Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

CDER USER FEE PERFORMANCE & NEW DRUG APPROVALS

2011

SUMMARY

JANUARY, 2012

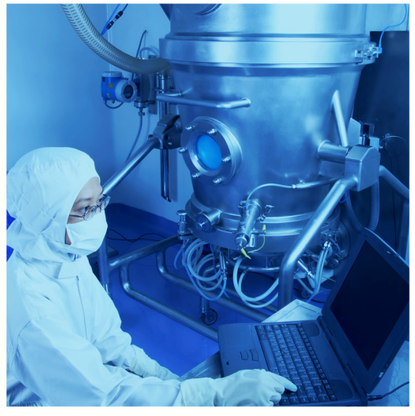
CDER User Fee Performance and New Drug Approvals, 2011

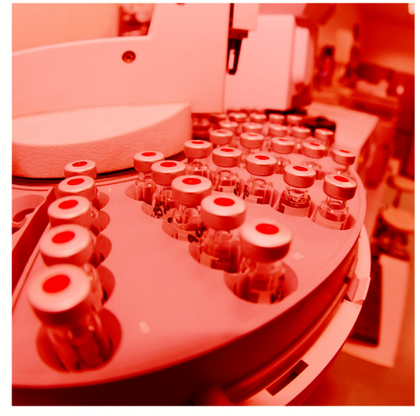
PDUFA OVERVIEW

CDER User Fee Performance & New Drug Approvals, 2011

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 and renewed in 1997 (PDUFA II), 2002 (PDUFA III), and 2007 (PDUFA IV). It authorizes the U.S. Food and Drug Administration (FDA) to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in providing additional resources to allow the FDA to modernize the drug approval process.

The following is an overview of FDA's Center for Drug Evaluation and Review's performance in meeting PDUFA goals, including data for calendar year 2011 and fiscal year 2011 (October 1, 2010 through September 31, 2011). This review also includes other measures relative to CDER's new drug review performance of FY 2011.





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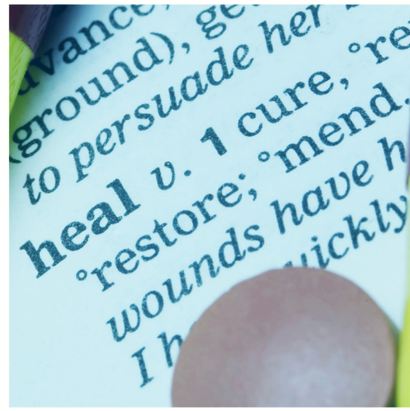
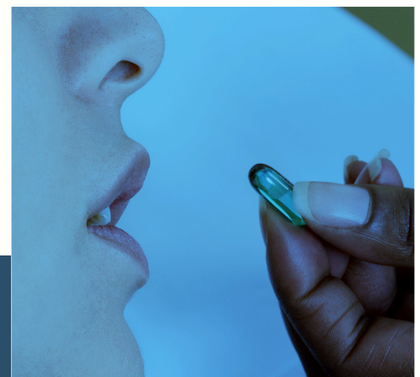




