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

**Re: Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing. 80 Fed. Reg. 16327-16329, March 27, 2015, Docket No. FDA-2015-N-0540**

The Consumer Healthcare Products Association (CHPA<sup>1</sup>) appreciates the opportunity to provide comments to the FDA in response to the March 27, 2015 Federal Register notice announcing a public hearing on the regulatory framework for homeopathic drug products. CHPA and its more than 80 manufacturer member companies have an interest and expertise in over-the-counter (OTC) drug products and approximately 10% of these members market homeopathic medicines.

These comments supplement oral remarks made at the April 20, 2015 hearing. They have been organized in order consistent with the questions posed in the Federal Register notice.

Consumer attitudes and information (Questions 1 and 8)

Seen through a consumer's eyes, a broad range of products are helpful as people take care of their own health needs. Consumers cite many reasons for OTC healthcare product usage, including 24/7 availability, greater control of their health, and cost savings. The table below shows partial data from a 2014 survey conducted by IRI for CHPA. The question asked was: What are the key benefits of self-treatment as it relates to the use of over-the-counter products and being healthy? The base size was 4500.

Benefit for OTC Usage	% of respondents
Saves time rather than visiting doctor	40
Keeps me in good health	37
24/7 access/availability	36
Feel greater ownership of my own health	21

Consumers report responsible attitudes toward OTC medicines and take an active role in their healthcare. They are confident in their ability to use OTC medicines, know that OTC medicines work from their own experience and state that OTC medicines let them take care of themselves<sup>2</sup>. Most U.S. adults are comfortable treating their own minor ailments before seeking professional care. In a survey

<sup>1</sup> CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements ([www.chpa.org](http://www.chpa.org)).

<sup>2</sup> TNS for CHPA, 2009

conducted in 2010 for CHPA<sup>3</sup>, more than 95% of respondents strongly or somewhat agreed that they were comfortable making treatment decisions before seeking medical care and tried to find a solution for a minor ailment before seeking professional care. More than 93% of respondents preferred to treat their minor ailments with an OTC medicine before seeking professional care.

CHPA recently conducted a telephone survey<sup>4</sup> among 1,000 U.S. adults to better understand consumer knowledge about homeopathic products. Whether from the perspective of satisfaction with the range of choices today, or the opportunity for even more options in the future, key findings include that consumers demand a range of treatment options. For instance, while seventy-four percent of those surveyed agree they have sufficient choices today, the same percentage would like to have even more options to treat their conditions. Seventy-nine percent of respondents agree that finding a product that works for them means they need multiple choices. When asked about familiarity with homeopathic products, one quarter of respondents were extremely or very familiar, one quarter were somewhat familiar, and one half were a little or not familiar. Thirty-eight percent of respondents said they had tried homeopathic products, and not surprisingly, those who were most familiar with homeopathic products were the most frequent users. Those trying homeopathic medicines were more frequently white, 45+ yrs. old and of higher income. Among respondents who said “yes” they have used homeopathic medications (n=379), 18.5% used frequently, 40.1% used sometimes and 40.6% used rarely.

Doctors and online websites are by far the major sources of information about medical treatments, with doctors being seen as the source of the most reliable information.

	Source of most information	Most reliable information
Your doctor	44.2%	59.8%
Online sites, like WebMD	41.0	22.2
Friends and family	7.3	9.5
Your local pharmacy	2.3	3.5
Newspapers	1.0	0.8
TV	0.9	0.7
The label on your medicine	0.8	0.5
Radio	0.5	0.2

Respondents said they had too little information about traditional prescription medicines (58.5%), traditional over-the-counter medicines (48.4%) and homeopathic medicines (81.7%) to make informed decisions about their health care. Respondents overwhelmingly would go to online sites to find more information on homeopathic medicines.

	Source of information
Online sites, like WebMD	61.7%
Your doctor	17.5
Friends and family	7.5
Other	4.6
Our local pharmacy	4.0

<sup>3</sup> StrategyOne for CHPA, 2010

<sup>4</sup> GS Strategy Group for CHPA, 2015

Newspapers	0.4
TV	0.2
Radio	0.1

We know from other research studies that consumers shop by indications and the symptoms they intend to treat.<sup>5</sup>

Safety profile (Question 2)

FDA asked about data sources to better understand homeopathic products. The American Association of Poison Control Centers National Poison Data System is one such source. Dr. Edward Krenzelok, a consulting toxicologist with the Rocky Mountain Poison and Drug Center, presented an analysis of poison center data covering 2006-2013. This research was funded by CHPA. Single product exposures over an eight year period were analyzed. The data show that homeopathic products have a very favorable safety profile, with low overall exposures, and with low or no health effects. Homeopathic exposures account for about one percent of all exposures reported to American poison centers as they relate to pharmaceutical agents, single exposures. The vast majority of exposures are unintentional (accidental) and involve children less than six years of age. As is the case with all medicines, there is an opportunity to reduce accidental and intentional exposures. Rocky Mountain Poison and Drug center is conducting a case-level analysis of these data and will be filing a separate report to FDA.

Compliance policy guide (Question 3)

CHPA supports the current regulatory framework for homeopathic drug products, including the FDA Compliance Policy Guide (CPG). The current regulatory framework meets the needs of consumer access and ensures standards of quality and safety for homeopathic drug manufacturers. Homeopathic drugs have been subject to regulation under the federal FD&C Act since 1938. Manufacturers of homeopathic medicines are subject to routine inspections and the CPG requires manufacturers to register with the FDA and list their drug products. Controls like cGMPs, serious adverse event reporting, standardized labeling and compendial standards are all in place to assure quality and safe use. Where products are not in compliance, FDA has the ability to act and to act swiftly. Should FDA undertake a re-examination of the CPG, the regulated industry should be involved the process.

CHPA appreciates the opportunity to submit these comments to FDA. We would welcome any additional opportunities for dialogue.

Sincerely,



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<sup>5</sup> Concentrics Research for CHPA, 2014.