FDA and Industry GDUFA II Implementation Quarterly Meetings – 1Q2017 Meeting
March 31, 2017, 10:00 AM – 12:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208

Agenda

- Establish meeting principles for the quarterly implementation meetings
- Discuss Abbreviated New Drug Application (ANDA) workload
- Discuss the facility related Generic Drug User Fee Amendments II (GDUFA II) enhancements

Participants

FDA:		Industry:	
Anna Abram	OC	John DiLoreto	BPTF
Donald Ashley	CDER	Bob Dollinger	BPTF (Dastech)
Amy Bertha	CDER	Ken Drew	EFCG (Flamma)
Mary Beth Clarke	CDER	Barbara Galbiati	BPTF (Albany Molecular)
Alonza Cruse	ORA	David Gaugh	AAM
Jack Kalavritinos	OC	Kiran Krishnan	AAM (Apotex)
Bob Iser	CDER (facilities advisor)	Marcie McClintic	AAM (Mylan)
Michael Kopcha	CDER	Lisa Parks	AAM
Edward Sherwood	CDER (workload advisor)	Ed Price	BPTF (PCI Synthesis)
Kathleen Uhl	CDER	Molly Rapp	AAM (Fresenius Kabi)
Janet Woodcock	CDER	Sam Ricchezza	PBOA (Wellspring)
		Gil Roth	PBOA
		Scott Tomsky	AAM (Teva)
		Elizabeth White	EFCG (Evonik)

Meeting Principles

FDA and Industry reviewed FDA's proposed draft of the meeting principles for the quarterly implementation meetings.

ANDA Workload

FDA and Industry discussed current ANDA workload statistics. Some FY2016 highlights included:

- 651 Approvals
- 184 Tentative approvals
- 1725 Complete response

For the pre-year 3 application cohort, approximately 2100 ANDA's have been approved to date. FDA is committed to continuing to work with Industry on the remaining pending ANDA's in the pre-year 3 cohort that have yet to receive approval or tentative approval.

In GDUFA II both FDA and Industry are committed to increasing first cycle approvals. Industry acknowledged that the Information Request process and guidances for industry have been helpful in better understanding FDA's expectations and standards. Industry indicated that FDA's increase efforts to enhance communications with Industry should mitigate multiple review cycles for original ANDAs and Prior Approval Supplements.

Facility Enhancements as part of GDUFA II

In regards to the Pre-Submission Facility Correspondence (PFC), FDA discussed that work is underway on developing policy and procedures. Timing of FDA publishing a policy document will support the submission of priority ANDAs on October 1, 2017. FDA will assess the completeness of a PFC after it is submitted. A PFC must be complete at the time of submission, meaning that the facilities must be identified in the PFC and there can't be any additions to the list after submission to continue to be eligible for a priority review classification.

FDA provided an update on its program alignment initiative. The Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA) are working together to develop roles, responsibilities, and processes to support an integrated drug regulatory program. As part of the Agency's program alignment initiative, the re-organization of ORA is expected to stand up in May 2017.

FDA is continuing to work towards a risk-based approach to surveillance inspections and acknowledges that predictability is important for Industry. Industry asked if FDA were able to share information on the model. FDA would be able to share general factors that go into the model some time in the future.

FDA also provided a status update on the New Inspection Protocol Project (NIPP). A protocol was developed for sterile drugs and a pilot was recently completed. FDA will develop other protocols for other dosage forms to pilot. As FDA completes the pilots, FDA will share more information.