FDA – Industry MDUFA IV Reauthorization Meeting
August 15, 2016; 9:30 am – 10:45 am

Teleconference

Purpose

To discuss MDUFA IV reauthorization.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marcy Busch	Office of Chief Counsel (OCC)
Joni Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Elizabeth Hillebrenner	CDRH
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Toby Lowe	CDRH
Thinh Nguyen	Office of Combination Products (OCP)
Geeta Pamidimukkala	CDRH
Don St. Pierre	CDRH
Jeff Shuren	CDRH
Darian Tarver	OC
Kim Worthington	CDRH
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Industry

Hans Beinke	Siemens (representing MITA)
Nathan Brown	Akin Gump (representing AdvaMed)
Phil Desjardins	Johnson & Johnson (representing AdvaMed)
Elisabeth George	Philips (representing MITA)
Allison Giles	Cook (representing MDMA)
Megan Hayes	Medical Imaging & Technology Alliance (MITA)
Donald Horton	Laboratory Corporation of America Holdings (representing ACLA)
Tamima Itani	Boston Scientific (representing MDMA)
Mark Leahey	Medical Device Manufacturers Association (MDMA)
John Manthei	Latham & Watkins (representing MDMA)

Michael Pfleger	Alcon (representing AdvaMed)
Paul Sheives	American Clinical Laboratory Association (ACLA)
Pat Shrader	Medtronic (representing AdvaMed)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)
Scott Whitaker	AdvaMed
Diane Wurzburger	GE Healthcare (representing MITA)

Meeting Start Time: 9:30 am

Executive Summary

During a series of working discussions in early August, FDA and Industry discussed performance goals and other commitments that were documented in a draft Commitment Letter. At the conclusion of discussions on August 15, FDA, AdvaMed, MDMA, MITA, and ACLA agreed to a draft Commitment Letter.

Summary of Commitments

FDA and Industry agreed to the following commitments for the medical device user fee program for the five years beginning in fiscal year (FY) 2018.

- FDA will improve consistency and predictability through enhanced supervisory oversight and routine quality audits;
- FDA will establish a dedicated premarket Quality Management team, which will be responsible for establishing a quality management framework for the premarket submission procession in CDRH and conducting routine quality audits;
- FDA will improve the quality and consistency of Additional Information and Major Deficiency letters by providing the basis for deficiencies and appropriate supervisory review;
- FDA will improve tracking and reporting of performance commitments;
- Together, FDA and Industry will reduce average total time to decision to 108 days for 510(k)s for submissions received in FY2022, and to 290 days for PMAs for the three-year submission cohort that ends in FY2022;
- FDA will improve the CLIA waiver by application process by establishing a centralized program management group within the Office of In Vitro Diagnostics and Radiological Health, implementing substantive interaction and "no submission left behind" milestones, offering CLIA Waiver vendor days, and completing 90% of stand-alone CLIA Waiver applications that do not have a panel meeting in 150 days, 90% of Dual 510(k) and CLIA

Waiver applications in 180 days, and 90% of stand-alone CLIA Waiver applications that have a panel meeting in 320 days;

- FDA will implement IT improvements that correspond to new performance goals and reporting, including an industry dashboard that displays near real-time submission status;
- FDA and Industry will participate in an independent assessment of the CDRH review process, including a more complete assessment of MDUFA III improvements and outcomes and an assessment of the effectiveness of the MDUFA IV programs;
- FDA will implement a more effective recruiting and hiring strategy;
- FDA will improve employee retention through incentive pay for managers funded in MDUFA IV and using existing authorities and policies;
- FDA will implement complete time reporting by the end of MDUFA IV;
- FDA and Industry will seek authority for FDA to eliminate the fifth-year fee offset and to use any and all fee collections, including those over the statutory revenue targets to improve performance on submission types with performance goals and/or quality management programs;
- FDA will improve the Pre-Submission process and ramp up to a performance goal for written feedback on at least 1,950 Pre-Submissions within 70 days or 5 calendar days prior to the scheduled meeting, whichever comes sooner, in FY2022 (which is equivalent to meeting the stated timeline for at least 83% of an assumed 2,350 Pre-Submissions). Industry affirmed its responsibility to provide draft meeting minutes within 15 days of the meeting;
- FDA will ramp up to a performance goal for completion of 70% of *De Novo* submissions within 150 days in FY2022;
- For PMA submissions that require Advisory Committee input, FDA will issue a MDUFA decision within 60 days of the Advisory Committee recommendation, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.
- For PMA submissions that receive a MDUFA decision of Approvable, FDA will issue a decision within 60 days of the sponsor's response to the Approvable letter, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.
- FDA will strengthen the Third Party Premarket Review program by offering training to Third Party review entities, conducting audits, ,publishing performance reports of

individual Third Party entities and seeking authority to expand the scope of the program with the goal of eliminating routine re-review by FDA of Third Party reviews;

