national center for homeopathy™

Update on Latest FDA Draft Guidance on Homeopathy

December 20, 2019

After reviewing in more detail the latest Draft Guidance on homeopathy released in October 2019 by the U.S. Food and Drug Administration (FDA), we in the homeopathy community remain deeply concerned about the approach the FDA is taking.

We were glad that the previous conceptually flawed and poorly worded guidance was withdrawn. That was a victory for all of us who participated in communicating our concerns to the FDA and to members of Congress.

To be fair, the new October 2019 guidance has some helpful changes. But it also has some detrimental ones. **Unfortunately, the detrimental ones are very detrimental, and those of us who want to protect the future of homeopathy in America 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 from the FDA while commenting on this new draft. Those who wish to make a comment can do so on a special FDA Comment page which can be reached by clicking here.

We desperately need a 180-day extension in order to respond adequately to the FDA. We need more time to analyze the complex legal and policy matters arising from this latest guidance so that we can respond appropriately and completely.

So far, our analysis reveals the following concerns:

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 The new Draft Guidance, if adopted, will allow the FDA to withdraw even properly manufactured and labeled homeopathic medicines from the marketplace.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 puzzling 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.

   But 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 Belladonna, Nux vomica, Lachesis muta and several other remedies are dangerous, we can anticipate that it will try to remove them from the marketplace as soon as the guidance is finalized.

5. Once this happens, the only conceivable way these remedies could be reinstated is to go through what the FDA calls a New Drug Application (NDA). But that's not going to happen for two reasons:

   First, no one can patent homeopathic remedies 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, NDAs are designed for pharmaceuticals. NDAs are 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. Those who believe they will simply be able to order homeopathic remedies from abroad will be in for a rude surprise. The FDA will stop shipments of homeopathic remedies that have been effectively banned in the United States at the border.

Our findings so far tell us that we are in for a long slog with the FDA. That's why we need a 180-day extension. Fortunately, representatives of the homeopathy community remain in communication with key officials at the FDA and are continuing our dialogue about the needs of the community.

Our position remains the same as it has from the beginning: We seek an approach that will protect access to the full range of homeopathic medicines while safeguarding the quality and purity of the products containing them.

This statement has been endorsed by the following organizations: