**FDA-Industry PDUFA VI Reauthorization Meeting**
**October 21st, 2015, 9:30-11:30am**
**FDA White Oak Campus, Silver Spring, MD**
**Building 51, Room 1215**

**Purpose:** To discuss FDA and Industry pre-market review process enhancement proposals.

**Participants**

| FDA | | Industry | |
|---|---|---|---|
| Alonza Cruz | ORA | Cartier Esham | BIO |
| Joseph Franklin | OCC | Sascha Haverfield | PhRMA |
| Patrick Frey | CDER | Mark Taisey | PhRMA (Amgen) |
| John Jenkins | CDER | | |
| Christopher Joneckis | CBER | | |
| Theresa Mullin | CDER | | |
| Michael Pacanowski | CDER | | |
| Mary Parks | CDER | | |
| James Smith | CDER | | |
| Sara Stradley | CDER | | |
| Kellie Taylor | CDER | | |
| Kimberly Taylor | CDER | | |

**Discussion of FDA Review Process Enhancement Proposals**

FDA and Industry continued discussing proposals to enhance the review process.

**1. PDUFA meeting management.** FDA and industry acknowledged separate issues related to meeting management: (a) the calendar capacity of FDA review staff and division leadership to be able to schedule meetings within a certain timeframe, and (b) the ability of FDA to have enough time to review background packages, meet internally, and consult necessary expertise within and, in some cases, outside CDER and CBER to provide quality advice to sponsors when the package is received 30 days before the meeting date. FDA also indicated that moving more meetings to the Written-Response-Only (WRO) format would also provide FDA with added flexibility in managing the meeting workload. FDA and Industry agreed to continue discussing this proposal.

2. **Proposed pediatric study request and written request amendment review**. FDA noted that the number of applications reviewed by FDA's Pediatric Review Committee (PeRC) has grown substantially since the Food and Drug Administration Safety Innovation Act (FDASIA) was enacted in 2012. PeRC carries out certain activities under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). The agency noted that industry's proposal for performance goals related to PPSR and WR review represents only a subset of overall PeRC reviews. FDA and Industry agreed to continue discussing this proposal.

3. **Responses to PMR/PMC protocols and amendments.** FDA discussed agency response times to PMR/PMC protocols. The agency also noted that FDA performance on responses to PMR/PMC protocols and amendments are currently part of the agency's good review management practices. FDA and Industry agreed to continue discussing this proposal.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.