- FDA will improve consistency in review of software as a medical device and software in a medical device through establishment of a centralized digital health unit, streamline and align FDA review processes with software lifecycles, continue engagement in international harmonization efforts related to software review, and conduct other activities related to Digital Health;

- FDA will develop internal expertise on patient engagement, support the increased use of patient preference information (PPI) and patient reported outcomes (PROs) in premarket submissions, publish a PRO validation guidance, hold one or more public meetings, and clarify that PROs are voluntary and can be one mechanism for demonstrating safety and effectiveness or substantial equivalence;

- FDA will provide funding for the National Evaluation System for health Technology (NEST) to conduct a pilot to establish the value of real world evidence (RWE) and linkages among data sources to enable greater use of RWE to accelerate patient access in the premarket setting, to develop guidance and hold a public meeting on the use of RWE including in the context of medical device reporting for certain devices. FDA and Industry agreed that an independent assessment would occur during MDUFA IV to assess whether the premarket efficiencies highlighted by FDA are being realized;

- FDA and Industry will establish a conformity assessment program for accredited testing laboratories that evaluate medical devices according to certain FDA-recognized standards;

- FDA will enhance IT infrastructure to collect and report on structured data; to develop and maintain a secure web-based application that allows sponsors to view individual submission status in near real-time; and to develop structured electronic submission templates as a tool to guide Industry's preparation of premarket submissions; and,

- FDA committed to treating LDTs no less favorably than other devices to which MDUFA performance goals apply and to report on corresponding key performance metrics.

Discussion

Shared Outcome Goals

FDA and Industry agreed that this package should result in a reduction of the average total time to decision to 108 days for 510(k)s and to 290 days for PMAs by FY2022.

De Novo Submissions

Regarding the new goals for *De Novo* submissions, Industry suggested that withdrawn submissions should not be included in the cohort for purposes of calculating the goal, particularly given that there may be a significant number of *De Novo* submissions that are withdrawn early in the process before much review work has been undertaken. FDA indicated that its workload estimates had included withdrawals, so removing them would change the amount of effort required to meet the goals. Industry suggested studying the volume and nature of withdrawals during MDUFA IV.

CLIA Waiver

The commitments incorporate goals for CLIA Waiver applications. Additional resources have not been included in the MDUFA agreement for CLIA Waiver applications.

While the requirement for a Pre-Submission has been de-coupled from the performance goal for review of Dual 510(k) and CLIA Waiver applications, Industry acknowledged that FDA will maintain its current approach that requires a Pre-Submission to precede a Dual, as experience has shown this to be critical to the success of a Dual.

Independent Assessment

FDA and Industry agreed to an independent assessment of the medical device review process at CDRH, including an evaluation of FDA's implementation of the corrective action plan developed in response to recommendations from the MDUFA III independent assessment. FDA and Industry agreed to various program areas for the independent assessor to evaluate. However, FDA noted that the scope of the assessment cannot exceed the allocated $6 million when the contract is awarded.

Retention

On July 26, 2016, FDA requested $41.7 million for incentive pay to prevent anticipated attrition to other Centers in the event that legislation currently being considered by Congress is enacted that would permit FDA to increase pay for qualified scientific, technical, or professional positions that support the development, review, and regulation of medical products. FDA explained that other Centers have sufficient funding to offer higher salaries if such legislation were to be enacted, and that these Centers often seek the same scientific and technical expertise as CDRH. Industry noted that it did not agree with the assumptions FDA made during the July 26th meeting. Furthermore, this request supplemented discussions in previous negotiation meetings between Industry and FDA that focused on providing user fee funding to assist in retaining high performing managers; those discussions resulted in an agreement to provide $7.5 million in user fee funding to improve retention. FDA and Industry agreed that if Congress enacts legislation in FY17 to pay key personnel engaged in the process for the review of device

applications salaries higher than the amount permitted as of September 30, 2016, FDA and Industry will work together to establish a plan that will address retaining key CDRH personnel currently funded in part by user fees, including additional appropriated funds and/or additional user fee funds, if warranted.

