



*Safeguarding the Freedom to Choose
Homeopathy for All Americans*

Background for Comments and Messages

Below is some background to help you construct your own comment to the FDA and/or message to Congress, the President, and the Vice President while highlighting key issues relating to the most recent Draft Guidance. You can write a comment and/or message that covers all of them or you can focus on just a few points. Keep in mind that on the FDA comment form you are limited to 5,000 characters including spaces. Congressional and Presidential/Vice Presidential message forms may have lower limits, a few quite a bit lower. The form will let you know whether you are over or under.

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 or vaccines 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 and message(s):

1. I request that the FDA grant a 180-day extension to the Notice-and-Comment Period for this Draft Guidance.
2. I am grateful to the FDA for responding to the concerns of the homeopathy community by issuing a revised Draft Guidance.
3. I request that the FDA revise the Draft Guidance to reflect the following:
 - Homeopathic medicines are nontoxic and inherently safe when properly manufactured and labeled.
 - Homeopathic medicines are not “new drugs.”
 - The agency’s risk-based approach will be applied to the FDA’s own enforcement process by examining the relative risk of each category of products it regulates. This would almost certainly put homeopathic medicines at the bottom of the list because they are nontoxic and inherently safe.

4. The Draft Guidance threatens all of homeopathy.
 - It allows the FDA to withdraw across all manufacturers any nontoxic, inherently safe single homeopathic ingredient both in single-ingredient medicines and all combination products containing a particular homeopathic ingredient even when in products that are properly manufactured and labeled.
 - A review of public FDA records by Americans for Homeopathy Choice did not find a single instance of a safety concern involving properly manufactured and labeled homeopathic medicines.
 - All problems cited by the FDA involved improperly manufactured and/or labeled products.
 - I am concerned that the FDA intends to remove nontoxic, inherently safe homeopathic medicines mentioned in its public statements such as Belladonna, Nux vomica and Lachesis muta even when they are properly manufactured and labeled.
 - The FDA's claim that homeopathic medicines are "new drugs" is misguided and legally incorrect.
 - The 1962 amendments to the Food, Drug and Cosmetic Act were designed to deal with inherently dangerous substances.
 - The process for New Drug Applications was created to determine whether the benefits of a proposed inherently dangerous substance used as a drug outweigh the risks.
 - Since properly manufactured and labeled homeopathic medicines are nontoxic and inherently safe, there is no need to weigh risks against benefits.
 - The New Drug Application simply doesn't apply to single homeopathic ingredient medicines in the Homeopathic Pharmacopeia of the United States and its supplements. Those medicines have already been tested for safety and effectiveness and undergone rigorous toxicological review.
5. The Draft Guide 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.