need Help? Contact the Public Health Law Center.

If you would like technical assistance with creating a citizen petition or commenting on an existing petition, please contact a staff attorney with the Public Health Law Center at (651) 290-7506 or email [publichealthlawcenter@mitchellhamline.edu](mailto:publichealthlawcenter@mitchellhamline.edu).

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## Endnotes

- 1 Please note that although engaging with a federal agency regarding regulations does not traditionally constitute lobbying, each organization must consider its own limitations based on its legal structure, funding sources, and relevant law. If you have any questions regarding what activities are permitted for your organization, please contact your funder or an attorney licensed in your jurisdiction.
- 2 21 C.F.R. § 10.30; see 5 U.S.C. § 553(e) (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”); U.S. CONST. amend. 1 (“Congress shall make no law ... abridging the freedom ... to petition the Government for a redress of grievances.”).
- 3 21 C.F.R. § 10.30(e)(1)-(2).
- 4 Calculated based on publicly available FDA citizen petition data on [regulations.gov](https://www.regulations.gov).
- 5 For example, a drug company might request a change in labeling for one of its products; a food company might ask that its product be exempted from some provision of a regulation; or a consumer group might petition FDA to tighten regulation of a certain product.
- 6 Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387) [hereinafter Tobacco Control Act].
- 7 Citizen Petition to Adopt Regulations to Protect Our Nation’s Health by Asserting Jurisdiction over All Tobacco Products, Docket No. FDA-2013-P-1127 (filed Sept. 9, 2013) (closed) (requesting that the FDA exercise its authority under the Tobacco Control Act to regulate all tobacco products, including cigars, e-cigarettes, hookah, and dissolvable tobacco products).
- 8 Citizen Petition to Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke, Docket No. FDA-2013-P-0435 (filed Apr. 12, 2013) (open) (requesting that the FDA exercise its authority under the Tobacco Control Act to prohibit menthol as a characterizing flavoring of cigarettes).
- 9 Citizen Petition Requesting the Implementation of a Track and Trace System to Monitor Manufacturing and the Flow of Tobacco Products from Production through Distribution to Retail Outlets, Docket No. FDA-2013-P-0285 (filed March 11, 2013) (open) (requesting that the FDA implement “a track-and-trace system to monitor manufacturing and the flow of tobacco products from production through distribution to retail outlets”).

- 10 Citizen Petition, Docket No. FDA-2020-P-1718 (filed 2020) (open) (requesting that the FDA regulate and enforce the labeling of toddler milks and transition formulas).
- 11 Citizen Petition Requesting the Issuance of Warning Letters to Coca-Cola Company and PepsiCo Because Use of the Term “Diet” Is False and Misleading, Docket No. FDA-2015-P-1187 (filed Apr. 9, 2015) (closed) (requesting that the FDA “(a) issue a warning letter to the Coca-Cola Company concluding that Diet Coke is misbranded under section 403 because the use of the term ‘diet’ is false and misleading; [and] (b) issue a warning letter to PepsiCo Inc. concluding that Diet Pepsi is misbranded under section 403 because the use of the term ‘diet’ is false and misleading”).
- 12 Citizen Petition to Ensure the Safe Use of Various Caloric Sweeteners, Docket No. FDA-2013-P-0217 (filed Feb. 20, 2013) (open) (requesting that “FDA take action as necessary to ensure the safe use of various caloric sweeteners (collectively, ‘added sugars’) that are added to certain beverages and other foods”).
- 13 Citizen Petition to Apply Changes to Regulations for the Food Color Additive “Caramel Color,” Docket No. FDA-2014-P-0123 (filed Jan. 24, 2014) (open) (requesting “changes to the regulations for the food color additive ‘caramel color’ ... to protect the public from exposure to byproducts that pose a cancer risk”).
- 14 21 C.F.R. § 10.30(b).
- 15 21 C.F.R. § 10.30(b)(A).
- 16 *Id.*
- 17 21 C.F.R. § 10.30(b)(B).
- 18 21 C.F.R. § 10.30(b)(C); see 21 C.F.R. § 25.40 (environmental assessment).
- 19 21 C.F.R. § 25.20 (actions requiring preparation of an environmental assessment); see 21 C.F.R. § 25.30-.35 (categorical exclusions).
- 20 21 C.F.R. § 10.30(b)(E).
- 21 *Id.*, see also 21 C.F.R. § 10.20(b) (“[a] submission is to be signed by the person making it, or by an attorney or other authorized representative”).
- 22 21 C.F.R. § 10.30(b)(D). If requested by the Commissioner, the economic impact statement must include the requested action’s effect on: “(1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.” *Id.*
- 23 21 C.F.R. § 10.30(b)(1). See [FDA website](#) for instructions on electronic filing.
- 24 21 C.F.R. § 10.30(b)(2) (“It is only necessary to submit two copies.”); 21 C.F.R. § 10.20(a) (“a submission ... of a petition ... is to be filed in four copies except as otherwise specifically provided in ... another section of this chapter”).
- 25 21 C.F.R. § 10.20(c) (“[i]nformation referred to or relied upon in a submission is to be included in full and may not be incorporated by reference”).
- 26 21 C.F.R. § 10.20(c)(1).
- 27 21 C.F.R. § 10.30(e)(1).
- 28 21 C.F.R. § 10.30(h)(1).
- 29 21 C.F.R. § 10.30(h)(2).
- 30 21 C.F.R. § 10.30(h)(3).
- 31 21 C.F.R. § 10.30(h)(4).
- 32 21 C.F.R. § 10.30(e)(2).

