# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Manufacturing Subgroup | Meeting Summary

*January 13th, 2021 | 1:00pm - 4:00pm*

*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.

### CMC Readiness Pilot Proposal

FDA and Industry continued to discuss details around a CMC readiness pilot for certain products. FDA and Industry both saw potential benefit in the pilot. FDA and Industry discussed the duration of the pilot program and potential outputs from the program. Industry expressed desire for lessons learned from the pilot program to be shared potentially during mid- PDUFA VII. FDA explained it will take time to gain sufficient experience via the pilot to provide lessons learned. Industry noted that they see the pilot as an opportunity to test science- and risk-based regulatory flexibility and gain experience on when and how that flexibility can be applied in IND development programs. FDA noted they see the pilot as an opportunity to increase CMC readiness for certain products with expedited clinical development timelines to ensure critical drugs get to patients in a timely manner. FDA and Industry discussed the potential of a multi-day workshop during mid-PDUFA VII to assess the pilot and share lessons learned. FDA agreed to draft updated language for Industry to review and to share resource estimates.

Industry and FDA continued to discuss draft commitment language for other proposals including information requests, mid-cycle language, and alternative tools to assess manufacturing facilities named in pending applications. Both parties agreed to extend future meetings to ensure negotiations and commitment language were finalized.

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