

Over-the-Counter Monograph User Fees – Stakeholder Webinar

August 23, 2017, 12:30 – 2:00pm

Purpose

- To provide stakeholders with a status update and an overview of the proposed performance goals and procedures contained in the OTC Monograph User Fee Program goals document.

Webinar Summary

Karen Mahoney, Deputy Director, Division of Nonprescription Drug Products, Center for Drug Evaluation and Research (CDER), presented for FDA. Chris Shreeve, Director, Office of Communications, CDER, moderated. FDA presented an overview of the OTC Monograph Drug User Fee Program, and the performance goals and activities established in the published goals document. Throughout the presentation, FDA emphasized that many of the parameters of reform would be addressed in statutory language established by Congress, which would supersede any conflicting content in the proposed goals document. After the presentation, FDA took questions from participants.

Current Monograph Review and Benefits of User Fee Programs

Industry and FDA user fee discussions began in July 2016 and ended in April 2017, and Secretary Price transmitted the resulting goals document to Congress in June 2017. OTC monograph reform and the establishment of a user fee program will require action by Congress.

The current OTC monograph regulatory system is burdensome and inefficient, as most changes take years to implement. The process was intended to cover products on the market in 1972 and does not promote innovation; additionally, the program is not supported by user fees and is significantly under-resourced. The reforms under consideration by Congress address these issues in several ways. First, the current system of monographs established via regulations would be replaced with a process of establishing and making changes to monographs through an administrative order. Actions on monograph issues could be made within the FDA, through a much more streamlined process, which would diminish the burden and improve the timeliness of monograph action. Second, innovation would be supported through the administrative order process, as industry could submit an over-the-counter monograph order request (OMOR), with efficacy and safety data to support a proposed change to the monograph. Third, an administrative order system supported by adequate resources would make it possible for FDA to respond much more quickly to safety issues. Finally, proposed reforms would finalize monographs that are in the process of rulemaking as tentative final monographs (or TFM's). Ingredients that are currently proposed as generally recognized as safe and effective (GRASE), or Category I, would be finalized as GRASE. Ingredients that are currently proposed as not GRASE, or Category II, would be finalized as not GRASE, and could not be marketed under the monograph. Ingredients that are currently proposed as Category III (meaning that FDA previously determined that more data are needed to determine GRASE status) could continue to

Over-the-Counter Monograph User Fees – Stakeholder Webinar
August 23, 2017, 12:30 – 2:00pm

be marketed until their GRASE status was finalized. User fee resources would enable FDA to finalize the Category III GRASE determinations.

Therefore, it is expected that the reforms under consideration by Congress would reduce regulatory burden; encourage innovation; increase efficiency, timeliness, and predictability; and streamline safety updates. The main goals of the proposed user fee goals document support these reforms, and are identified in the goals document to: build basic infrastructure; enable innovation; enhance communication and transparency; streamline safety activities; complete final GRASE determinations; and measure program success using timelines and performance goals.

Goal: Build Basic Infrastructure

FDA explained the process of building the basic infrastructure to support an OTC monograph user fee program over a five year period within the framework of managed growth. This would involve hiring new employees and training them to full review capacity at a measured pace over the course of the five year agreement. The specific yearly goals for hiring can be found in the goals document.

The goal of building infrastructure also establishes a new information technology (IT) platform for monographs. No IT platform currently exists for the OTC monograph, a lack that greatly hampers efficiency. The proposed platform would allow receipt of electronic submissions; review management; archiving; tracking; reporting; forecasting; and public availability of monograph orders and other documents. In order to keep the cost of the system as low as possible, FDA would plan to leverage aspects of a platform already in use by other CDER programs, and to adapt that program to meet monograph needs.

Goal: Enable Innovation

FDA presented two mechanisms for supporting innovation. The first is a system of over-the-counter monograph order requests, referred to by the acronym OMORs. Using an innovation OMOR, industry requestors could submit a request for FDA to make a change or an addition to the monograph. The goals document identifies two tiers of innovation OMORs – Tier One would include most innovations, such as new ingredients, indications, combinations, test methods, routes of administration, doses, or concentrations. Tier Two innovation OMORs would include a defined set of smaller, finite changes, such as standardization of doses of a finalized ingredient within a particular finalized monograph. All innovation OMORs that do not fit the definition of Tier 2 would be considered to be Tier 1 OMORs.

While most innovation would occur through OMORs, it is possible that some types of changes, such as minor dosage form changes, would not require an OMOR. The second mechanism for supporting innovation would be the issuance of order/guidance pairs, in which FDA would issue administrative orders regarding types of minor changes that could be made without submitting an

Over-the-Counter Monograph User Fees – Stakeholder Webinar
August 23, 2017, 12:30 – 2:00pm

OMOR, along with accompanying guidance to explain how sponsors could comply with these orders.

With the user fee reforms, the timeline of innovation under the monograph shortens from the current reality of many years per innovation, to 17.5-22.5 months, and the specific potential review timelines and processes for innovation OMORs can be found in the goals document.

Goal: Enhance Communication and Transparency

The two activities under this goal include meetings between the FDA and individual monograph sponsors (similar to Prescription Drug User Fee Act (PDUFA) meetings), and an annual forecast of FDA's planned monograph activities over the ensuing 3 years. Meeting management goals, types of meetings, and meeting processes can be found in the goals document.

Goal: Streamline Safety Activities

The goals document specifies the timelines for safety change OMORs, which could be initiated by FDA or requested by industry. Safety OMORs would have a shorter timeline than innovation OMORs or GRASE finalization OMORs, and would have no fee. The total time to implement a safety change would be estimated to shorten from the current reality of six plus years (at a minimum) to 11.5-14.5 months after monograph reform. Additional information on timelines and goals for safety OMORs are found in the goals document.

