FOR CONSUMERS:

OVERVIEW OF THE SITUATION

The FDA is attempting to repeal historic guidance documents (CPG 400.400) *Conditions Under Which Homeopathic Drugs May Be Marketed*, that has for decades acknowledged and protected the unique nature of homeopathic remedies and provided clear guidance to manufacturers regarding the marketing of these remedies.

Over the past few months our industry representatives and consumer activists have worked together to make our legislators aware of the need and urgency for their participation. Our multi-prong approach targeted key influencers. **Senator Orrin Hatch of Utah and Congressman Ryan Costello of Arizona** agree with our position and have created letters asking the FDA to maintain the current CPG 400.400 supporting advice of the American Association of Homeopathic Pharmacists (AAHP). We need as many legislators as possible to sign onto those letters.

National Health Freedom Advocacy (**NHFA) has reviewed the Draft Guidance and submitted a 20 page formal comment to the FDA** opposing the Draft Guidance and recommending changes. This review is the most comprehensive statement that has been generated from the legal perspective. There are two key reasons why NHFA opposes the draft guidance:

1. **The FDA is attempting to repeal historic guidance documents (CPG 400.400)** that has for decades acknowledged and protected the unique nature of homeopathic remedies and provided clear guidance to manufacturers regarding the marketing of these remedies.

2. **In addition, FDA is now attempting to establish enforcement priorities for homeopathic remedies similar to all other pharmaceutical drug unapproved drugs,** based on a general "risk-based" approach, but with even added restrictions not imposed on pharmaceutical unapproved drugs.

Read FDA Draft Guidance Here.

Read NHFA's Comments Here.

Read CPG 400.400 Here.

Our most opportune time to affect the FDA's decision is NOW.

We need you all to do THREE THINGS: Sample letters and links are provided below.

1) **Send a letter to your Senators** asking them to sign onto the letter of Senator Orrin Hatch.
2) **Send a letter to your Representative(s)** asking them to sign onto the letter of Congressman Ryan Castello.
3) **Send a letter to the FDA** explaining your position as a consumer on this concern.

As a consumer, you can uniquely attest to experiences that particularly concern the FDA. The fundamental consumer protection concerns of the FDA center on safety and the consumers' ability to differentiate homeopathic products. Unlike the professional, you can offer the following information:

- You can describe how the CPG 400.400 provides for ingredient identification with the Latin name and potency nomenclature making it easy for you to distinguish a homeopathic product both in the US as well as anyplace in the world.
- You can share your understanding that homeopathic products should contain only homeopathic ingredients as CPG 400.400 describes.
- You can share that literature and product websites as well as other homeopathic information sites provide clear information about the unique trials in homeopathy called ‘provings’ and the principle by which you choose a homeopathic product for your health concern.
- You can attest to your use of homeopathic products for acute and chronic issues that truly correct your health concerns without complications, side effects, or risks of addiction.
- You can tell the FDA that you want to maintain the affordability of homeopathic products. Trials, outside of ‘provings’, are inconsistent with homeopathic principles. Added trials in the proposal would be unnecessary for consumer use. Such trials would add confusion to the distinction of homeopathic products, increase the cost and decrease accessibility of remedies.
- You alone can tell them that homeopathic products and professionals are an essential component of your healthcare and access must be protected both for over-the-counter products and professional products.