



May 21, 2018

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Draft Guidance for FDA Staff and Industry Drug Products Labeled as Homeopathic  
(Docket ID: FDA-2017-D-6580)**

Dear Sir/Madam:

APhA is pleased to submit these comments to the Food and Drug Administration's ("FDA") draft guidance, "Drug Products Labeled as Homeopathic" (hereinafter "Draft Guidance"). The American Pharmacists Association ("APhA") was founded in 1852, and represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and other parties invested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates FDA's efforts to improve its regulatory framework for homeopathic drug products. APhA supports the demonstration of safety and efficacy of homeopathic products from adequate, well-designed scientific studies before pharmacists advocate or sell homeopathic products. APhA encourages FDA to provide information to pharmacists, patients and other health care practitioners regarding the safety and efficacy of homeopathic products and encourages the FDA to provide education regarding this regulatory shift to limit patient and practitioner confusion.

Thank you for your leadership and work on this issue. If you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email [jventresca@aphanet.org](mailto:jventresca@aphanet.org) or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSP Pharm, MBA, ScD (Hon), FAPhA  
Executive Vice President and CEO

cc: Stacie Maass, BSP Pharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs