Over-the-Counter Drug Monograph System – Past, Present, and Future; Public Hearing
March 25-26, 2014

CHPA and its member companies – who manufacture more than 90 percent of the over-the-counter medicines in this country – strongly support the Over-the-Counter (OTC) Monograph System, which effectively and efficiently regulates the majority of OTC medicines on the U.S. market. The Monograph System provides consumers with a wide range of safe and effective products that save them time and money.

Most OTC medicines in our homes are regulated under the Monograph System. This includes nearly 300 ingredients and several hundred thousand products, ranging from antacids to diaper rash creams, from analgesics to cough/cold products. Without OTC medicines, more than 60 million Americans would simply choose to not treat their illness, according to a 2011 Booz and Co. study commissioned by CHPA.

The system ensures consumers have access to a wide variety of safe and effective medicines, while at the same time providing FDA with access to important information on safety and quality. This regulatory framework works well and is not in need of fundamental changes. However, because the rulemaking has slowed in recent years, we join FDA in looking for solutions on improving consumer access to safe and effective medicines. In addition, our presentation today includes the following recommendations:

- **We support finalizing all monographs currently in tentative status and with a reasonable timeframe**. Monographs provide certainty for consumers, industry, and FDA. Today, 80 percent of the monographs are final, and we encourage FDA to identify what the obstacles are to completing the remaining 20 percent. To achieve this, we believe FDA should designate a single point leader with accountability and establish reasonable timelines for completion and measurements of progress. Where FDA cannot finalize tentative monographs on an entire category of medicines, they can finalize sub-categories.
- **We support a more transparent process in the rulemaking clearance process**. OTC manufacturers want to be helpful in expediting the approval of the tentative Monographs, and, to do so, we need a clearer understanding of slow progress on finalizing the remaining monographs. We recommend a public meeting to explain the process in detail and for FDA to provide publicly available information on the state of rulemaking.
- **We recommend FDA use its existing broad authority to update and improve the Monograph process.** In particular, there are three steps we believe FDA can take under the current system. FDA can issue guidance documents to explain what types of data are needed to support innovation such as new dose forms. FDA can shorten the Time and Extent Application process from three steps to fewer steps to support addition of new ingredients to Monographs. Finally, FDA can exercise enforcement discretion to allow new/updated information to be added to product labels.