

**CDER Approval Times for Priority and Standard NDAs and BLAs
Calendar Years 1993 – 2015**

Calendar Year of Approval	Priority			Standard		
	Number Approved	Median FDA Review Time (Months)	Median Total Approval Time (Months)	Number Approved	Median FDA Review Time (Months)	Median Total Approval Time (Months)
1993	19	16.3	20.5	51	20.8	26.9
1994	16	13.9	14.0	45	16.8	21.0
1995	16	7.9	7.9	67	16.2	18.7
1996	29	7.8	7.8	102	15.1	17.8
1997	20	6.3	6.4	101	14.7	15.0
1998	25	6.2	6.4	65	12.0	12.0
1999	28	6.1	6.1	55	12.0	13.8
2000	20	6.0	6.0	78	12.0	12.0
2001	10	6.0	6.0	56	12.0	14.0
2002	11	13.8	19.1	67	12.7	15.3
2003 (1)	14	7.7	7.7	58	11.9	15.4
2004	29	6.0	6.0	89	11.8	12.7
2005	22	6.0	6.0	58	11.8	13.1
2006	21	6.0	6.0	80	12.0	13.0
2007	23	6.0	6.0	55	10.2	10.4
2008	18	6.0	6.0	70	13.0	13.1
2009	19	9.0	12.0	78	12.5	13.0
2010	16	9.0	9.0	76	10.4	12.0
2011	26	6.0	6.9	68	10.8	10.8
2012 (2)	23	6.0	6.0	77	10.0	10.0
2013	16	6.2	6.2	82	10.1	10.1
2014	34	8.0	8.0	84	11.8	12.0
2015	37	8.0	8.0	84	12.0	12.0

Notes:

(1) Beginning in Fiscal Year 2004 (October 1, 2003) CDER started reviewing therapeutic biologic products transferred from CBER to CDER.

(2) Beginning with the implementation of PDUFA V, FY2013 (October 1, 2012), NME NDAs and Original BLAs were reviewed under the Program for Enhanced Review Transparency and Communication (the Program), which provided additional review clock time for the agency, as the PDUFA clock begins after conclusion of the 60 day filing period. This additional time may skew the median review times.

Updated through 12/31/2015