



U.S. Food and Drug Administration



CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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Approval Times

The Center for Biologics Evaluation and Research continues to ensure the safety of the nation's blood supply and the safety and efficacy of counter-terrorism and other vaccines and antitoxins, as well as cutting edge technologies such as somatic cell and gene therapies. CBER also continues to approve new biological licenses as well as biological license supplements.

Approval Times for Priority and Standard Biological License Applications and Device Applications

Calendar Year	BLAs		PMAs		510ks		
	Priority Review	Standard Review	Blood Banking	Number Approved	Median Total Approval Time (months)	Number Approved	Median Total Approval Time (months)
1995	2	16	11	0	--	51	6.7
1996	3	24	10	3	11.7	31	5.0
1997	7	22	8	0	--	46	11.1
1998	8	13	6	0	--	52	15.1
1999	3	4	3	2	24.7	44	7.0

2000	1	8.52	9	28.67	2	16.80	0	--	22	3.3
2001	2	13.18	8	23.74	5	16.63	3	10.5	25	5.5
2002	6	14.69	10	19.91	4	10.61	2	19.9	42	6.2
2003	5	22.18	11	30.00	6	8.66	3	8.5	47	2.3
2004*	0	--	2	19.77	2	12.91	1	5.9	62	2.5

* Beginning in 2004, these figures exclude BLAs for therapeutic biological products transferred from CBER to CDER effective 10/1/2003.

Description of approval time information

Transfer of therapeutic products from CBER to CDER

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