

EXHIBIT 5

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Approval Times for Priority and Standard BLAs and Device Applications

[Approval times table](#)

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.

Beginning in 2004, these figures exclude BLAs for [therapeutic biological products transferred from CBER to CDER](#) effective 10/1/2003.

2004 Review of 510ks resulted in 62 approvals with a median total approval time of 2.5 months.

2004 Review of PMAs resulted in 1 approvals with a median total approval time of 5.9 months.

2004 Blood Banking Review of BLAs resulted in 2 approvals with a median total approval time of 12.91 months.

2004 Standard Review of BLAs resulted in 2 approvals with a median total approval time of 19.77 months.

2004 Priority Review of BLAs resulted in 0 approvals.

2003 Review of 510ks resulted in 47 approvals with a median total approval time of 2.3 months.

2003 Review of PMAs resulted in 3 approvals with a median total approval time of 8.5 months.

2003 Blood Banking Review of BLAs resulted in 6 approvals with a median total approval time of 8.66 months.

2003 Standard Review of BLAs resulted in 11 approvals with a median total approval time of 30 months.

2003 Priority Review of BLAs resulted in 5 approvals with a median total approval time of 22.18 months.

2002 Review of 510ks resulted in 42 approvals with a median total approval time of 6.2 months.

2002 Review of PMAs resulted in 2 approvals with a median total approval time of 19.9 months.

2002 Blood Banking Review of BLAs resulted in 4 approvals with a median total approval time of 10.61

months.

2002 Standard Review of BLAs resulted in 10 approvals with a median total approval time of 19.91 months.

2002 Priority Review of BLAs resulted in 6 approvals with a median total approval time of 14.69 months.

2001 Review of 510ks resulted in 25 approvals with a median total approval time of 5.5 months.

2001 Review of PMAs resulted in 3 approvals with a median total approval time of 10.5 months.

2001 Blood Banking Review of BLAs resulted in 5 approvals with a median total approval time of 16.63 months.

2001 Standard Review of BLAs resulted in 8 approvals with a median total approval time of 23.74 months.

2001 Priority Review of BLAs resulted in 2 approvals with a median total approval time of 13.18 months.

2000 Review of 510ks resulted in 22 approvals with a median total approval time of 3.3 months.

2000 Review of PMAs resulted in 0 approvals.

2000 Blood Banking Review of BLAs resulted in 2 approvals with a median total approval time of 16.80 months.

2000 Standard Review of BLAs resulted in 9 approvals with a median total approval time of 28.67 months.

2000 Priority Review of BLAs resulted in 1 approvals with a median total approval time of 8.52 months.

1999 Review of 510ks resulted in 44 approvals with a median total approval time of 7 months.

1999 Review of PMAs resulted in 2 approvals with a median total approval time of 24.7 months.

1999 Blood Banking Review of BLAs resulted in 3 approvals with a median total approval time of 8.32 months.

1999 Standard Review of BLAs resulted in 4 approvals with a median total approval time of 24.18 months.

1999 Priority Review of BLAs resulted in 3 approvals with a median total approval time of 13.87 months.

1998 Review of 510ks resulted in 52 approvals with a median total approval time of 15.1 months.

1998 Review of PMAs resulted in 0 approvals.

1998 Blood Banking Review of BLAs resulted in 6 approvals with a median total approval time of 11.94 months.

1998 Standard Review of BLAs resulted in 13 approvals with a median total approval time of 23.42 months.

1998 Priority Review of BLAs resulted in 8 approvals with a median total approval time of 6.91 months.

1997 Review of 510ks resulted in 46 approvals with a median total approval time of 11.1 months.

1997 Review of PMAs resulted in 0 approvals.

1997 Blood Banking Review of BLAs resulted in 8 approvals with a median total approval time of 10.99 months.

1997 Standard Review of BLAs resulted in 22 approvals with a median total approval time of 22.07 months.

1997 Priority Review of BLAs resulted in 7 approvals with a median total approval time of 8.94 months.

1996 Review of 510ks resulted in 31 approvals with a median total approval time of 5 months.

1996 Review of PMAs resulted in 3 approvals with a median total approval time of 11.7 months.

1996 Blood Banking Review of BLAs resulted in 10 approvals with a median total approval time of 10.18 months.

1996 Standard Review of BLAs resulted in 24 approvals with a median total approval time of 39.63 months.

1996 Priority Review of BLAs resulted in 3 approvals with a median total approval time of 11.87 months.

1995 Review of 510ks resulted in 51 approvals with a median total approval time of 6.7 months.

1995 Review of PMAs resulted in 0 approvals.

1995 Blood Banking Review of BLAs resulted in 11 approvals with a median total approval time of 10.13 months.

1995 Standard Review of BLAs resulted in 16 approvals with a median total approval time of 34.42 months.

1995 Priority Review of BLAs resulted in 2 approvals with a median total approval time of 50.37 months.

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