# Prescription Drug User Fee Act (PDUFA) Reauthorization

## Manufacturing and Inspections Workgroup | Meeting Summary

*November 18th, 2020 | 2:00pm-4:00pm*

*Virtual Format (Zoom)*

### PURPOSE

To discuss Industry's manufacturing and inspections related interests 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 | | |
| Steven Oh | CBER | | |
| Mahesh Ramanadham | CDER | | |
| Carol Rehkopf | CBER | | |
| Nicole Trudel | CBER | | |

The meeting focused on finalizing discussions at the subgroup level for Industry proposals relating to pre-approval/pre-licensure inspections (PAI/PLI) waivers, application content versus inspection content, and announced PAI/PLIs.

**PAI/PLI Waivers**

FDA explained its existing risk-based facilities assessment practices and information it uses to determine if a PAI/PLI is needed. FDA then explained that introducing a sponsor-requested waiver into that process is unlikely to alter FDA's decision, given FDA's access to facility information, and could add burden to the review timeline. Industry shared their perspective on the information sponsors may be able to provide the agency to make inspection decisions. FDA explained that applicants can currently share information with FDA in their submissions. Industry noted that it may be helpful to sponsors if FDA can provide additional clarity on risk-based facilities assessment practices and information FDA uses for inspection decisions through public facing documents. The parties discussed the existing opportunities for sharing information. FDA asked that Industry share more information on what they feel needs to be clarified regarding PAI/PLI inspections that is not already available to the public.

**Application Content versus Inspection Content**

FDA and Industry continued to discuss Industry's proposal around delineating what information should be submitted in an application and what is provided as part of an inspection. Industry shared examples of what they believe to be inspection content that FDA is now requesting as part of the application. After reviewing examples provided by Industry, FDA noted that the inspection content requested in the examples is consistent with published guidance on what FDA expects in an application. FDA and Industry discussed the guidances and the role information requests play in this topic. FDA suggested that updating FDA procedures to include four-part harmony while writing information requests and implementing related training may address aspects of this issue.

**Notifications of PAI/PLIs**

FDA and Industry continued to discuss Industry's proposal for announced PAI/PLIs. FDA shared their perspective that they see potential value to the review process if FDA and applicants can align on BLA manufacturing schedules and inspections timeframes, potentially through a notification of a PLI. FDA maintained (and Industry agreed) that it is important for the agency to reserve the right to inspect a facility unannounced. Industry asked that certain NDAs also be considered, and the FDA asked for additional clarity regarding the need for announced inspections in that program.

FDA and Industry discussed the agenda for the remaining meetings in the calendar year. The group agreed to not meet on November 25th, due to the Thanksgiving holiday. FDA and Industry agreed to reconvene on December 2nd.

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