

# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Manufacturing Subgroup | Meeting Summary

January 27<sup>th</sup>, 2021 | 1:00pm - 4:00pm

Virtual Format (Zoom)

### PARTICIPANTS

#### FDA

David Burrow	CDER
Alonza Cruse	ORA
Laurie Graham	CDER
Don Henry	CDER
Andrew Kish	CDER
Ted Liazos	OCC
KaLonna Maull	CDER
Steven Oh	CBER
Mahesh Ramanadham	CDER
Carol Rehkopf	CBER
Nicole Trudel	CBER

#### Industry

Rob Blanks	BIO (Ardelyx)
Danielle Friend	BIO
Carl Garner	PhRMA (Eli Lilly)
Olivia Shopshear	PhRMA

The meeting discussion focused on reviewing Industry’s edits on draft commitment language.

The parties discussed language and rationale for the timeline of an independent assessment for product quality information requests. FDA and Industry clarified terms and understanding of the commitment regarding the use of alternative tools to assess manufacturing facilities named in pending applications.

FDA and Industry discussed eligibility criteria for a pilot program to facilitate Chemistry, Manufacturing, and Controls (CMC) readiness for products with expedited clinical development. Industry noted that they would like to see proposals accepted into the pilot program in areas where FDA would like to gain more experience.

Both parties reviewed the section titles and discussed drafting language for the preamble. FDA and Industry agreed to keep the meeting on the calendar for February 3, 2021 in the event outstanding revisions could not be resolved by the end of the week.

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