

Over-the-Counter Monograph User Fees – Stakeholder Webinar

September 6, 2016, 10:30 am-12:00 pm

Purpose

- To be a follow-up to the June 10, 2016, public meeting on potential Over-the-Counter (OTC) monograph drug user fees
- To provide stakeholders with a status update on the process of FDA and industry discussion that began in July 2016

Webinar Summary

Karen Mahoney, Deputy Director, Division of Nonprescription Drug Products, Center for Drug Evaluation and Research (CDER); and Donal Parks, Director, Division of User Fee Management and Budget Formulation, CDER, presented for FDA. Chris Shreeve, Director Office of Communications, CDER moderated. FDA presented the current status and challenges of OTC drug monograph review process and provided a brief overview of the monograph regulatory history and of user fee principles. FDA also summarized FDA and industry discussions to date, and outlined the many potential benefits of additional resources for monograph review activities. After the presentation, FDA took questions from participants.

Current Status and Challenges of Current Monograph Review

OTC monograph remains one of the largest and most complex regulatory programs ever undertaken at FDA. There are approximately 88 simultaneous rulemaking in 26 broad therapeutic categories encompassing over 100,000 OTC drug products. Despite the scope of the responsibilities, the monograph review program is very small. The current resources are often consumed by external mandates, such as focused statutes (e.g. the Sunscreen Innovation Act) or Consent decrees (e.g. for antiseptic rule making). Even without current external mandates, and even with desired monograph reforms, it would take many decades to finalize GRASE determinations for pending monographs, if resources remain at current levels. Additionally, FDA does not have adequate resources to consider proposed innovations to the monograph, and it is a challenge even to address safety issues in a speedy manner. FDA reiterated that the monograph review program needs sufficient resources to give priority to matters of high public health importance, while still meeting other mandates.

Currently, the Prescription Drug User Fee Act (PDUFA) and other FDA user fee programs have provided vital resources that have enabled more timely evaluation of the safety and efficacy of many drugs, biologics and devices. These programs have significantly shortened review times and increased the number of innovative drugs coming to the market. There is currently no user fee program for OTC monograph drug products, and funds from other user fee programs cannot be used for monograph work. The limited funds for OTC monograph review come entirely from budget authority. FDA is critically under-resourced in this regulatory area.

User Fee Principles

User fees are not a tax. The payer of a user fee receives a benefit from having paid a fee. There is a direct relationship between the amount of total fee revenue and FDA's total cost of providing the service. The fees defray the cost of government service and the government does not make a profit. FDA presented a high-level comparison of CDER drug user fee programs, including those established by PDUFA, the Generic Drug User Fee Amendments (GDUFA), the Biosimilar User Fee Act (BSUFA), and the Compounding Quality Act (CQA). FDA reiterated that all resources that come from budget authority and user fees for a particular user fee program go into one

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consolidated fund. The money that comes out of that consolidated fund goes to all the costs of that program, including salaries, information technology (IT) support, application reviews, facility inspections, rent, etc.

Summary of FDA and Industry Discussions

FDA and Industry discussions regarding the details of a potential monograph user fee program began in July 2016. During the discussions, Industry presented information on some activities that it can see being funded by user fees, and FDA added the activities that it must perform in order to meet its public health mandate. FDA provided estimates of the FDA resources needed for each activity; however, the total program size cannot yet be determined, in part because separate policy monograph reform discussions are ongoing. So far, Industry and FDA have discussed topics such as a potential information technology platform for the monograph, possible fee types, and possible use of Drug Registration and Listing System as a tool to track relevant monograph information. FDA stated that no final agreements have been reached with Industry, and stressed that a user fee program would have to be authorized by Congress.

Why Additional Monograph Review Resources Could Benefit Public Health

FDA presented several potential public health benefits of an OTC monograph user fee program and additional monograph resources. Since science is constantly evolving, new safety data arise frequently. FDA needs resources to keep pace with evolving knowledge, and to take safety actions in a more timely and efficient manner. A user fee program would provide FDA with the ability to make regulatory decisions faster, and to take actions faster. User fee systems are associated with timelines and performance goals; however, FDA cannot have these without adequate resources. Current monograph actions generally do not have timelines, and FDA has so few resources that FDA would find it extremely challenging to meet timelines even if they were imposed. After PDUFA began, review times decreased dramatically: 96% of actions for brand new drugs were on time in FY 2014; 100% in FY 2015. Predictability of review and decision process spurs innovation.

