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Deborah A. Dupnik, CAE, CCSM-A

To: Dr. Gottlieb, Dockets Management Staff, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and other pertinent FDA Staff

Re: FDA-2017-D-6580, Docket No. 6580-27157
Draft Guidance "Drug Products Labeled as Homeopathic"

The National Center for Homeopathy, the largest homeopathy consumer organization in the US, thanks the Food and Drug Administration for the opportunity to comment on the recently released Draft Guidance "Drug Products Labeled as Homeopathic."

On behalf of our over 2600 consumer members, we want to share our serious concerns about this proposal and urge the FDA to reconsider some proposed actions.

Our primary concern is that the Draft Guidance proposes removing the existing Compliance Policy Guide 400.400 that has provided guidance and safety for decades and suggests, instead, substituting a less effective, less comprehensive Risk Assessment Criteria:

- Risk Assessment is designed for and essential to the oversight of chemically-based medicines, but not for low-risk, highly-diluted homeopathy medicines.
- Homeopathic medicines are unique and are not the equivalent of chemically-based conventional drugs. They are prepared and manufactured differently and are used based upon a distinct set of principles. They should not be shoehorned into a category intended to increase the safety of chemically-based medicines, but completely unsuited for homeopathic medicines.
- The proposed Risk Assessment categories overlook the characteristic preparation and dilution of homeopathy medicines, which are in the nanoscale range and remove the potential for toxicity from the sourced substances.
- The CPG 400.400, created by the FDA and used by manufacturers for 30 years, has ensured the manufacturing of homeopathy medicines to high standards and has resulted in an exemplary safety record for homeopathic medicines.
- Removal of the CPG 400.400, which specifically identifies homeopathy medicines within the HPUS protocols, opens the door for hybrid products to be sold improperly as homeopathic medicines.
- Removal of the CPG 400.400 takes away the standardized production of homeopathy medicines, which may jeopardize safety.
- The CPG 400.400 has guided the manufacturers and protected the consumers of homeopathy for 30 years. It is a comprehensive document and contains all the needed solutions to the challenges raised by the FDA in the Draft Guidance.

We understand that the main goal of the FDA is to protect consumers from unsafe products. However, we believe that many of the proposed actions in the FDA Draft Guidance will instead limit consumers' choice and access to homeopathy products, while potentially opening up other areas of risk.

In our experience, consumers of homeopathy are intelligent and well-prepared to assess and make their own health care choices, especially with inherently safe homeopathy products. The increasingly positive experience of consumers with homeopathy and their confidence in the medicines are due in large part to the influence of the CPG 400.400, providing guidance and standardization of homeopathy medicines.

It is of equal concern to us that in creating the proposed Draft Guidance, the FDA officials seem to have overlooked the two days of presentations to the FDA panel in 2015 and thousands of individual comments posted to the FDA comment page. Among the presentations and subsequent comments were significant documentation of the long and admirable safety record of homeopathy medicine and a survey by the National Center for Homeopathy showing consumer use and satisfaction.

In this age of dramatic advances in health care, new medicines require novel approaches of study and regulation. Homeopathy is a 200-year-old medicine that foretold the modern use of nanotechnology. It is not appropriate to regulate it with criteria developed for chemically-based conventional medicines.

Consumers like homeopathy; they use homeopathy; they understand homeopathy. We encourage the FDA to engage the consumers and others in the homeopathy community, the manufacturers and practitioners, to successfully support this health promoting, holistic medicine. We urge the FDA to continue the CPG 400.400 that has protected consumers for decades and safeguard our consumers' choice of and access to all homeopathy medicines.

Sincerely,

The National Center for Homeopathy (Representing over 2600 satisfied consumers of homeopathy)

Deborah Dupnik, Executive Director

Abby Beale, Board President

Tina Quirk, President-Elect; Public Policy and Advocacy Committee

Glenna Tinney, Treasurer; Public Policy and Advocacy Committee