



## **CITIZEN PETITIONS: AN UNDERUTILIZED TOOL IN TOBACCO REGULATION**

As tobacco control advocates are learning, public involvement in the federal regulatory process involves a lot of waiting and reacting to action taken by the U.S. Food and Drug Administration (FDA). Fortunately, in addition to submitting comments and testimony, there is another tool to influence the FDA's regulation of tobacco that allows the public health community to take the initiative: petition the agency to issue, change or cancel a regulation, or to take other action.<sup>12</sup> Called a Citizen Petition, this is one of the few tools that allow advocates to take the initiative in shaping the agenda and pressing the FDA Center for Tobacco Products to do more with its authority under the Family Smoking Prevention and Tobacco Control Act (Act).

The FDA receives about 200 petitions each year,<sup>3</sup> very few of which address tobacco regulation. Individuals sometimes submit petitions, but most come from regulated industry or consumer groups.<sup>4</sup> 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.

A Citizen Petition is different than a general grassroots petition directed at a federal agency. The Citizen Petition is a tool created by federal regulations to allow the public to request a specific action by the agency. Under Citizen Petition rules, the agency is then required to respond.<sup>5</sup> Unfortunately, the agency's response is not always particularly timely, but it is important that the agency ultimately responds to the petition.

Petitions require significant preparation by the submitter, including very specific format and content requirements. According to the federal rules, petitions submitted to FDA must include the following information:<sup>6</sup>

- **Action requested** — Identify the rule, order, or other administrative action that the petitioner wants the FDA to issue, amend or revoke.<sup>7</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>8</sup>
- **Environmental impact** — This information is generally required if the petition requests approval of food or color additives, drugs, biological products, animal drugs, or certain medical devices, or for a food to be categorized as GRAS (generally recognized as safe). Procedures for preparing environmental impact statements can be found in Title 21, Part

25 of the Code of Federal Regulations. If an environmental impact statement is not required, petitions should include a statement to that effect.<sup>9</sup>

- **The following official certification statement** — "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 petitioner that are unfavorable to the petition."<sup>10</sup>
- **Identifying information** — The petition must be signed and include the petitioner's address and phone number.<sup>11</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>12</sup>

In addition to these content requirements, there are also procedural details to be aware of. For example, the filing must include four copies of the complete petition and any attachments.<sup>13</sup> Any information referred to or relied upon by a petition must be submitted as well.<sup>14</sup> For example, if you reference an article or other document in your petition, you must attach it to the petition.<sup>15</sup> Finally, petitions must be mailed or delivered to: Dockets Management Branch, Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852.<sup>16</sup> At this time, the FDA will not accept petitions via email or fax.

After a petition is submitted, the FDA will post the petition on [www.regulations.gov](http://www.regulations.gov) where members of the public may submit a comment supporting or opposing the petition. Before drafting your own petition, it may be useful to review submitted petitions related to tobacco regulation to see what issues are already before the FDA. If the topic you are most interested asking the FDA to address has already been raised in a Citizen Petition, you may choose to provide your input to the Center in the form of a comment on the previous petition rather than submitting a separate petition.

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.<sup>17</sup> The FDA is required to rule upon each petition after considering agency resources, the priority of the petition topic, and statutory time requirements.<sup>18</sup> The evaluation of the petition may include: meetings, discussions, and correspondence;<sup>19</sup> a hearing;<sup>20</sup> a notice in the Federal Register requesting information and views;<sup>21</sup> and a proposal to issue, amend, or revoke a regulation.<sup>22</sup>

The FDA must respond within 180 days of receipt of the petition.<sup>23</sup> The agency's response must either: (1) grant the petition; (2) deny the petition; or (3) provide a tentative response, indicating why the agency has been unable to reach a decision on the petition.<sup>24</sup> If the FDA grants the petition, it must simultaneously take appropriate action to implement the approval.<sup>25</sup> If the FDA provides a tentative response, it may also indicate the likely ultimate agency response, and may state when a final response may be furnished.<sup>26</sup> After the FDA grants or denies the petition, the agency will notify the petitioner directly. If not satisfied, the petitioner can take the matter to court.

For more information on submitting petitions, and sample formats, consult Title 21 of the Code of Federal Regulations, Sections 10.30, 10.33, and 10.35.

If you would like technical assistance with creating a Citizen Petition or commenting on an existing petition, please contact a staff attorney with the Tobacco Control Legal Consortium at (651) 290-7506. If you have questions about the petition process, contact the FDA Dockets Management Branch, (301) 827-6860.

*Last updated: August 2012*

## Notes

---

<sup>1</sup> 21 C.F.R. 10.30.

<sup>2</sup> 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.

<sup>3</sup> FDA [website](http://www.fda.gov/AboutFDA/ContactFDA/CommentonRegulations/default.htm) at <http://www.fda.gov/AboutFDA/ContactFDA/CommentonRegulations/default.htm> (last viewed 8/2/2012).

<sup>4</sup> *Id.*

<sup>5</sup> 21 C.F.R. 10.30(e)(2).

<sup>6</sup> 21 C.F.R. 10.30(b).

<sup>7</sup> 21 C.F.R. 10.30(b)(A).

<sup>8</sup> 21 C.F.R. 10.30(b)(B).

<sup>9</sup> 21 C.F.R. 10.30(b)(C).

<sup>10</sup> 21 C.F.R. 10.30(b)(E).

<sup>11</sup> *Id.*, *see also* 21 C.F.R. 10.20(b).

<sup>12</sup> 21 C.F.R. 10.30(b)(D).

<sup>13</sup> 21 C.F.R. 10.20(a).

<sup>14</sup> 21 C.F.R. 10.20(c).

<sup>15</sup> 21 C.F.R. 10.20(c)(1).

<sup>16</sup> 21 C.F.R. 10.30(b).

<sup>17</sup> FDA [website](http://www.fda.gov/AboutFDA/ContactFDA/CommentonRegulations/default.htm) at <http://www.fda.gov/AboutFDA/ContactFDA/CommentonRegulations/default.htm> (last viewed 8/2/2012).

<sup>18</sup> 21 C.F.R. 10.30(e)(1).

<sup>19</sup> 21 C.F.R. 10.30(h)(1).

<sup>20</sup> 21 C.F.R. 10.30(h)(2).

<sup>21</sup> 21 C.F.R. 10.30(h)(3).

<sup>22</sup> 21 C.F.R. 10.30(h)(4).

<sup>23</sup> 21 C.F.R. 10.30(e)(2).

<sup>24</sup> *Id.*

<sup>25</sup> 21 C.F.R. 10.30(e)(2)(i).

<sup>26</sup> 21 C.F.R. 10.30 (e)(2)(iii).