FDA – Industry MDUFA IV Reauthorization Meeting
September 9, 2015, 9:30 am – 2:45 pm
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose
To discuss MDUFA IV reauthorization.

Participants
FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Jonette Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Elizabeth Hillebrenner	CDRH
Louise Howe	OCC
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
Prakash Rath	Office of Legislation (OL)
Don St. Pierre	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)
Sergio Gadaleta	Becton, Dickinson (representing AdvaMed)
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)
Michael Pfleger	Alcon (representing AdvaMed)
Jim Ruger	Quest Diagnostics (representing ACLA)
Paul Sheives	American Clinical Laboratories Association (ACLA)

Patricia Shrader	Medtronic (representing AdvaMed)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)
Diane Wurzburger	GE Healthcare (representing MITA)

Meeting Start Time: 9:30 am

Ground Rules

The ground rules governing MDUFA IV Reauthorization negotiations were discussed and agreed to without amendment. A summary of key aspects of the ground rules follows:

FDA invites national associations that it believes best represent medical device manufacturers who may be subject to fees under the negotiated agreement. All parties agree to work in good faith throughout the negotiations. The parties include Industry (represented by the Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturers Association (MDMA), the Medical Imaging and Technology Alliance (MITA), and the American Clinical Laboratory Association (ACLA)) and the Food and Drug Administration (FDA), including all employees of the Agency. The scope of these negotiations includes discussion of the Medical Device User Fee Program as reauthorized in 2012 for fiscal years 2013 through 2017, including the reauthorization of the third party review and third party inspection programs, and potential recommendations that FDA and Industry would agree to be presented to Congress relating to reauthorization of the Medical Device User Fee Program for the five years after fiscal year 2017.

The ground rules further establish that there will be core negotiating teams for FDA and Industry, agreement to respond to requests for data related to the Scope of these negotiations, and agreement to work diligently and in good faith to complete negotiations by March 31, 2016. The ground rules state that FDA will summarize key topics of discussion in public meeting minutes, which will be distributed to Industry for review and comment before posting to the FDA web page.

FDA and Industry agree to support any final agreement resulting from these negotiations as a package deal through the legislative process.

FDA Perspective on Reauthorization

FDA expressed its commitment to achieving the goal of patient access to high-quality, safe, and effective medical devices. A central objective for FDA is to improve outcomes via operational excellence. FDA is striving to ensure the reliability and sustainability of the current Medical Device User Fee program, and to improve consistency, predictability, and efficiency, in addition to reducing total time to decision. In order to reach this goal, FDA intends to build on MDUFA III successes by focusing on more productive interactions between FDA and Industry and continuing to improve the premarket review process. Another FDA goal is to use innovative regulatory tools and processes to improve consistency, predictability, and efficiency. FDA

intends to pursue increased use of structured data, modern technology platforms, and ways to use real-world clinical experience and patient input to support premarket review.

FDA outlined program successes during MDUFA III, including a structured pre-submission process, established submission acceptance criteria, better communications through interactive review, increased number of timely and applicable guidance documents, development of a framework to consider patient input in benefit/risk determinations, low risk medical device exemptions, and development of a transitional *in vitro* diagnostic approach for the regulation of emerging diagnostics. FDA reported on MDUFA III performance goals, including meeting all decision goals for FY13 and FY14. FDA also reported that the shared outcome goal for Total Time to Decision for 510(k) submissions of 135 total days has been met in FY13. FDA further discussed progress towards infrastructure goals for MDUFA III, including meeting the target number of new hires, maintaining existing training programs, the implementation of new training programs for both staff and managers, and the development of tracking systems to manage performance goals. In addition, FDA described the positive, continuing impact of the independent assessment of the premarket review program conducted by Booz Allen Hamilton (BAH).

FDA described additional program advances beyond MDUFA III commitments, such as the development and implementation of programs for 510(k) Triage, Expedited Access Pathway, parallel review with CMS, and Clinical Trials. FDA achieved faster review times for IDE and *de novo* submissions, despite the lack of performance goals in these areas. FDA also launched the Case for Quality, co-founded the Medical Device Innovation Consortium, helped establish the International Medical Device Regulators Forum, has taken initial steps towards establishing a national medical device postmarket surveillance system, and focused on providing excellent customer service.

FDA provided a high-level MDUFA financial analysis that described some historical trends. FDA also estimated the amount of user fees needed throughout MDUFA IV to maintain the level of staffing and other activities supported by MDUFA III user fees in FY17 (the final year of MDUFA III), under current payroll and inflation assumptions. FDA calculated this estimate by starting with the amount of user fees authorized in the final year of MDUFA III (approximately $130 million, before adjustments for inflation) and held that baseline amount constant over each of the five years of MDUFA IV. FDA then added the projected annual inflation adjustment (which is estimated to be approximately $11 million in FY17), based on an assumption that the authorized inflation adjustment formula would yield a 2% annual inflation rate. Based on this methodology, FDA estimates that the total authorized fee amount will be approximately $141 million in FY17, the final year of MDUFA III. Using this methodology to project forward into MDUFA IV, the results of these calculations summed to a total of approximately $750 million for FY18 through FY22. Industry questioned the methodology and assumptions made by FDA, such as not accounting for any one time expenditures under MDUFA III and not accounting for efficiencies in the premarket process that should be realized from process improvements under

MDUFA III. FDA and industry agreed that the assumptions underlying this fee projection warrant further discussion.

