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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)
	Number Approved	Median Total Approval Time (months)	Number Approved	Median Total Approval Time (months)	Number Approved	Median Total Approval Time (months)				
1995	2	50.37	16	34.42	11	10.13	0	--	51	6.7
1996	3	11.87	24	39.63	10	10.18	3	11.7	31	5.0
1997	7	8.94	22	22.07	8	10.99	0	--	46	11.1
1998	8	6.91	13	23.42	6	11.94	0	--	52	15.1
1999	3	13.87	4	24.18	3	8.32	2	24.7	44	7.0

Amgen Inc. v. F. Hoffmann-LaRoche LTD et al
 Case 1:05-cv-12237-WGY
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 Filed 04/11/2006
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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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