

## CDER Approval Times for Priority and Standard NDAs and BLAs Calendar Years 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	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	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	59	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

**\*Beginning in 2004, these figures include new BLAs for therapeutic biologic products transferred from CBER to CDER.**

*Updated through 12/31/2008*