Finally, FDA reviewed key topics of interest for the negotiations, including implementing recommendations from the Booz Allen Hamilton (BAH) independent assessment, incorporating stakeholder input in the negotiations, and discussions of workload and performance trends in key program areas. In response to questions from ACLA, FDA clarified that its workload and performance projections did not account for possible future regulation of laboratory developed tests (LDTs) as medical devices. FDA provided an overview of stakeholder feedback during the public workshop and comment period, noting the following themes: MDUFA IV should focus on process improvements that build on the MDUFA III groundwork, improve infrastructure to promote pre and postmarket efficiency and quality, strengthen capabilities for Total Product Life Cycle evidence generation, expand incorporation of patient perspectives, and encourage innovation for rare diseases and pediatric populations.

Industry Perspective on Reauthorization

All Industry participants reiterated their shared commitment to the goal of timely access to safe and effective medical devices. Each association discussed its goals for reauthorization and, in general, noted improvements to the premarket review program over the past few years under the MDUFA III agreement and their desire to identify targeted areas for enhancements for MDUFA IV.

AdvaMed discussed the purpose of user fees – to provide a stable, predictable funding source for FDA as the Agency embarks on performance agreements. AdvaMed acknowledged that FDA has been meeting performance goals for MDUFA III and noted that the revised goal structure is improved over MDUFA I and II. AdvaMed especially noted the value of the average total time to decision goals for 510(k)s and PMAs. AdvaMed also recognized the improved interactions between sponsors and reviewers and attributed this to the improvements in pre-submissions and interactive review processes. Furthermore, AdvaMed noted that Quarterly Meetings between Industry and FDA provided a valuable opportunity to identify and address issues early. AdvaMed agreed with FDA that the independent assessment provided by BAH has been a positive step towards improving the program. For the MDUFA IV reauthorization, AdvaMed's goals include improving on the success of MDUFA III, including the predictability and efficiency of the review process, and implementing the recommendations from the independent assessment.

MDMA described several principles to guide the goal of bringing technologies to patients, including: congressional appropriations as the primary source of funding for the program, the use of user fees for the premarket program and not for postmarket programs, a need for a stable funding source, appropriate goals for the premarket program, and the need for continued use of fee reductions and waivers for small businesses. MDMA further expressed concern that the historical doubling of the user fee program every five years is not sustainable. MDMA believes

that the current program is the appropriate size and that the focus should now be on efficiency and predictability. MDMA expressed a willingness to discuss targeted investments and focused improvements.

MITA expressed appreciation for FDA's efforts in MDUFA III. MITA also expressed agreement with other Industry representatives that user fees should be used to supplement the appropriated budget. MITA also agreed that the BAH assessment has been helpful for the program. MITA noted that the negotiations should focus on continuing improvement of the premarket approval process towards additional efficiencies and that any goals should be appropriate, measureable, and predictable.

ACLA expressed the position that LDTs are not medical devices. ACLA further noted that its participation is not intended to constitute, and shall not be construed as, a waiver or release of any potential argument or legal relief to which ACLA and/or its members may be entitled with respect to the potential regulatory oversight of LDTs or clinical laboratories by FDA. ACLA further noted that participation of ACLA and its members in these negotiations is intended to allow labs to address MDUFA issues that would arise if LDTs are regulated as medical devices and if labs are required to register as device manufacturers. ACLA noted that uncertainties related to the regulation of LDTs may affect the medical device user fee negotiations.

In response to Industry, FDA agreed that reducing variation and continuing improvement of the premarket approval process is an important focus for the negotiations. In response to ACLA's statements, FDA noted that the Agency defined Industry within the ground rules, and that the ACLA statements do not change the Agency's position on LDTs.

Discussion

In response to the data request that Industry submitted to FDA on August 17, 2015, FDA agreed to provide the response to Industry on September 25, 2015. Industry agreed to provide a list of questions on the response at least one day before the next negotiation meeting, in order to allow FDA time to gather relevant experts. Based on the discussions, FDA and Industry identified potential topics for upcoming meetings. These topics include: a discussion and explanation of FDA's response to Industry's data request; an extended financial discussion, including a description of continuing versus one-time costs; a summary of progress on the implementation of BAH recommendations; and a presentation on CDRH databases and its document tracking system to explain in greater detail the data that are available and the limitations of the systems.

Next Meeting

The next meeting is scheduled on October 1, 2015.

Meeting End Time: 2:45 pm