Report of Summary Level Review
Under Section 3031 of 21st Century Cures

Section 3031 of the 21st Century Cures Act[1] (or "Cures Act"), enacted December 13, 2016, authorizes FDA to rely on "qualified data summaries" to support approval of a supplemental Biologics License Application (sBLA) or supplemental New Drug Application (sNDA) for a "qualified indication" of a drug. Qualified data summaries refer to the summary information contained in the sBLA/sNDA (e.g., protocol, integrated summary of safety (ISS), integrated summary of effectiveness (ISE), clinical study report (CSR)). A sBLA or sNDA is eligible for review of qualified data summaries (i.e., summary level review), only if there is existing data to demonstrate the safety of the drug, and all data used to develop the qualified data summary are included in the supplemental application. Summary level review is not an approval pathway and the evidentiary standards for demonstrating the safety and effectiveness of a product are unchanged.

	Calendar Year					
	2017	**2018**	**2019**	**2020**	**2021**	**2022**
Total Number of Approved Efficacy Supplements	212	248	254	259	243	220
Number of supplemental applications reviewed using the flexibility allowed under Section 3031 of the Cures Act	1	1	1	4	9	5
Number of supplemental applications reviewed using full datasets in addition to the qualified data summary	1	0	1	4	5	0
Average Time[1] for review (months)	9.9*	4.5*	10*	5.4	4.2	7.4
Average time[1] for review (months) **of approved supplemental applications *not* reviewed using the flexibility allowed under Section 3031 of the Cures Act** (i.e., full dataset review)	8.1	8.0	7.9	7.2	8.0	8.2

[1] The Cures Act requires FDA to report on "the average time for completion of review" which is calculated based upon the review time for approval (i.e., the time from application receipt to date of approval action)

*The average time for review for calendar years 2017, 2018, 2019 reflects the actual review time to approval because there was only a single summary level review in each of those calendar years.

[1] Section 351(a)(2)(E) of the Public Health Service Act (PHSA) and Section 505(c)(5)(A) of the Food, Drug, and Cosmetic Act (FDCA). https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act