FDA CITIZEN PETITION PROCESS & PUBLIC HEALTH ADVOCACY

Quick Facts

What is a "citizen petition"?

The citizen petition process allows public health advocates to take initiative in shaping the regulatory agenda of agencies like the U.S. Food and Drug Administration (FDA).[1] By filing a citizen petition, advocates can influence agency action by petitioning the agency to issue, change, or cancel a regulation, or take other action.[2]

A citizen petition is different from a general grassroots petition directed at a federal agency because under agency rules, the agency **must** respond to a citizen petition.[3] Public health advocates have used the FDA citizen petition process to advance nutrition standards and improve labeling to help consumers make healthy, informed choices about their food and encourage the FDA Center for Tobacco Products to fully exercise its authority to regulate the commercial tobacco industry.[4]

What should be included in a citizen petition?

Petitions require significant preparation, including very specific format and content requirements. Petitions submitted to the FDA must include the following information:[5]

- **Action requested.** Identify the rule, order, or other administrative action that the petitioner wants the FDA to address and specify the specific action or relief requested.[6]
- **Statement of grounds.** Describe the factual and legal grounds for the petition, including all supporting material and any information that may be unfavorable to the petition.[7]
- **Environmental impact.** Include impact assessment or statement claiming an exclusion.[8]
- **Certification statement.**[9]
- **Petitioner's identifying information.**[10]
- **Economic impact.** Not required; may be requested by FDA after review of petition.[11]

What does the petition process look like?

Filing: The FDA provides instructions for electronic filing of petitions on its website.[12]

Public comment: Once the petition is filed, the FDA will post the petition on www.regulations.gov for the public to submit comments supporting or opposing the petition.

FDA response: The FDA is required to rule on each petition.[13] The FDA must respond within 180 days of receipt of the petition.[14] The agency's response must either: (1) grant the petition; (2) deny the petition; (3) dismiss the petition, if moot; or (4) provide a tentative response, indicating why the agency has been unable to reach a decision on the petition.[15]

Reconsideration process and litigation: Within 30 days of receiving an agency decision, an interested person may file a petition for reconsideration or for a stay of action.[16] If not satisfied with the agency response, the petitioner can take the matter to court.

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.

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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 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].

5 21 C.F.R. § 10.30(b).

6 21 C.F.R. § 10.30(b)(A).

7 21 C.F.R. § 10.30(b)(B).

8 21 C.F.R. § 10.30(b)(C); *see* 21 C.F.R. § 25.40 (environmental assessment).

9 21 C.F.R. § 10.30(b)(E).

10 *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").

11 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.*

12 21 C.F.R. § 10.30(b)(1). See FDA website for instructions on electronic filing.

13 21 C.F.R. § 10.30(e)(1).

14 21 C.F.R. § 10.30(e)(2).

15 *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").

16 21 C.F.R. § 10.30(j).