For Allied Organizations
FDA Comments
Email Template No. 1

FINAL

Subject: Homeopathy Remains At Risk – We Need More Time!

Dear Homeopathy Supporter,

I'm sending you this urgent message today requesting that you do two very important things:

1. Submit a comment to the FDA docket about homeopathy telling the agency that we need a 180-day extension in order to respond adequately to the FDA's latest proposed rules. When you're ready to do that, you can click the button below.

2. Forward this email to your contacts and get every family member in each household—regardless of age—to submit a comment to the docket.

You may have been hearing about new proposed rules for homeopathy put out by the FDA. We were glad that the previous conceptually flawed and poorly worded rules (called "guidance" by the FDA) were recently withdrawn.

In their place the FDA proposed a revised guidance. This revised guidance has some helpful changes and some detrimental ones. **Unfortunately, the detrimental ones are serious, and we must now pressure the FDA to revise this guidance considerably.** We can do that by getting a very large number of people to ask for an extension while commenting on this new draft.

If you are familiar with the changes the FDA made, you can go directly to the FDA Comments page on the Americans for Homeopathy Choice site by clicking the link below. There you'll find out how to make a comment that will help us get an extension.

https://homeopathychoice.org/fda-comments-landing/

If you want to know more about the changes, here's a summary of the most important points:

1. The new Draft Guidance, if adopted, will allow the FDA to withdraw even properly manufactured and labeled homeopathic medicines from the marketplace. This is peculiar because these have never posed any sort of safety concern according to an initial review of public FDA records by Americans for Homeopathy Choice.

2. It is clear that the FDA intends to use this authority and has even mentioned specific medicines such as Belladonna, Nux vomica and Lachesis muta in its public statements regarding enforcement.

3. The authority for this kind of assault on homeopathy will result from the declaration by the FDA that all homeopathic medicines are "new drugs." We all know that legally speaking, this is nonsense. Homeopathic medicines have been around for 200 years.

   This nonsense declaration means that under federal law all homeopathic drugs will become technically "illegal" and subject to withdrawal from the marketplace. If the FDA just *thinks* there is a problem with a homeopathic medicine, it can withdraw it forever without conducting any sort of investigation.

4. Since the agency has already told us that it thinks that Belladona, Nux vomica, Lachesis muta and several other homeopathic medicines are dangerous, we can anticipate that it will try to remove them from the marketplace as soon as the guidance is finalized.

5. Once medicines are removed, the only conceivable way they could be reinstated is to go through what the FDA calls a New Drug Application (NDA). That won't happen for two reasons:

   First, no one can patent homeopathic medicines because they are made from common substances. So, no company would be able to make back the huge cost of going through the NDA.

   Second, the NDA is designed for pharmaceuticals and is unable to test the effectiveness of a medicine that is tailored to each individual, rather than given to a large mass of people who supposedly have the same condition. Hence, it is unlikely that any homeopathic medicine would be ruled both safe and effective by the FDA.

   That means that when the FDA removes a homeopathic remedy from the market, it will be the equivalent of banning it forever. And, don't think that you'll be able to order your remedies from abroad. The FDA will be legally permitted to stop them at the border.

I could tell you more, but what I've told you so far should convince you that we must get the FDA to change its unreasonable and misinformed guidance to reflect the realities of homeopathic medicines: Homeopathic medicines are nontoxic, mild, effective and have few, if any, side-effects.

Homeopaths use homeopathic medicines in ways that individualize treatment. Samuel Hahnemann determined 200 years ago that individualization is the best way to treat patients. (Pharmaceutical companies are only now discovering that Hahnemann was right; unfortunately, the FDA has not yet come to understand this.)

Help us get an extension so that there will be enough time to prepare a response properly. We need the time in order to show the FDA step-by-step how to change the Draft Guidance in ways that will protect rather than imperil homeopathy. Please click the link below to go to a form that will allow you to make a comment to the FDA in just a minute or two.

https://homeopathychoice.org/fda-comments-landing/

With urgency and gratitude,

[YOUR NAME] [YOUR TITLE]
[YOUR ORGANIZATION NAME]

P.S. Please send this message on to anyone you can think of who cares about homeopathy. Time is running out!