

Meeting Summary

Over the Counter Drug Monograph System – Past, Present and Future

The Over-the-Counter (OTC) Monograph Process (or OTC Drug Review) was established in 1972, using a system of drug monographs set up by active ingredients and grouped by therapeutic class. The OTC Drug Review includes a three-stage public notice and comment rulemaking process for each therapeutic class. Under the OTC Drug Review, FDA has been able to evaluate the safety and efficacy of thousands of OTC active ingredients, thereby, obviating the need for a new drug application (NDA) for each OTC drug product, while allowing for the safe and effective use of these products and implementation of consistent labeling. Despite considerable success, the OTC Monograph system has become less efficient over the years. For example, there are large numbers of products for which there are no final monographs. These Tentative Final Monographs (or TFMs) may lack sufficient data for FDA to determine if the products are safe, and/or effective. There are also limitations on FDA's ability to quickly require new warnings or other labeling changes to address emerging safety or effectiveness issues. The purpose of this March 25 and 26, 2014 public hearing was to obtain feedback from the public on the strengths and weaknesses of the process and to receive recommendations about what actions are needed to address important challenges.

Some Key Themes Presented by Stakeholders

1. Some presenters said that the Agency should not make major changes to the current OTC Monograph Process since approximately 80 percent of monographs are already final. Instead, the agency should establish clear goals and timelines in order to finish the remaining 20 percent (the TFMs). There is a need to improve transparency of the process as well as facilitate data sharing by collaborating with stakeholders, including potentially through the use of public private partnerships. FDA should develop guidance to encourage OTC drug innovation and clarify FDA expectations in order to incorporate new safety information more quickly into the Drug Facts Label. The Agency should use enforcement discretion so industry can make changes to drug labels while rulemaking is pending.
2. Changes should be made to the Time and Extent Application (TEA) process to allow for the acceptance of foreign data where OTC drug ingredients have been safely marketed outside the United States over a prolonged period.
3. We heard that OTC drugs should be subject to the same safety and efficacy standards as other drugs based on risk versus benefit. Reliance on enforcement discretion for compliance with proposed rules and voluntary industry action to address safety concerns is not optimal for patient protection. FDA should conduct regular inspections of OTC manufacturing facilities to ensure OTC drug quality.

4. FDA's current OTC Monograph Process is inadequate to address older adult OTC medication needs. Before making changes to modernize the OTC Monograph Process, FDA should take into account emerging safety issues such as dosing, labeling and packaging for older adults using OTC medications.
5. The OTC Monograph Process should be overhauled to allow FDA to quickly require the data necessary to develop appropriate pediatric drug labeling. This includes giving FDA the authority to transition the product from OTC monograph to NDA status when significant safety and/or efficacy concerns arise.
6. OTC drugs should be broken into three distinct categories and given priority review based on requirements for safety, efficacy and labeling. Ingested drugs with dose restrictions should be given top review priority. Topically applied drugs with dose restrictions should be in the second category and topical drugs without dose restrictions should be in third category.
7. It was suggested that the OTC Drug Review could be improved by applying administrative remedies such as relocating the Office of Nonprescription Drugs to a more centralized location within the Center for Drug Evaluation and Research such as the Office of Regulatory Policy or the Center Director's Office. In addition, some commenters recommended appointing a pharmacist to oversee the review, and said that the Center should provide the necessary resources and support to ensure the remaining monographs are completed in a timely manner.

The multi-step OTC Monograph Process is a complicated one that has become burdensome and inefficient. Although, the OTC Monograph Process claims some past successes, the challenges described above cannot be overcome simply by increasing resources. Instead, we need to consider more direct and efficient strategies to modernize this process and achieve our public health goals. We held this meeting in order to hear stakeholder input about how the OTC monograph process might be transformed in order to respond more efficiently to a changing healthcare environment. We will take stakeholder comments into consideration as we move forward.