FDA stated that additional resources would facilitate innovation, which could lead to expansion of the number and types of monograph products (i.e. new ingredients; new and potentially more convenient dosage forms; new uses). The expansion could allow more choices for consumers and increase their ability for self-care. FDA stated that the current absence of monograph IT system greatly hampers review efficiency, and makes transparency very difficult. A robust public-facing IT system could make it easier for the public to see which monograph ingredients have had a final GRASE (Generally Recognized as Safe and Effective) determination, the record of FDA's decision regarding monograph issues, and the basis behind the decisions, as well as which monograph ingredients FDA intends to act on in coming years. FDA also stated that an OTC monograph user fee system would fund modernizing the monograph regulatory system which has many positive aspects. It has a low regulatory burden, since manufacturers would not have to come back to FDA for every new product, as long as they are adhering to the monograph.

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Q&A Session

FDA received questions from participants regarding when user fees are targeted to be implemented, whether it will be new legislation or part of PDUFA reauthorization/funding vehicle and if there is Congressional interest. FDA responded that in early June FDA held a public meeting on the user fee topic to gather stakeholder input. At the June 10, 2016 public meeting regarding potential monograph user fees, stakeholders expressed general agreement that additional monograph resources are needed. In early July FDA and industry began discussions on a potential OTC monograph user fee program. FDA is unable to speculate on the date for reaching completion. Only Congress has authority to establish a user fee program, and would need to enact new legislation to do so. Additionally, it is up to Congress to decide on which piece of legislation it would use for a new user fee program. If there is agreement reached between FDA and Industry and if Congress does decide to include OTC monograph user fee authorization with the other drug user fee Acts, the earliest a user fee program would start would be FY2018.

The participants asked what prohibits more appropriated money being spent on the OTC monograph system, and if FDA has tried to get additional appropriated money from Congress for this effort. FDA responded that there is an imbalance between supply and demand when it comes to appropriated money. There isn't enough appropriated money for all the activities that FDA has to perform. Congress is aware of the resource challenges that the monograph review program faces, and FDA would welcome additional non-user-fee appropriated funds that could be directed toward monograph review activities. A user fee program would provide additional resources. The success of past user fee efforts such as PDUFA and GDUFA illustrate the positive aspects these programs have had in speeding up review times, facilitating innovation, increasing transparency and predictability, and modernizing the drug review process for prescription and generic drugs – making a user fee program a strong candidate for obtaining additional resources.

FDA received questions from the audience regarding which stakeholders are involved in the user fee negotiations and how FDA will inform the public of the outcome of discussions with industry once discussions have concluded. FDA responded that at this point, the Consumer Healthcare Products Association (CHPA) is representing industry. CHPA has stated that it represents the overwhelming majority of manufacturers of OTC monograph drug products. However, as discussions progress, if it becomes apparent that another party will be significantly affected and/or it is proposed that significant user fees will be levied on a party that is not represented by CHPA, appropriate representation may be invited to participate in discussions. In order to keep stakeholders informed of the progress, the FDA is posting meeting minutes from the FDA and industry discussions on its website: www.fda.gov/OMUF. If an agreement is reached between the FDA and industry, the FDA plans to hold a second public meeting to discuss the details of the agreement. The FDA will announce any second public meeting in the Federal Register, which will include an open comment period for feedback from interested parties.

FDA received several questions regarding what possible fee types and list of activities that FDA and industry are considering as part of their discussion. Participants also asked if exclusivity has been discussed, what review activities a user fee structure would emphasize, and what improvements industry would see in return of a user fee program. FDA responded that FDA and industry are exploring several possible fee types, such as facility, product/formula, and application-type fees. FDA and industry have not yet reached any final agreements. FDA's two

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priorities are to efficiently act on safety issues and make Category 3 ingredient GRASE determinations. Exclusivity is not part of a user fee program and is outside the scope of user fee talks. Additionally, only Congress has authority to establish exclusivity and would need to enact new legislation to do so. A user fee program would emphasize promoting innovation, acting on safety issues, making Category 3 ingredient GRASE determinations, and finalizing Tentative Final Monographs. With additional resources, FDA can consider the expansion of the number and types of monograph products, and propose timelines and performance goals for more rapid regulatory decisions, which would benefit industry and public health.

Closing Remarks

FDA stated that the docket (81 FR 29275) is reopened for public comments until October 6, 2016 and information regarding potential OTC monograph user fees can be found at <http://www.fda.gov/omuf>