



June 14, 2016

Division of Dockets Management, FDA  
Over-the-Counter Monograph User Fees: Public Meeting; Request for Comments  
Docket No. FDA-2016-N-1092

The following remarks were delivered on June 10, 2016.

“Good morning.

I’m Barbara Kochanowski, Vice President of Regulatory & Scientific Affairs at the Consumer Healthcare Products Association. Our members, the manufacturers of nonprescription medicines, have a strong interest in the topic of this hearing and are pleased to offer our comments.

My remarks will be divided into 3 topics:

1. FDA resources
2. The need for OTC Monograph reform
3. User fees for nonprescription medicines

For over 40 years, the vast majority of nonprescription medicines have been marketed under the OTC monograph system, which provides consumers with access to safe and effective treatment options for a variety of conditions. In fact, the majority of pharmaceuticals used in the United States, approximately 60% by volume, are actually nonprescription pharmaceuticals. The prevalence of OTC medicines in our healthcare system is widespread. Because of the importance of these products to public health, consumers, stakeholders and the regulated industry need to know that these products are marketed under a sound and adequately-funded regulatory system. Currently, FDA is under-resourced for regulating nonprescription medicines under the monograph system. Fewer than 30 FTEs, or about \$8 million is insufficient to cover the 400 active ingredients for over 700 therapeutic uses that is the OTC market.

While the monograph system has served our nation well, it has become cumbersome and outdated and needs to be modernized. The rule making process upon which it is based is stalled, a bigger issue than just for the Monograph process. FDA needs the ability to protect the public health by completing unfinished monographs and making labeling updates in a timely fashion. In addition, industry desires the ability to innovate and provide consumers with modern technology to support safety, efficacy and compliance. CHPA submitted comments on the topic of monograph reform in 2014.

There are now several examples of user fee programs under FDA’s jurisdiction. In each case, the regulated industry supported user fees when, added to baseline appropriations, they enable FDA to accomplish very specific goals agreed to with the user fee-payers. For example, in the case of new prescription drugs, in order to make the drug review process more efficient and to get medicines to patients quicker, Congress worked on a bi-partisan basis with FDA, patient organizations, industry, and other stakeholders to craft a remedy to *supplement* FDA resources while preserving agency fiscal and management discipline and independence. The remedy was a framework for user fees, paid by drug sponsors, with funds dedicated to enlarging the FDA workforce committed to new drug reviews. At the same time, FDA agreed to performance review goals and maintenance of baseline appropriations. More recently, in the case of generic drugs, a lack of FDA resources to manage a backlog of ANDAs resulted in an agreement by industry to pay user fees. In these cases, there were incentives for both industry and FDA to develop user fee programs.

A user fee program for nonprescription medicines will need thorough discussion and study. Unlike other drugs subject to user fees, nonprescription drugs under the monograph system are not subject to FDA approval prior to marketing. Many of these ingredients have been marketed for more than 40 years, with a long history of safe use. There is no backlog of applications. Therefore, we must define value differently than industries subject to FDA approval prior to marketing. As FDA correctly identifies in the meeting notice, assessment of fees can create certain incentives or disincentives for activities that are subject to fees. Neither we, nor FDA, nor the public want to discourage activities that could benefit public health.

Fees for nonprescription medicines under the monograph system could be a disincentive for innovation, or they could incentivize innovation, depending on how they are applied. For example, today, very few manufacturers are filing New Drug Applications and paying the PDUFA fee to innovate with monograph ingredients. Discussion of a potential user fee program should include identifying mechanisms to support innovation.

In terms of fees in general, we would expect fees to be justified and spending transparent. Fees should not be disproportionately targeted to rebuilding and maintaining capability. We would expect to see a balance in the application of fees between long-standing, needed actions under the monographs and acting on innovation.

In summary, our members are supportive of a robust monograph system to regulate nonprescription medicines. The current system needs to be modernized and we welcome the opportunity to discuss reforms, and in that context, how a user fee program may fit.

Thank you for the opportunity to share our comments.”

Sincerely,



Barbara A. Kochanowski, Ph.D.  
Vice President, Regulatory & Scientific Affairs