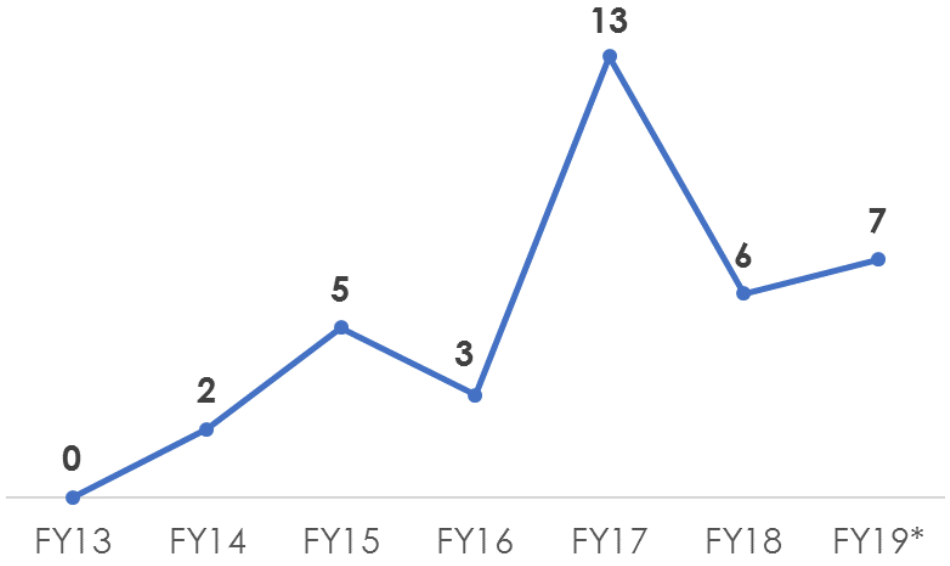
Important Progress From BsUFA I to II

From...	*To...*
No 351(k) Applications	**36** 351(k) Applications*
No Approved Products	**23** Approved Biosimilar Products
New Pathway and Process	Experience with Pathway and Process
Dependent Financial Structure	Independent Financial Structure

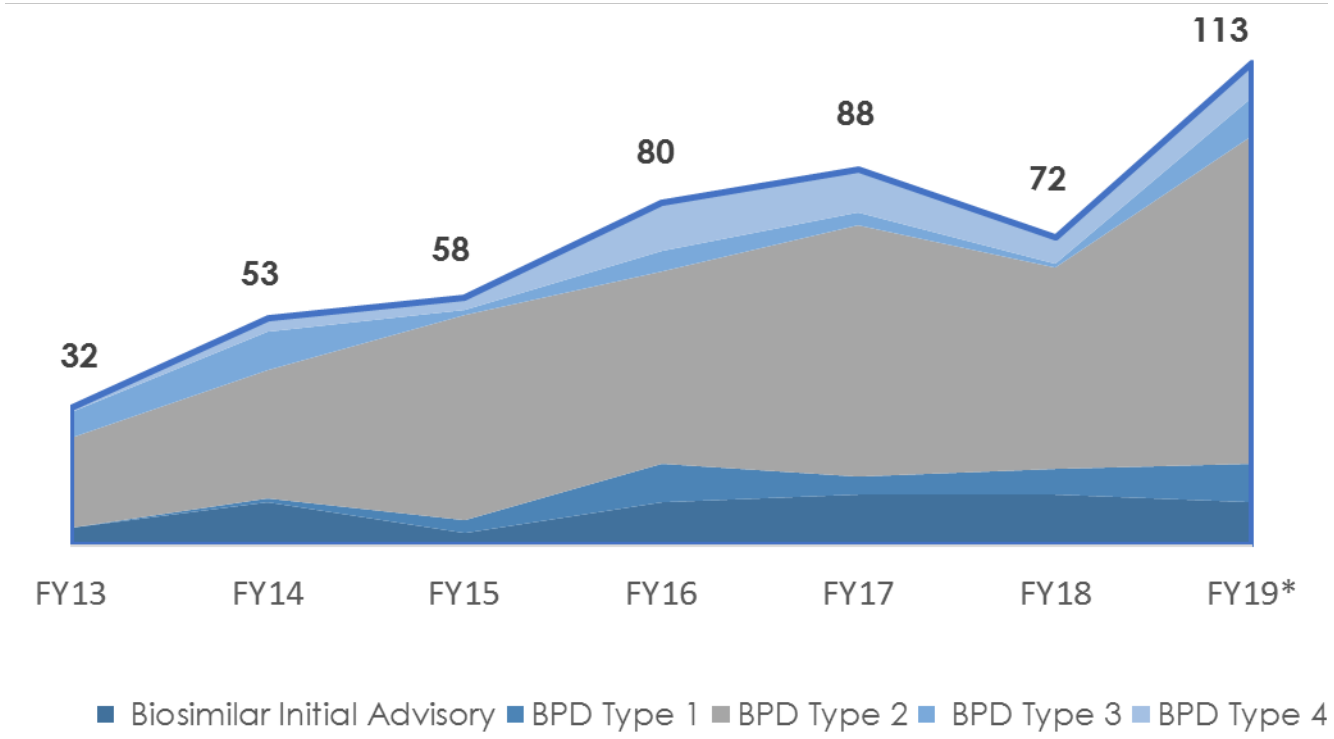
*Includes preliminary FY19 data

Historical View of BsUFA Program Workload

While there is variability, **original biosimilar product applications** continue to trend up