Fee Setting and Workload

FDA reiterated the need to implement capacity planning to manage the medical device program and that this could best be accomplished in MDUFA IV through a workload adjustment mechanism. FDA proposed a workload adjustment mechanism that ties revenue to aggregate workload. Industry noted concerns with fee predictability under FDA's proposed workload adjustment mechanism.

Industry made a counter proposal to FDA to seek authorization to use over-collections and eliminate the fifth-year fee offset. FDA stated that Industry's proposal does not account for the fact that submission fees do not correspond directly to the workload necessary to review the submission. Accordingly, the use of over-collection of submission fees, as proposed by Industry, is not necessarily sufficient to account for increased workload. For example, Pre-Submissions, which have no fees and have a history of steadily increasing volume, will be subject to performance goals under this agreement. FDA has maintained its expectation that Pre-Submission volume will continue to increase, while Industry anticipates the volume will plateau, in part due to the planned clarification of appropriate use of the Pre-Submission program in MDUFA IV.

Industry subsequently clarified details of how its proposal would ensure that individual submission and establishment registration fees would be no less than the inflation-adjusted statutory amounts. Industry noted that its proposal might well lead to significantly greater aggregate collections, through increases in submission volume and/or registration volume, than FDA's capped proposal, but also provided greater predictability for applicants. FDA subsequently agreed to Industry's proposal to allow for user fee collections in excess of the authorized amount to be used to support the premarket review process, with no fifth-year fee offset. Because this approach leaves FDA performance vulnerable to excess workload strain if the program experiences increases in Pre-Submission volume greater than 2,350 submissions (assuming that aggregate workload in the rest of the MDUFA program does not decline), the structure of the Pre-Submission performance goal was changed to indicate the number of Pre-Submissions subject to the goal rather than a percentage of all receipts. Industry accepted this proposal, but noted that both the Agency and Industry need to strive to ensure that the Pre-Submission process is used in appropriate circumstances. In the event that inflation-adjusted revenues exceed the amounts needed to meet performance goals given the planned aggregate workload, FDA and Industry will work together to assess how best to utilize those excess resources to improve performance on submission types with performance goals and/or quality management programs.

Real World Evidence (RWE)

One of the goals of the NEST Coordinating Center is to centralize the approach of collecting RWE. FDA stated that this includes MDEpiNet. FDA also stated that investing in RWE will result in more efficient and timely premarket reviews. The work on this should begin as soon as the NEST Coordinating Center contract is approved. FDA also stated its intent to make NEST self-sufficient. Industry noted that it's funding for RWE is limited to the MDUFA IV agreement and no commitments were made to fund beyond MDUFA IV.

Standards

FDA and Industry agreed to establish an Accreditation Scheme for Conformity Assessment (ASCA) Program for certified testing laboratories that evaluate medical devices according to certain FDA-recognized standards. In order to accomplish this commitment, FDA will consider stakeholder input for many aspects of the Accreditation Scheme for Conformity Assessment (ASCA) program. Stakeholders in the ASCA are Accrediting Bodies (ABs)/ Certification Bodies (CBs)/ Test Laboratories (TLs) and industry representatives and other governmental agencies, such as the National Institute for Standards and Technology (NIST).

Conclusion

FDA, AdvaMed, MDMA, MITA, and ACLA agreed to the draft Commitment Letter incorporating the commitments described above. In subsequent communications, all parties agreed to a total MDUFA fee revenue target of $999.5 million (in FY 2015 dollars) for FY 2018 through 2022, to be adjusted for inflation using the current-law fee inflation adjustment methodology from FY 2016 going forward. FDA agreed to provide additional detail regarding allocation of the 113 FTEs that support the following aspects of the program: quality management, managers, and review capacity. Industry understands that these aspects of the agreement rely on each other and efficiencies gained collectively to be successful.

Industry noted the importance of maintaining sufficient congressional appropriations through MDUFA IV and FDA committed to supporting an update to the MDUFA IV trigger to ensure adequate appropriations. Industry also noted that any operating or one-time expenses under MDUFA IV will not be assumed to be included in the MDUFA V baseline. Operational and one-time costs in the MDUFA IV agreement total $92,389,000 in FY 2015 dollars.

FDA and industry also agreed to revisit the methodology and manner in which FDA calculates cost per FTE since the numbers reported to Congress in the MDUFA Financial Reports are not consistent and a more accurate way to assess actual costs is needed.

Meeting End Time: 10:45 am