Testimony of Will Woodlee on behalf of AHPA

- Introduction of AHPA

- AHPA believes that the present Federal Food, Drug, and Cosmetic Act (FFDCA) regulation of homeopathic drug products, as outlined in CPG Sec. 400.400 ("Conditions Under Which Homeopathic Drugs May be Marketed") (rev. Mar. 1995), provides a sufficiently substantial regulatory platform for homeopathic drug product oversight:

1. Section 510 of the FFDCA requires firms that manufacture drugs in the U.S. or that are offered for import into the U.S. to register and to list their drug products with the FDA. Registration information must be renewed annually.

The 2012 Food and Drug Administration Safety and Innovation Act now requires drug firms to submit annual establishment registrations in the period from October 1st to December 31st of each calendar year. In addition, at the time of annual registration, firms must list any drugs not previously listed. Firms also must submit this information electronically.

The various types of information required to be submitted for each drug listing is substantial and is spelled out in detail in FDA's May 2009 *Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Drug Establishment Registration and Drug Listing*. The requirements for drug listing are the same for prescription and OTC drugs.

FDA may easily obtain information regarding homeopathic drug products and manufacturers that do not comply with these requirements by searching the Internet, thus obviating a process like that required in the early 1970s when the OTC drug product review was begun. In this fashion, the Internet may have obviated the need for a formal regulatory process to gather information about this product category and provides a means of identifying manufacturers, marketers, and products as candidates for education, administrative, or enforcement action.

2. The 2006 Dietary Supplement and Nonprescription Drug Consumer Protection Act established requirements for the reporting of serious adverse events associated with OTC homeopathic drug products. The law also requires manufacturers to maintain records of all adverse events reported to them. Under the cGMP regulations for finished pharmaceuticals, manufacturers must maintain records and reports regarding complaints and, where required, must investigate those complaints. 21 C.F.R. §§ 211.198, 211.192.

3. Homeopathic drug products by their very nature present a very small safety risk because of their ultra-dilute character. Nevertheless, the additional mechanisms in place in the United States, including reporting of adverse events to FDA by poison control centers, healthcare professionals, and the general public, augment mandatory industry reporting and FDA's acquisition of other "signals" of possible safety issues associated with such products.

4. AHPA is not aware of any data indicating that consumers perceive OTC homeopathic drug products as substitutes for prescription drugs approved for treating serious medical conditions. Under the existing regulatory framework, if an OTC homeopathic drug product is inappropriately marketed for treating such conditions, FDA has adequate enforcement authority to address the situation and to effectively communicate any public health concerns to health care professionals and the general public.

- In light of the adequacy of the existing regulatory framework for OTC homeopathic drug products, AHPA urges FDA not to increase regulatory burdens on manufacturers of such products, which could limit consumer choice and access to products that, in some cases, have been available for decades.