

CDER Approval Times for Priority and Standard NMEs and New BLAs*
CY 1993 – 2008

Calendar Year	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	13	13.9	14.9	12	27.2	27.2
1994	12	13.9	14.0	9	22.2	23.7
1995	10	7.9	7.9	19	15.9	17.8
1996	18	7.7	9.6	35	14.6	15.1
1997	9	6.4	6.7	30	14.4	15.0
1998	16	6.2	6.2	14	12.3	13.4
1999	19	6.3	6.9	16	14.0	16.3
2000	9	6.0	6.0	18	15.4	19.9
2001	7	6.0	6.0	17	15.7	19.0
2002	7	13.8	16.3	10	12.5	15.9
2003	9	6.7	6.7	12	13.8	23.1
2004*	21	6.0	6.0	15	16.0	24.7
2005*	15	6.0	6.0	5	15.8	23.0
2006*	10	6.0	6.0	12	12.5	13.7
2007*	8	6.0	6.0	10	12.9	12.9
2008*	9	6.0	6.0	15	13.0	13.0

* Beginning in 2004, figures include BLAs, and the # of BLAs included in the total is shown in parentheses. CY 2006 filed figures include applications received in the last 60 days of the calendar year that are still pending a filing decision.