



# U.S. Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Department of Health and Human Services

[FDA Home Page](#) | [CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)

---

CDER Home
About CDER
Drug Information
Regulatory Guidance
CDER Calendar
Specific Audiences
CDER Archives

Search   powered by 

### CDER Approval Times for Priority and Standard NMEs and New BLAs Calendar Years 1993 - 2004\*

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

Amgen Inc. v. F. Hoffmann-LaRoche LTD et al  
 Case 1:05-cv-12237-WGY  
 Document 49-9  
 Filed 04/11/2006  
 Page 1 of 2  
**EXHIBIT 4**  
 Doc. 49 Att. 8

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

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

*updated through 12/31/2004*

[↑ Back to Top](#)   [↩ Back to Index](#)

Date created: March 22, 2005

---

[CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)  
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

FDA/Center for Drug Evaluation and Research