



*Safeguarding the Freedom to Choose
Homeopathy for All Americans*

Background for Your Citizens' Petition Comment

Below is some background to help you construct your own comments to the FDA, Congress and the President and Vice President. You can write a comment that covers all of the points listed below or you can focus on just a few points. Keep in mind that limits on the number characters including spaces will vary on different forms. The form will let you know whether you are over the limit.

If you have a personal story that illustrates an important point, that story can be much more effective than simply covering all the points listed below.

- We ask you NOT to use stories about cancer as this remains very controversial.
- Do NOT criticize pharmaceuticals except that you may relate a situation in which pharmaceuticals were giving you unpleasant side-effects and switching to homeopathic medicines allowed the side-effects to go away.

Here are some notes to help you with your comment:

1. Ask the FDA to adopt the rule* contained in the Citizens' Petition or, when commenting to a member of Congress or the Executive, ask that person to contact the FDA to voice support for the Citizens' Petition.
2. Say that homeopathic medicines are nontoxic and inherently safe when properly manufactured and labeled. They are used by millions of Americans to restore and maintain their health and the health of their families.
3. The FDA's Draft Guidance on homeopathy is inadequate because it fails to distinguish between homeopathic medicines—which when properly manufactured and labeled are nontoxic and inherently safe—and improperly labeled products that do not meet homeopathic standards.
4. If adopted, this guidance could lead to the removal of many popular homeopathic medicines from the market without justification.
5. The rule proposed in the Citizens' Petition solves this problem because it provides for the following:

- Clear guidelines for protecting consumers from improperly manufactured and/or labeled products.
 - Methods for assuring continuing access to the full range of homeopathic medicines on the market today.
 - Clear regulations for manufacturers that tell them what they should do in order to adhere to the law and meet the FDA's expectations for quality and purity. Right now, the FDA's proposed guidance provides no clear guidelines and so manufacturers are in the dark about the FDA's expectations.
 - A framework for moving genuine homeopathic medicines into the Homeopathic Pharmacopeia of the United States in a way that protects consumers and allows the expansion of homeopathic medicines available in the United States.
6. The Petition was written with input from medical doctors and other practitioners, pharmacists, domestic manufacturers, and consumers.
7. The FDA's Draft Guidance actually increases risks to consumers.
- If consumers are denied access to nontoxic, inherently safe homeopathic medicine applicable to their condition, they will seek out higher-risk alternatives including pharmaceuticals which can have dangerous and even fatal side-effects.
 - Nontoxic, inherently safe homeopathic medicines may no longer be available to consumers to help address infections without creating antibiotic resistance or to treat pain without risking opioid dependence and death.
 - The FDA's risk-based approach as currently conceived would increase risk to consumers overall by disproportionately focusing the agency's enforcement resources on nontoxic, inherently safe homeopathic medicines.
8. To view the Citizens' Petition please visit:

<https://www.regulations.gov/docket?D=FDA-2020-P-1510>

*The FDA and members of Congress and the Executive branch will understand you when you use the term "rule" which is the way federal law refers to a set of regulations on a particular topic issued by a federal agency or department.