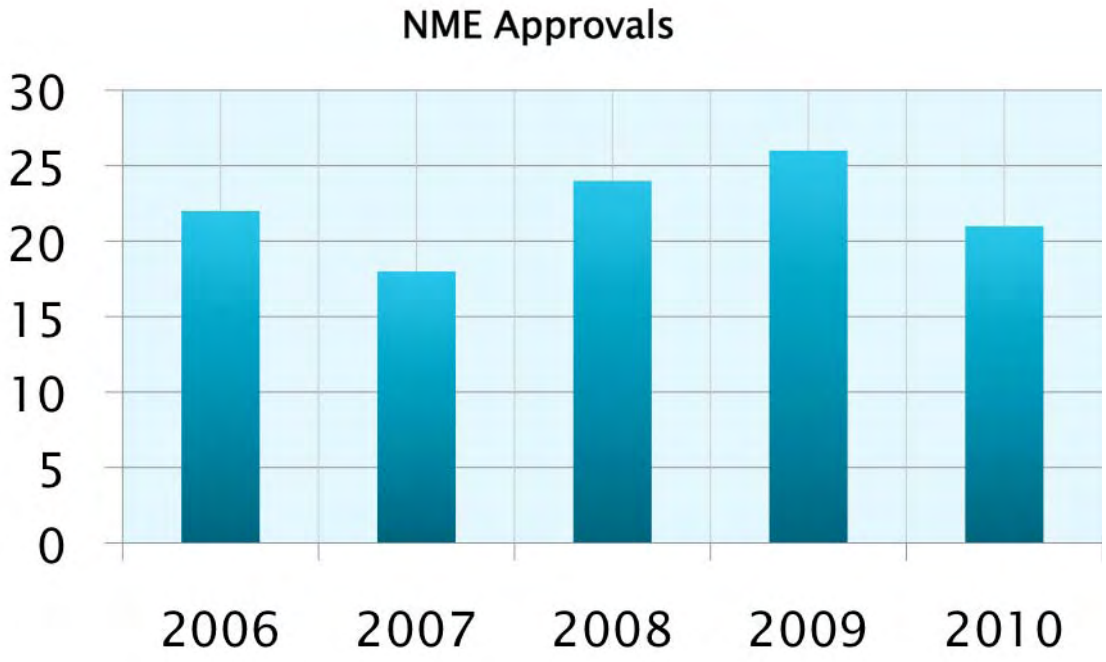
NMEs* Approved by CDER

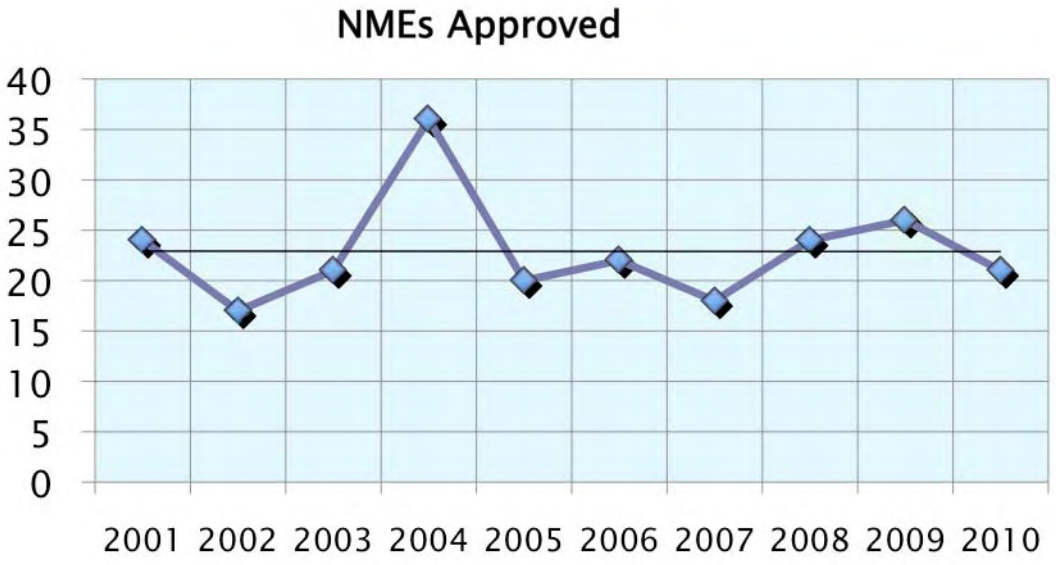


Calendar Year	NMEs Approved
2006	22
2007	18
2008	24
2009	26
2010	21

FDA's Center for Drug Evaluation and Research (CDER) approved 21 New Molecular Entities (NMEs) in 2010. This is within an 18-26 range approved for the last several years.

*Represents applications for New Molecular Entities (NMEs) filed under New Drug Applications (NDAs) and therapeutic biologics filed under Original Biologic License Applications (BLAs)

