# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Manufacturing Subgroup | Meeting Summary

*January 21st, 2021 | 9:00am - 11:00am*

*Virtual Format (Zoom)*

**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 | Olivia Shopshear | PhRMA |
| Andrew Kish | CDER | | |
| Ted Liazos | OCC | | |
| KaLonna Maull | CDER | | |
| Steven Oh | CBER | | |
| Mahesh Ramanadham | CDER | | |
| Carol Rehkopf | CBER | | |
| Nicole Trudel | CBER | | |

The meeting discussion was focused on exploring Industry's PDUFA VII manufacturing and inspection topics. FDA began by reviewing the upcoming schedule for negotiation meetings and then recapped the outstanding action items for both sides.

**Alternative Tools to Assess Manufacturing Facilities Named in Pending Applications**

FDA and Industry continued discussion of draft commitment letter language related to alternative tools to assess manufacturing facilities. FDA and industry discussed the timeline of a proposed guidance on the topic and definitions of certain terms used in the proposed language.

**Advanced Manufacturing**

FDA and Industry discussed draft commitment language regarding a workshop on advanced manufacturing-related topics. FDA and Industry discussed having a proposed strategy document as an output from the workshop and the feasibility of providing updates to the document throughout PDUFA VII.

**CMC Readiness Pilot Proposal**

FDA and Industry shared perspectives on various aspects of the potential CMC readiness pilot. Both parties continued to discuss draft commitment language and agreed to further edit the language and provide updates prior to the next meeting.

The remaining negotiation schedule was discussed and expectations to finalize negotiations by early February were established.

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