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[a]				
	2020	**2021**	**2022**	**2023[b]**	**2024**
Total Number of Approved Efficacy Supplements	259	243	220	214	224
Number of supplemental applications reviewed using the flexibility allowed under Section 3031 of the Cures Act	4	9	5	6	1
Number of supplemental applications reviewed using full datasets in addition to the qualified data summary	4	6	0	4	0
Average Time[c] for review (months)	5.4	4.2	7.4	3.6	8.0[d]
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)	7.2	8.0	8.2	7.9	9.0

[a] The Summary level Review Report for prior calendar years (2017 – 2019) is available on the FDA web page at: https://www.fda.gov/drugs/nda-and-bla-approvals/efficacy-supplement-approvals.
[b] The numbers for calendar year 2023 were revised to reflect data corrections made after December 31, 2023.
[c] 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)
[d] The average time for review for calendar year 2024 reflects the actual review time to approval because there was only a single summary level review in that calendar year.

[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