

## **Background: Medical Device User Fees Agreement in Principle between Industry and FDA**

### **Overview**

Unless Congress acts to reauthorize it, the Food and Drug Administration's (FDA) authority to collect user fees under the Medical Device User Fee and Modernization Act (MDUFA) and, by reference, FDA's obligation to meet specified performance goals, will expire on September 30, 2012. If reauthorized, this would represent the third authorization in the history of the medical device user fee program, originally enacted in 2002.

Industry and FDA negotiators have been meeting for over a year to come to terms on a new user fee package. These negotiations have resulted in an agreement in principle among the parties, which still has to go through several procedural steps before formal transmission to Congress.

The user fee agreement is a good one for patients, industry and the FDA. It is a substantial improvement over MDUFA II and lays the groundwork for significantly improved performance through increased accountability, more meaningful goals, important process improvements, better metrics and additional resources.

At the same time, although a good user fee agreement may be an important condition for improving FDA performance, it is not a sufficient condition. No user fee agreement is self-executing. Success will depend on consistent and efficient administration of the program by FDA and its Center for Devices and Radiological Health (CDRH), as well as a commitment by industry to work with FDA to make sure that the goals of the agreement are achieved.

### **Conditions for success**

The user fee agreement builds the conditions for success in five major ways:

- **Ground-breaking agreement that FDA will be responsible for total review time goals:** The new total time goal should achieve reductions in total review times, measuring from the time of submission to the time the technology is available to patients. This is the most meaningful measure of the approval process. All previous agreements were expressed in terms of FDA days. The result was that while FDA technically met its 510(k) time goals, total time was actually increasing because FDA would frequently stop the clock late in the review process, making additional data requests that would prolong the review and thus the total time.
- **Significantly improved review times:** The goals for FDA review days represent very substantial improvements over current performance, particularly for premarket approvals (PMAs).
  - For PMAs without panel reviews, the current performance is that 70% receive a decision in 180 days. The new goal is 90% receive a decision in 180 days.
  - For PMAs with a panel review, the current performance is 38% receive a decision in 320 days. The new goal is 90% will receive a decision in 320 days.
  - For 510(k)s the current performance is 90% receive a decision in 90 days vs. the new goal of 95% in 90 days.

- **Process improvements that should improve the consistency and timeliness of the approval process independent of the specific time goals:**
  - Mid-submission review. This provision requires a substantive interaction between FDA and applicants halfway through the targeted time for completion of review, thus ensuring that a company can have time to properly respond to appropriate questions.
  - No submission left behind. Too often, once the MDUFA II goal was exceeded for a particular submission and FDA was no longer measured on the speed of review of that submission, important product submissions languished. No submission left behind requires FDA to meet with companies if the goal is missed and work out a plan for completing work on the submission.
  - Meaningful pre-submission interaction. FDA will be required to adhere to commitments it has reached in pre-submission interactions. Moreover, companies will get the first opportunity to write the minutes from pre-submission meetings to help assure that the FDA commitments are precise and actionable.
  
- **Greater accountability:** The agreement provides for improved transparency and greater accountability. New reporting tools and an independent management report will provide key data to track FDA performance, will highlight any failures to meet key goals and will provide the basis for corrective action. Provisions include:
  - Quarterly and annual reporting on key metrics;
  - Tracking of new performance indicators, including total review time, withdrawals, NSEs, number of review cycles and additional information requests (AI letters);
  - A required analysis of FDA's management of the review process by an independent consulting organization, coupled with an FDA corrective action plan to address opportunities for improvement.
  
- **Enhanced resources:** To give FDA the tools necessary to meet the new goals, the agreement provides for \$595 million in user fees for 2013 – 2017. Additional reviewers, lower manager- to-reviewer ratio, enhanced training and the other resources provided by the agreement will give FDA what it needs to improve performance.

### **Process/Next Steps**

While industry and the FDA have reached this agreement in principle, several steps remain before official transmission to Congress of the commitment letter and proposed legislative language:

- Industry and FDA must finalize the wording of the commitment letter and the proposed legislative language, as well as determine appropriate fee structures.
- The agreement must be cleared through the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB).
- A 30-day public notice and comment period must take place to allow for additional interested parties to provide input.
- Following these steps, the agreement will be formally transmitted to Congress.