FDA and Industry GDUFA II Implementation Quarterly Meetings – 3Q2018 Meeting
July 18, 2018, 1:30 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1309

Agenda

- FDARA Title VIII Update (FDA Led)
- Industry Inventory – Industry will provide a detailed description of the existing Industry led education efforts (Industry Led)
- Updates to Various Discussion Topics – Facility Classification, Refuse to Receives (RTRs), FDA working through the goal date for an imminent approval or Tentative Approval (TA), Complete Response Letter (CRL) Timelines, CRL utilized to Communicate Minor Deficiencies, and Complex Products Mid-Cycle Meetings (FDA Led)
- Increasing First Cycle Approvals and Decreasing Number of Cycles to Approval (Industry Led)

Participants

FDA:		Industry:	
Donald Ashley	CDER	Deborah Autor	AAM (Mylan)
Tiana Barnes	CDER	John DiLoreto	BPTF
Mary Beth Clarke	CDER	Kenneth Drew	EFCG (Flamma SpA)
Alonza Cruse	ORA	Mark Hendrickson	AAM
Kristin Davis	CDER *(FDARA Title VIII)*	Kiran Krishnan	AAM (Apotex)
Ellen Morrison	ORA	Lisa Parks	AAM
Maryll Toufanian	CDER	Gil Roth	PBOA
Kathleen Uhl	CDER	Rachael Sher	AAM
Lawrence Yu	CDER	Cornell Stamoran	PBOA (Catalent)
		Scott Tomsky	AAM (Teva)
		Molly Ventrelli	AAM (Fresenius Kabi)
		Elizabeth White	EFCG (Evonik Corp.)

FDARA Title VIII Update

FDA provided an update to Industry on the implementation of FDARA Title VIII.

Industry Inventory

AAM presented on its current Industry-led education efforts. AAM stated its industry led education and advocacy efforts ranged from AAM members, consumers, state and federal lawmakers all the way to ally groups and global stakeholders. The format of the education and advocacy work by AAM are member on-site visits to talk about GDUFA, various monthly functional working group meetings with member companies, publications and

whitepapers/position papers, meetings and conferences, and other alike activities. FDA requested additional details on what guidances Industry is providing education on, specifically topics, venue, frequency, what efforts have worked best for AAM, and how industry can increase its educational efforts on new guidances.

Updates to Various Discussion Topics

Facility Classification
FDA noted that the Facilities Amendments Guidance published earlier in the month and included changes to the language around requests for reconsideration in the appendix section.

CRL Timelines
FDA will not be making changes to the language in CRLs.

FDA Working Through the Goal Date for an Imminent Approval or TA
FDA is working on an internal process document and plans to report out on missed goals for imminent TA/AP in the GDUFA II Annual Report to Congress.

RTR's
FDA requested further details from Industry on its issues around RTR's. Industry stated it would be sharing a document outlining FDA in the near future.

CRL Utilized to Communicate Minor Deficiencies
FDA noted that there are specific goal dates and associated metrics for minor amendments to CR letters. This was negotiated as a workload management tool under GDUFA II

Complex Products Mid-Cycle Teleconference
In advance of the meeting, an ANDA applicant that had a mid-cycle teleconference with FDA shared their experience. FDA stated that the GDUFA II mid-cycle teleconferences were not the same as NDA PDUFA teleconferences between FDA and industry. FDA also indicated that they are still learning as this is a new commitment under GDUFA II and appreciated the feedback from the applicant.

Increasing First Cycle Approvals and Decreasing Number of Cycles to Approval

In the interest of time, both Industry and FDA agreed to table this topic and revisit it at a future meeting.