Steady increase **of meeting requests** driven by **BPD Type 2** requests



*Includes preliminary FY19 data

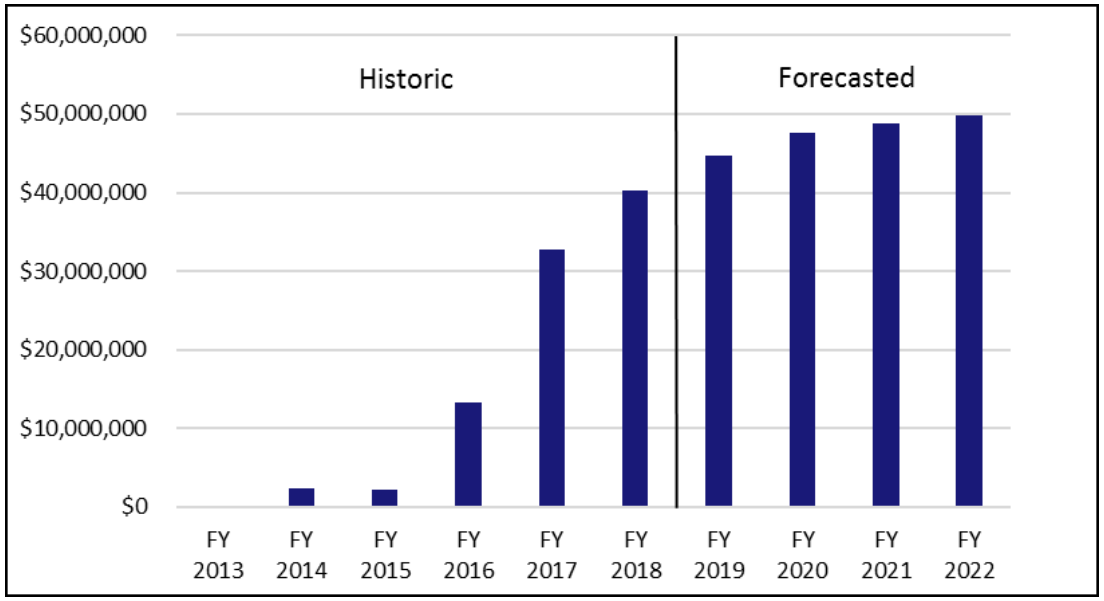
Historical View of BsUFA Program Resources

- The biosimilar review program started with a very limited budget to build review capacity. In FY 2013, FDA obligated $28M from non-user fee funds and $0 from BsUFA fees to support the program.

- Structural aspects of the BsUFA I user fee design resulted in conservative expenditure of user fee resources in the early years of BsUFA I.

- The creation of an independent, efficient, user fee structure in BsUFA II improved FDA's ability to manage program resources and engage in long-term planning. As a result, FDA plans to spend more resources to build program capacity.

Historic and Forecasted User Fee Obligations by Fiscal Year



Meeting Performance By FY

	Performance by Fiscal Year					
Meeting Goal	2013	2014	2015	2016	2017	2018*
Meeting Requests: Biosimilar Initial Advisory	100%	100%	100%	70%	50%	100%
Meeting Requests: BPD Type 1	--	100%	100%	100%	100%	100%
Meeting Requests: BPD Type 2	95%	73%	98%	91%	95%	94%
Meeting Requests: BPD Type 3	100%	89%	100%	80%	33%	100%
Meeting Requests: BPD Type 4	100%	100%	100%	82%	80%	100%
Scheduling Meetings: Biosimilar Initial Advisory	33%	78%	50%	75%	44%	60%
Scheduling Meetings: BPD Type 1	--	0%	67%	75%	50%	80%
Scheduling Meetings: BPD Type 2	55%	44%	49%	73%	76%	91%
Scheduling Meetings: BPD Type 3	100%	89%	100%	100%	100%	100%
Scheduling Meetings: BPD Type 4	100%	67%	0%	50%	60%	83%
Written Response: Biosimilar Initial Advisory						100%
Written Response: BPD Type 2						100%
Preliminary Responses: BPD Type 2						94%
Preliminary Responses: BPD Type 3						100%
Meeting Minutes: All Meeting Types	76%	82%	77%	72%	86%	95%

Data as of 9/30/2019
*2018 data is preliminary and represents highest possible performance

Overview of FY 2018 Performance

- FDA has the potential to meet or exceed 88% (22 of the 25) the review performance, procedural, and meetings goals that apply to the FY 2018 cohort. However, many actions were still pending at the time of the report.

- FY 2018 preliminary meeting management performance data shows potential improvement compared to FY 2017, but this area continues to present challenges.

  Circumstances and trends impacting FDA's ability to meet the goal dates include:
  - The meeting cohort is small relative to other programs. Thus, missing a single goal date can have a large impact on performance metrics.
  - Program is impacted by FDA understaffing.
  - Increasingly challenging performance goals, common across all programs, strain limited resources within relevant offices/divisions.

- FDA made all performance enhancement goals except for the timely posting of quarterly hiring data and the hiring goals (8 of 15 hires).