Goal: Finalize GRASE Determinations for Important Nonfinal Ingredients

Finalization of a pending ingredient as GRASE could be initiated by the FDA or by industry. Industry could submit a GRASE Finalization OMOR, which would have the same timeline as an Innovation OMOR. Industry estimates that no GRASE Finalization OMORs would be submitted in the first 5 years, as Industry will likely concentrate its activities on Innovation OMORs. FDA estimates that, at steady state, the agency would request data for an additional 6 ingredients per year to finalize GRASE determinations for ingredients of high public health importance. For FDA-initiated GRASE finalizations, once the requested data package was received, FDA would plan to follow the same timelines as for Industry-initiated GRASE Finalization OMORs.

Estimated Size of Program, Types of Fees, and Timeline of Implementation

The program size and types of fees are not part of the goals document and would be specified in the statute. The target amounts would be \$22M in Year 1, building to \$34M by Year 4 (exclusive of inflation and other adjustments). Industry does not expect to submit many OMORs in the first five years, but if OMORs were submitted, Tier 1 OMORs would have a \$500,000 fee, and Tier 2 OMORs would have a \$100,000 fee (with adjustments for inflation). There would be no fee for Safety OMORs.

Over-the-Counter Monograph User Fees – Stakeholder Webinar

August 23, 2017, 12:30 – 2:00pm

The goals document includes performance goals that target the percentage of the time that FDA would meet the timelines for various activities. Two key factors affect the performance goals for the first 5 years of the program. First, as mentioned previously, effective review capacity will grow at a measured pace, with modest growth during the first three years of the program as new reviewers undergo specialized monograph training. Second, the fact that industry anticipates very small numbers of OMORs in the 5 year period affects the performance goal value itself – a performance goal of 90% is not feasible if fewer than 10 units of an activity are projected.

During Years 1-3, when effective review capacity would be slowly growing, FDA would continue its safety activities and mandates under the Sunscreen Innovation Act and an antiseptic consent decree. Activities under the goals document include hiring, training, leadership development, IT specifications development and contract award, and establishment of an early IT platform to receive electronic submissions. Meetings with individual sponsors would begin and meetings guidance would be issued, with meeting timelines and performance goals beginning in Year 3. The annual forecasting list would begin, and the user fee collection system would be implemented. Sponsors would also be able to submit Innovation OMORs, Safety OMORs, and GRASE Finalization OMORs, although OMORs won't yet be under timelines. Several foundational guidances would be issued to communicate procedures under reform, and the goal dates for these guidances would be staggered to enable workload management.

In Year 4, timelines and performance goals would begin for Innovation OMORs, Safety OMORs, and dispute resolution. In Year 5, GRASE finalization OMOR timelines and performance goals would begin, and the IT Platform would be expected to be fully functional by that time as well. Refer to the goals document for the details of negotiated performance goals and deliverables.

Potential Statutory Provisions for the OTC Monograph User Fee Program

A user fee program would require enactment by Congress, and Congress would determine the content of the legislative language. With that caveat, a user fee program, as tentatively envisioned, would include an amendment to the Food, Drug, & Cosmetic Act that would authorize FDA to collect fees from the OTC monograph industry to supplement non-user-fee appropriations spent in this area. It would also require that user fees be collected and used only in years when the FDA spends a specified minimum amount of appropriated funds for OTC monograph review activities; set facility fee amounts to generate fee revenue based on facility identification through electronic drug listing registration; and set application fee amounts and fee revenues to be generated through application fees.

The next step for an OTC monograph user fee program is for FDA to continue to listen to input from stakeholders, while Congress considers whether to enact monograph reform.

Over-the-Counter Monograph User Fees – Stakeholder Webinar
August 23, 2017, 12:30 – 2:00pm

Q&A Session

After the presentation, FDA opened the session to take questions from stakeholders.

FDA received several questions about the specific user fee structure, such as which manufacturers would be required to pay certain fees and what types of fees there will be. FDA answered that although there is an envisioned user fee structure, the final structure would be decided by Congress.

FDA received a question about the potential October 1, 2017, start date of the monograph reform and if the projected date has changed, since the FDA Reauthorization Act of 2017 (known as FDARA) did not include monograph reform. FDA answered that the October 1 date from the goals document is just a potential date and if Congress passes monograph reform, FDA will adjust the dates and related goals accordingly, guided by the statute.

FDA was asked whether stakeholders support monograph reform and user fees. FDA stated that there has been broad support from a wide range of stakeholders across the monograph industry, consumer groups, medical professional organizations, and public health advocates. Examples of groups supporting reform include the Consumer Healthcare Products Association, the Pew Charitable Trusts, the American Academy of Pediatrics, the Pharma and Biopharma Outsourcing Association, the Public Access to Sunscreens Coalition, and numerous other organizations.

FDA received several questions about the structure of a potential user fee system. As currently proposed, facility fees would generate the target revenue for the program in its initial years. The manufacturers of OTC monograph products will be assessed the user fee, and facility fees are per facility, not per monograph. Requestors for changes to a monograph will pay an order request fee per change requested (except for specified safety changes). There is no separate fee proposed for meetings or safety OMOR requests.

FDA was asked whether monograph reform includes exclusivity for monograph change sponsors. FDA replied that exclusivity is outside the scope of the user fee agreement and that Congress would make the decision regarding whether to include an exclusivity provision in the statute.

FDA received a question about whether any aspects of the proposed reform would be implemented even without user fees. FDA responded that it would not be possible to implement and sustain the beneficial reforms envisioned without user fees.

Closing Remarks

FDA stated that there will be a meeting summary of the seminar posted to:
www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm