Patient and Consumer Stakeholder Meeting on MDUFA IV Reauthorization
August 25, 2016, 9:00 – 11:00 AM
FDA White Oak Campus, Silver Spring, MD
Building 31, Great Room Section A

Purpose
To provide a status update on the conclusion of MDUFA IV negotiations.

Participants
FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Sonja Fulmer	CDRH
Louise Howe	OCC
Prakash Rath	Office of Legislation (OL)
Don St. Pierre	CDRH
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Paul Brown	National Center for Health Research
Beatriz Duque Long	Epilepsy Foundation
Lisa Goldstein	American College of Cardiology
Marisol Goss	AAOS
Cynthia Grossman	FasterCures
Jason Harris	National Health Council
Bennie Johnson	JDRF
Anqi Lu	Pew Charitable Trusts
Paul Melmeyer	National Organization for Rare Disorders
Ben Moscovitch	Pew Charitable Trusts

Meeting Start Time: 9:11 am

FDA welcomed stakeholders and briefly reiterated the role of patient and consumer stakeholder input during MDUFA negotiations.

FDA provided a general overview of the agreement in principle that was reached between FDA and Industry. FDA explained that the agreement in principle was reached as a result of a series of working discussions as well as a face-to-face negotiation meeting with industry held on August 15, 2016. FDA stated that because negotiations have concluded, this meeting would be the last scheduled patient and consumer stakeholder meeting. FDA explained the next steps with respect to getting clearance for the commitment letter and plans for a public meeting later in the year.

FDA discussed the conclusions of the negotiations
FDA provided a general overview of the August 15, 2015 FDA/Industry negotiation meeting. At the conclusion of that meeting, FDA and Industry reached an agreement on the proposals for improving the program. Specifically, FDA explained that there were agreements around process improvement to help build a more robust review program. FDA described the details around improving the pre-submission program, establishing goals for de novo submissions, improving manager-to-reviewer ratios, addressing unplanned workload, investing in the Real World Evidence (RWE) program and funding for the national evaluation system, among others.

FDA provided some additional background on each of the commitments
FDA explained that the establishment of a dedicated premarket quality management team was an important component of the negotiations in that they will be responsible for establishing a quality management framework for the premarket submission process and conducting routine quality audits. The audits are to support process improvements, such as improving consistency and transparency around how deficiency letters are handled. FDA explained that the agreement also includes IT enhancements to improve the robustness and efficiency of data collection to support audits and report on performance commitments. The IT enhancements will also provide industry with a dashboard so that they can track the status of their submissions.

FDA explained the agreement regarding the shared outcome goals for the 510(k) program and PMA programs. FDA explained that the average total time to decision (TTD) goals will be reduced to 108 days for 510(k)s and 290 days for PMAs by FY2022. FDA explained that this reduction will be a challenge for the program.

FDA explained that there was agreement in principle on proposals that would improve manager to reviewer ratios and provide additional retention incentives following current law and policy. FDA reported that it will implement a more effective recruiting and hiring strategy. This strategy may include hiring outside recruiting firms or others that will specialize in the kind of recruiting that is needed to identify the necessary talent for advancing the program.

FDA explained that although there was not agreement on the workload adjuster to handle the unplanned workload, there was agreement to seek authority to eliminate the fifth-year fee offset and use any excess fee collections for the program. FDA also agreed to go to full time reporting by the end of MDUFA IV, which is different from the current approach of reporting two weeks each quarter.

FDA reported that there will be another independent assessment in MDUFA IV that will be conducted in two phases. Specifically, one phase will occur early in MDUFA IV and will involve completing the assessment of those aspects of MDUFA III for which there were insufficient time and data to assess under the previous study. The second phase will occur toward the latter part of MDUFA IV and will look at the improvements and the outcomes of the investments being made as part of MDUFA IV.

FDA explained that improvements are being made in the area of pre-submissions. Specifically, performance goals for the number of days to provide written feedback to industry were added,

while industry affirmed its responsibility to provide meeting minutes within 15 days of the meeting.

FDA reported that there was agreement in ramping up to a performance goal for completion of 70% of de novo submissions within 150 days by FY2022.

FDA explained that there will be resources provided for strengthening the third party (3P) review program by offering training to the 3P review entities, conducting systemic audits and publishing performance reports on these entities and seeking authority to expand the scope of the program with the goal of eliminating routine re-review by the branch chiefs in the division of 3P reviews.

FDA indicated that funding to support the digital health program was agreed upon. The agreement will provide improvements on how we review software as a medical device and software in a medical device by establishing a dedicated digital health unit. Additionally there will be continued engagement in international harmonization efforts related to software review.

FDA explained that there was agreement to provide significant resources in patient input that will cover both patient preference information (PPI) and patient reported outcomes (PRO). The funding will be to hire internal experts to strengthen this program and provide consistency in review of premarket submissions. The agency agreed to publish a PRO validation guidance, hold public meetings and clarify that PROs are voluntary and can be one mechanism for demonstrating safety and effectiveness or substantial equivalence. FDA explained that funding will be provided for the National Evaluation System for health Technology (NEST).

FDA explained that a conformity assessment program for accredited testing laboratories would be established.

FDA addressed clarifying questions from the patient and consumer stakeholders
FDA addressed questions around the total number of FTE slots that will be provided in MDUFA IV. FDA also addressed questions regarding elaborating on funding for the de novo and 3P programs. The patient and consumer stakeholders expressed gratitude for making sure provisions for patient input and the national evaluation system were included in the final agreement.

To close the meeting, FDA informed the patient and consumer stakeholders that a link to the Federal Register notice for the public meeting would be sent when available.

End: 10:25am