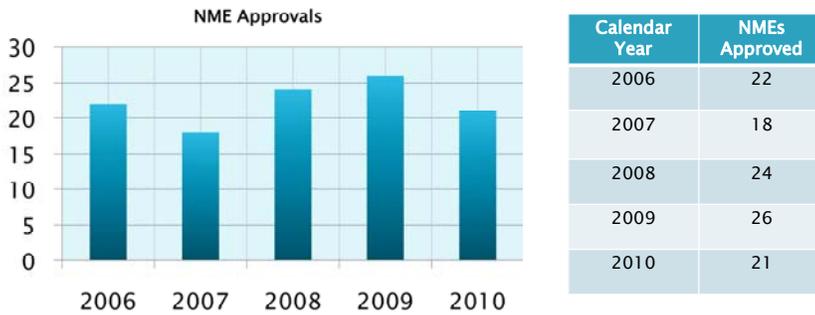


Is it true FDA is approving fewer new drugs lately?

FDA sometimes hears concerns from the public that the Agency is not approving enough new drugs. Actually, the number of new drugs FDA approves each year has remained relatively steady over time. For instance, In 2010 FDA's Center for Drug Evaluation and Research (CDER) approved 21 novel new drugs known as New Molecular Entities (NMEs). The chart below shows that this number is similar to NME approvals over the past five years.

NMEs* Approved by CDER

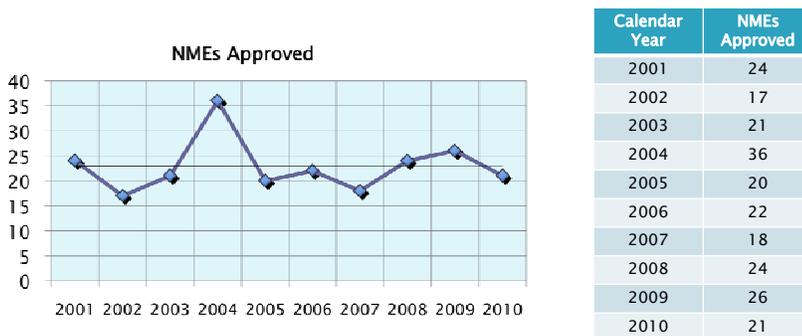


FDA's Center for Drug Evaluation and Research (CDER) approved 21 New Molecular Entities (NMEs) in 2010. This is within an 18-26 range approved for the last several years.

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

In fact, 21 NME approvals in one year is about in line for yearly approvals for the past decade. The chart below shows a ten year period from 2001 through 2010, in which FDA averaged about 23 NME approvals per year (22.9).

Ten Year Average NME* Approvals Per Year

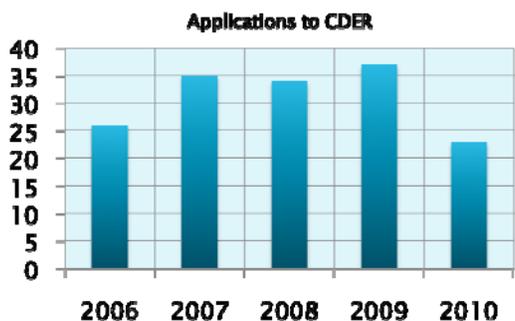


Since 2001 CDER has averaged slightly fewer than 23 NME approvals per year (22.9), similar to the 21 approved in 2010.

*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.

While 21 approvals in 2010 is typical of previous years, an increase in approvals would be the ideal scenario. A good part of the reason for this flat approval rate over time is that drug companies are not filing as many applications with FDA for new drug approval as they have in the past. The chart below shows that over the past five years, applications filed with FDA for NMEs have not been increasing. If applications do not increase, the likelihood of approvals increasing is reduced.

NME* Applications to CDER (Last 5 Years)



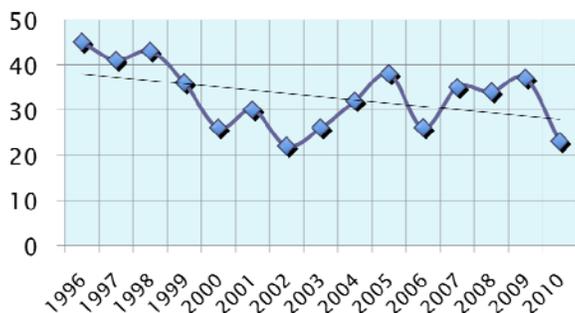
Calendar Year	Applications Filed
2006	26
2007	35
2008	34
2009	37
2010	23

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)

The trend towards fewer filings for NMEs extends beyond the past five years. The chart below shows that except for 2002, in which 22 applications were filed with FDA for new NMEs, the 23 applications for NMEs in 2010 is the lowest number in over 15 years.

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.

FDA has been taking action for some time to help drive new drug development and increase applications for novel new products. In 2004, noting a slowdown, FDA launched its Critical Path Initiative, FDA's national strategy to help advance pharmaceutical innovation. Our long-term efforts are showing positive signs and FDA will continue to support the scientific community to advance new drug development. For more information on FDA's Critical Path Initiative visit:

<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>