

FDA – Industry MDUFA IV Reauthorization Meeting
April 6 and 7, 2016; 9:30 am – 4:00 pm
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose

To hold working group discussions on proposal components for MDUFA IV reauthorization.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Joni 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)
Mike Lanthier	OC
Toby Lowe	CDRH
Thinh Nguyen	Office of Combination Products (OCP)
Katie O’Callaghan	CDRH
Brendan O’Leary	CDRH
Greg Pappas	CDRH
Bakul Patel	CDRH
Prakash Rath	Office of Legislation (OL)
Darian Tarver	OC
Jacqueline Yancy	CDRH
Barb Zimmerman	CDRH

Industry

Hans Beinke	Siemens (representing MITA)
Nathan Brown	Akin Gump (representing AdvaMed)
Phil Desjardins	Johnson & Johnson (representing AdvaMed)
Allison Giles	Cook (representing MDMA)
Mark Gordon	Abbott (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 Pflieger	Alcon (representing AdvaMed)
Jim Ruger	Quest Diagnostics (representing ACLA)
Paul Sheives	American Clinical Laboratory Association (ACLA)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)
Diane Wurzbarger	GE Healthcare (representing MITA)

Meeting Start Time: April 6, 9:30 am

Executive Summary

FDA and Industry engaged in working group discussions on the details of proposal components. They discussed Pre-Submissions, *De Novo* Requests, Patient Input, Quality Management, Workload Adjustment mechanism, Real World Evidence, Digital Health, and Third Party Premarket Review.

Working Group Discussions

FDA and Industry engaged in working group discussions focused on the details of proposals. Neither FDA nor Industry presented new proposals during the negotiation meeting; instead, the parties discussed some assumptions for the proposals and how those assumptions and the proposals could be amended to maximize value for all stakeholders.

Pre-Submissions: FDA described the evolution of the Pre-Submission program since its inception in 2013 and provided data on the types of Pre-Submissions FDA receives. FDA provided performance projections and described various options to address the growing Pre-Submission working inventory.

De Novo: FDA described the evolution of the *De Novo* program and noted that significant improvements and efficiencies have been made during MDUFA III. FDA described its estimates of the resources needed to address the growing *De Novo* working inventory and improve performance, which is beginning to decline. FDA described how the volume of receipts increased beginning with FY 2015, and that recent data suggest FDA will struggle to complete its reviews and consistently issue a decision in a timely manner with existing resources. FDA provided performance projections and described options to reduce working inventory, achieve stability, and improve performance.

Patient Input: FDA provided a summary of FDA's previous proposal on Patient Input and clarified potential deliverables and metrics that an investment in this program could provide. Industry provided feedback and asked about the selection process, governance and rules for participation in user fee-funded projects conducted through public-private partnerships.

Quality Management: AdvaMed, MDMA, and MITA provided feedback in the form of suggestions for guiding principles and activities for CDRH's Quality Management (QM) program.

Workload Adjustment: FDA presented details regarding its proposed workload adjustment mechanism, including a description of the components of the model and how various submission types and review efforts are incorporated. FDA provided several scenarios to estimate the potential impact of changes in actual versus planned workload in specific submission areas, based on available data and subject to model limitations. Industry provided feedback and requested details on specific scenarios.

Real World Evidence: FDA provided a summary of FDA's previous proposal on Real World Evidence (RWE) and clarified potential deliverables and metrics that an investment in this program could provide. Industry asked questions about where user fee money would be directed, governance models, and the process for sharing data and infrastructure.

Digital Health: FDA provided a summary of FDA's previous proposal on Digital Health and clarified potential deliverables and metrics that a further investment of user fee funding in this program could provide.

Third Party Review Program: FDA provided a summary of FDA's previous proposal on the Third Party Review Program and clarified potential deliverables and metrics that an investment in this program could provide.

Next Steps

Industry will provide a counter proposal at the next negotiation meeting.

Next Meeting

The next meeting is scheduled for April 27, 2016.

Meeting End Time: April 7, 4:00 pm