# Prescription Drug User Fee Act (PDUFA) Reauthorization

## Manufacturing and Inspections Workgroup | Meeting Summary

*October 21st, 2020 | 2:00pm-4:00pm*

*Virtual Format (Zoom)*

### PURPOSE

To discuss Industry's manufacturing and inspections related topics in PDUFA VII.

### PARTICIPANTS

| FDA | | Industry | |
|---|---|---|---|
| David Burrow | CDER | Rob Blanks | BIO (Ardelyx) |
| Alonza Cruse | ORA | Danielle Friend | BIO |
| Laurie Graham | CDER | Carl Garner | PhRMA (Eli Lilly) |
| Don Henry | CDER | Ryan Kaat | PhRMA |
| Andrew Kish | CDER | | |
| Ted Liazos | OCC | | |
| KaLonna Maull | CDER | | |
| Steven Oh | CBER | | |
| Mahesh Ramanadham | CDER | | |
| Carol Rehkopf | CBER | | |
| Nicole Trudel | CBER | | |
| Grant Young | OCC | | |

The meeting discussion was focused on exploring Industry's PDUFA VII manufacturing proposals related to inspection communications. FDA and Industry reviewed action items from the previous meeting and discussed additional updates to the schedule for the negotiation process.

FDA discussed opportunities related to communications that were raised in prior meetings. FDA discussed updating current process documents, particularly around Information Requests and mid-cycle meeting communications, and training to ensure consistency. FDA agreed to provide more information on the Four-Part Harmony approach to information requests.

FDA and Industry discussed Industry's proposals related to inspections. Industry shared information on the benefit of early awareness of announced pre-approval/pre-licensure inspections for sponsor logistics and the ability to plan manufacturing schedules. FDA and Industry discussed information submitted in applications compared to what is provided as part of an inspection. The

discussion also touched on inspections during COVID-19 and the use of other tools and approaches.

FDA explained existing risk-based facilities assessment practices, the current notification process for announced pre-approval/pre-licensure inspections and shared information related to the frequency of those inspections. FDA and Industry agreed to share more information around inspections in the subsequent meetings. FDA noted there are active work streams outside of user fee negotiations that are evaluating inspection topics related to COVID-19.

FDA and Industry agreed to discuss emerging technology and pre-approval supplement topics at the next meeting.

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