33 *Id.*; see *Henley v. FDA*, 873 F. Supp. 776 (E.D.N.Y. 1195), *aff'd sub nom.* (2d Cir. 1996) (holding FDA Commissioner “must give written notice of the decision accompanied by an explanatory statement”).

34 21 C.F.R. § 10.30(e)(2)(i).

35 21 C.F.R. § 10.30 (e)(2)(iv). Reasons typically given by the agency for providing a tentative response include: competing agency priorities, complexity of the issue raised in the petition, significant impact of the proposed change, or supplemental information is needed for the agency to reach a decision.

36 21 C.F.R. § 10.30(j).

37 See 5 U.S.C. § 555(b) (stating an agency must “proceed to conclude a matter presented to it” within “a reasonable time”); 5 U.S.C. § 706(1) (providing for judicial review of “agency action unlawfully withheld or unreasonably delayed”); 5 U.S.C. § 706(2)(A) (providing for judicial review of agency action (or inaction) “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”).

38 See 5 U.S.C. § 553(e) (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”); 21 C.F.R. § 10.30(e) (providing 180 days for the agency to provide a response to a citizen petition). See *also Henley v. FDA*, 873 F. Supp. 776 (E.D.N.Y. 1195), *aff'd sub nom.* (2d Cir. 1996) (holding FDA Commissioner “must give written notice of the decision accompanied by an explanatory statement”).

39 See 21 U.S.C. § 393 (stating the FDA shall “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner”).

40 *African American Tobacco Control Leadership Council v. U.S. Food & Drug Admin. et al.*, No. 3:20-cv-04012 (N.D. Cal. filed June 17, 2020) (seeking to compel the FDA to act on 2013 citizen petition requesting the agency prohibit menthol as a characterizing flavor for tobacco products); *Center for Science in the Public Interest v. U.S. Food & Drug Admin.*, No. 15-cv-01651 (DDC June 3, 2016) (granting voluntary dismissal of suit seeking to compel the FDA to act on 2005 citizen petition requesting the agency revoke the GRAS status of salt); *Center for Science in the Public Interest v. U.S. Food & Drug Admin.*, No. 14-cv-00375 (DDC Nov. 21, 2014) (granting summary judgment in favor of the FDA in suit seeking to compel agency to act on 2011 citizen petition requesting the agency provide recommendations and safety labeling regarding mercury levels in fish).

41 *Natural Resources Defense Council v. U.S. Food & Drug Admin.*, No. 19-CV-10005 (SDNY filed Oct. 29, 2019) (arguing FDA denial of citizen petition to ban the use of the chemical, perchlorate, in materials that contact food was arbitrary and capricious).