**FDA and Industry GDUFA II Implementation Quarterly Meetings – 4Q2019 Meeting**
**October 15, 2019, 1:30 PM – 3:30 PM**
**FDA White Oak Campus, Silver Spring, MD**
**Building 32, Room 1211**

## Agenda

- Ground Rules and Guiding Principles of Implementation Meetings (FDA Led)
- Outstanding Items from FY 2019 (Industry Led)
- Imminent Approval Position Paper (Industry Led)

## Participants

| FDA: | | Industry: | |
|---|---|---|---|
| Tiana Barnes | CDER | Rafael Antunes | EFCG (Hovione) |
| Ashley Boam | CDER | Joel Carpenter | BPTF (Albermarle) |
| Sally Choe | CDER | John DiLoreto | BPTF |
| Mary Beth Clarke | CDER | David Gaugh | AAM |
| Alonza Cruse | ORA | Kiran Krishnan | AAM (Apotex) |
| Michael Kopcha | CDER | Lisa Parks | AAM |
| Ellen Morrison | ORA | Cornell Stamoran | PBOA (Catalent) |
| Donal Parks - SME | CDER | Chuck Stankovic | BPTF (Piramal) |
| Joy Scott | CDER | Wayne Talton | AAM (Mylan) |
| Maryll Toufanian | CDER | Scott Tomsky | AAM (Teva) |
| Susan Zuk - SME | CDER | Bethany Walls | BPTF (MilleporeSigma) |
| | | Elizabeth White | EFCG (Evonik) |

## Ground Rules and Guiding Principles of Implementation Meetings

FDA led a discussion on ground rules and guiding principles to establish protocols for addressing Industry concerns and issues.

## Outstanding Items from FY2019

Industry and FDA discussed, provided clarity, and closed out several outstanding GDUFA II Implementation issues that arose during FY2019.

## Imminent Approval Position Paper

Industry presented a position paper to FDA on Imminent Approval. FDA commented that further discussion would be needed before any feedback could be provided.