

**CDER Approval Times for Priority and Standard NDAs and BLAs
Calendar Years 1993 – 2016**

| Calendar Year of Approval | 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 (1) | 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 | 58 | 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 |
| 2009 | 19 | 9.0 | 12.0 | 78 | 12.5 | 13.0 |
| 2010 | 16 | 9.0 | 9.0 | 76 | 10.4 | 12.0 |
| 2011 | 26 | 6.0 | 6.9 | 68 | 10.8 | 10.8 |
| 2012 (2) | 23 | 6.0 | 6.0 | 77 | 10.0 | 10.0 |
| 2013 | 16 | 6.2 | 6.2 | 82 | 10.1 | 10.1 |
| 2014 | 34 | 8.0 | 8.0 | 84 | 11.8 | 12.0 |
| 2015 | 37 | 8.0 | 8.0 | 84 | 12.0 | 12.0 |
| 2016 | 24 | 8.0 | 8.0 | 70 | 10.1 | 10.1 |

Notes:

(1) Beginning in Fiscal Year 2004 (October 1, 2003) CDER started reviewing therapeutic biologic products transferred from CBER to CDER.

(2) Beginning with the implementation of PDUFA V, FY2013 (October 1, 2012), NME NDAs and Original BLAs were reviewed under the Program for Enhanced Review Transparency and Communication (the Program), which provided additional review clock time for the agency, as the PDUFA clock begins after conclusion of the 60 day filing period. This additional time may skew the median review times.

Updated through 12/31/2016