FDA and Industry GDUFA II Implementation Quarterly Meetings – 1Q2019 Meeting
January 15, 2019, 1:30 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1211

Agenda

- ANDA Labeling (FDA Led)
- Review Action Items and Future Planning (All)

Participants

FDA:		Industry:	
Donald Ashley	CDER	Deb Autor	AAM (Mylan)
Tiana Barnes	CDER	John DiLoreto	BPTF
Ashley Boam	CDER	David Gaugh	AAM
Mary Beth Clarke	CDER	Kiran Krishnan	AAM (Apotex)
Alonza Cruse	ORA	Matthew Moran	EFCG (IBEC)
Michael Kopcha	CDER	Lisa Parks	AAM
Aaron Sigler	CDER	Gil Roth	PBOA
Maryll Toufanian	CDER	Scott Tomsky	AAM (Teva)
Kathleen Uhl	CDER	Molly Ventrelli	AAM (Fresenius Kabi)
Ruby Wu	CDER		

ANDA Labeling

FDA and Industry discussed the Labeling process for ANDAs and how to potentially reduce review cycles due to Labeling issues.

Review Action Items and Future Planning

FDA and Industry reviewed pending action items on the topics of DMFs, Facilities, and REMS. Both FDA and Industry are continuing to monitor issues that arise under these topics and may revisit them at a future meeting.