Ten Year Average NME* Approvals Per Year

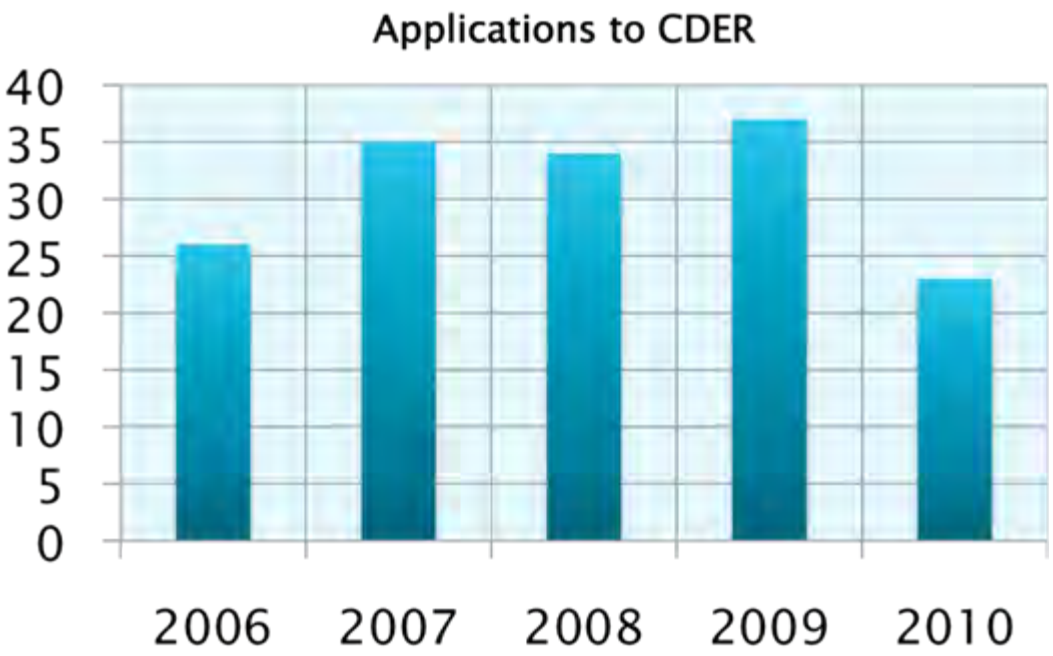


Calendar Year	NMEs Approved
2001	24
2002	17
2003	21
2004	36
2005	20
2006	22
2007	18
2008	24
2009	26
2010	21

Since 2001 CDER has averaged slightly fewer than 23 NME approvals per year (22.9), similar to the 21 approved in 2010.

*2004-2010 represents applications for New Molecular Entities (NMEs) filed under New Drug Applications (NDAs) and therapeutic biologics filed under Original Biologic License Applications (BLAs). 2001-2003 represents NMEs but not therapeutic biologics.

NME* Applications to CDER (Last 5 Years)

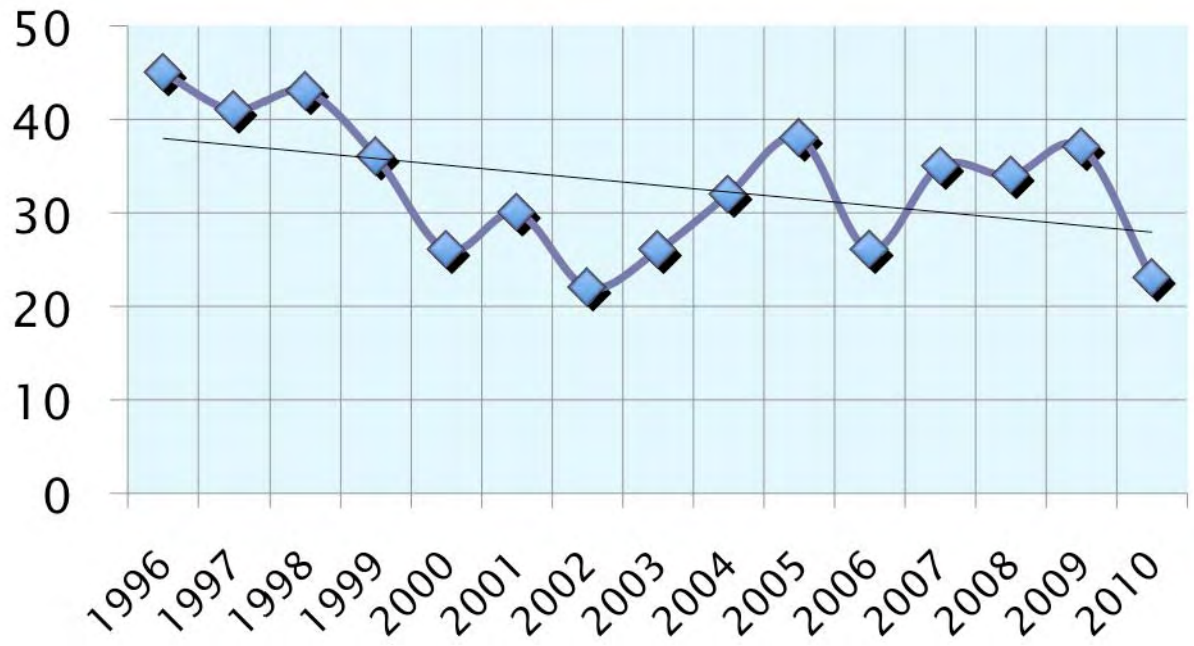


Calendar Year	Applications Filed
2006	26
2007	35
2008	34
2009	37
2010	23

NME applications to CDER are not increasing. If the number of applications does not increase, CDER does not expect to see much of a year-to-year increase in approvals.

*Represents applications for New Molecular Entities (NMEs) filed under New Drug Applications (NDAs) and Original Biologic License Applications (BLAs)

NME* Applications to CDER (Last 15 Years)



Calendar Year	Applications Filed
1996	45
1997	41
1998	43
1999	36
2000	26
2001	30
2002	22
2003	26
2004	32
2005	38
2006	26
2007	35
2008	34
2009	37
2010	23

In fact, except for 2002, the 23 NME applications to CDER filed in 2010 is the lowest number filed in more than 15 years.

*2004-2010 represents applications for New Molecular Entities (NMEs) filed under New Drug Applications (NDAs) and therapeutic biologics filed under Original Biologic License Applications (BLAs). 2001-2003 represents NMEs but not therapeutic biologics.