U.S. FOOD & DRUG ADMINISTRATION

FDA and Industry GDUFA II Implementation Quarterly Meetings – 2Q2019 Meeting
April 16, 2019, 1:30 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Agenda

- ANDA Labeling – Follow Up (FDA Led)
- Industry Issues Related to DMFs (Industry Led)
- RPM Communication and Transparency During the Review Process (FDA Led)

Participants

FDA:		Industry:	
Tiana Barnes	CDER	Rafael Antunes	EFCG (Hovione)
Sally Choe	CDER	John DiLoreto	BPTF
Mary Beth Clarke	CDER	Bob Dollinger	BPTF (Dastech)
Alonza Cruse	ORA	David Gaugh	AAM
Lyndsay Hennessey	CDER	Kiran Krishnan	AAM (Apotex)
Michael Kopcha	CDER	Matthew Moran	EFCG (IBEC)
Aaron Sigler	CDER	Lisa Parks	AAM
Dave Skanchy	CDER	Gil Roth	PBOA
Maryll Toufanian	CDER	Wayne Talton	AAM (Mylan)
Ruby Wu	CDER	Scott Tomsky	AAM (Teva)
		Molly Ventrelli	AAM (Fresenius Kabi)
		Bethany Walls	BPTF (MilleporeSigma)

ANDA Labeling – Follow Up

FDA and Industry continued discussions on the challenges on both sides around the Labeling process. FDA also responded to previously raised issued provided by Industry.

Industry Issues Related to DMFs

Industry led a discussion with FDA on the impact of DMF First-Cycle Approvals and the importance of not allowing them to unnecessarily delay or halt the review and approval process of ANDAs. Industry will provide FDA with bucketed examples of instances of DMF issues to be discussed at a future meeting.

RPM Communication and Transparency During the Review Process

FDA discussed its efforts to improve communication and enhance transparency by RPMs during the ANDA review process.