GOALS & APPROVAL TIMES

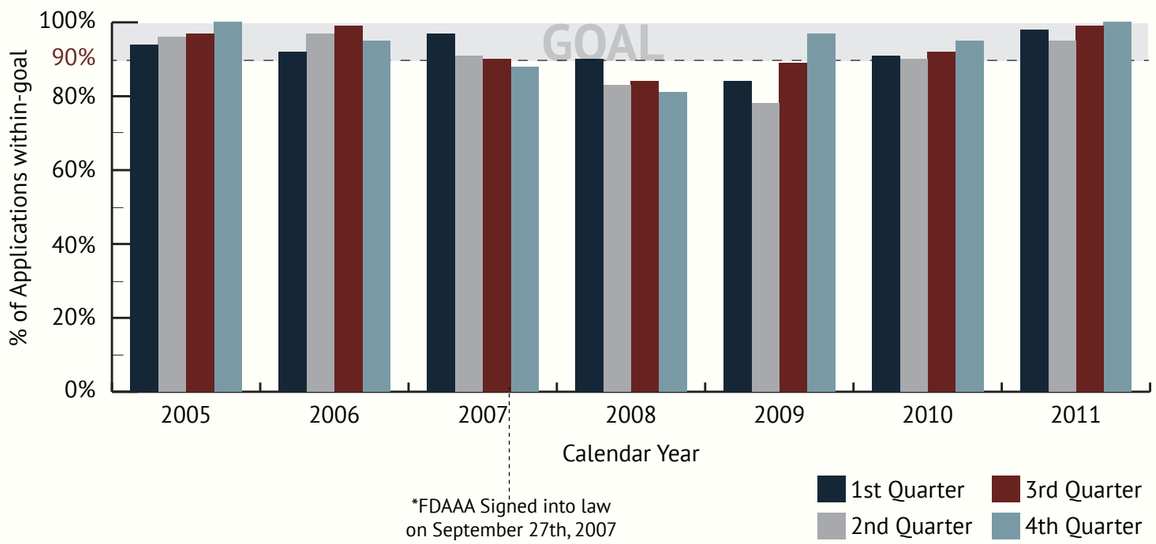
Meeting and exceeding review goals

PDUFA sets a goal for CDER to achieve a 90% on-time success rate for completing reviews of applications within designated goal times. This includes applications for new drugs, both New Drug Applications (NDAs) and Biologics License Applications (BLAs), as well as applications for new uses for already-approved products (Efficacy Supplements).

PDUFA sets a goal for CDER to achieve a 90% on-time success rate for completing reviews of applications within designated goal times.

The graph below shows that CDER has consistently met or exceeded the goal of reviewing new applications on time for at least 90% of the applications. A period from 2007 through 2009 marks an exception as a time in which CDER did not achieve that goal. This time period overlaps with an adjustment period in which CDER was implementing new requirements under a comprehensive reform act known as the Food and Drug Administration Amendments Act (FDAAA)*, signed into law on September 27th, 2007.

CDER Performance by Quarter: consistently meeting the 90% goal



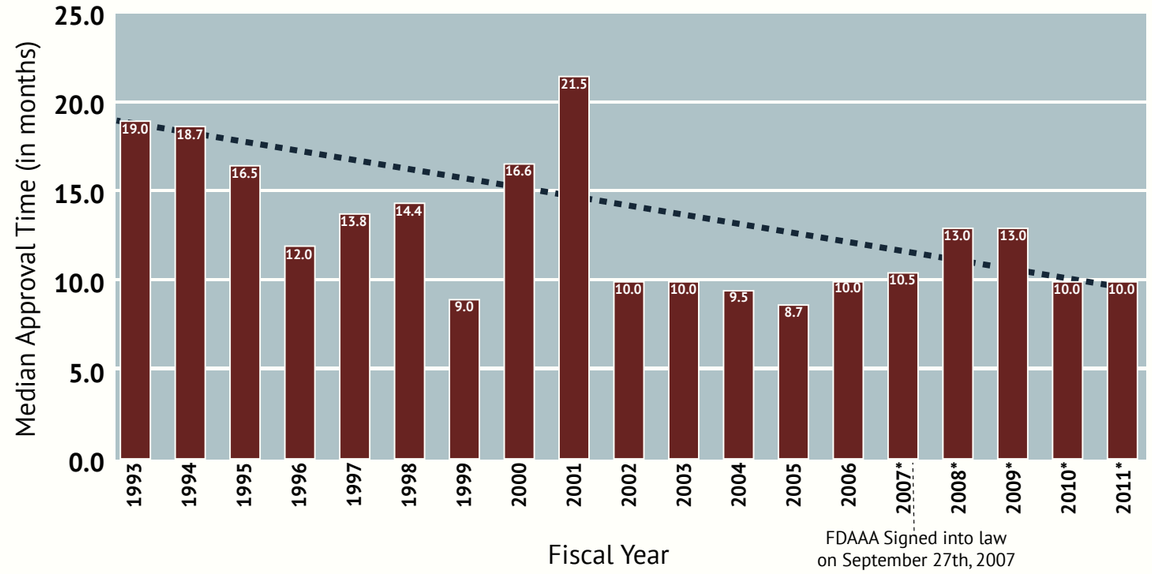
The median approval time for 2011 NMEs is approximately the same as that for 2010, and is generally consistent with markedly improved times that began in 2002.

Median approval times for NMEs

An important measure of CDER's efficiency in the drug approval process is the amount of time it takes to approve new drugs, especially new molecular entities (NMEs), which often represent new advances in drug therapy. Below shows CDER's median approval time for all NMEs per fiscal year dating back to 1993. The median approval time for 2011 NMEs is approximately the same as that for 2010, and is generally consistent with markedly improved times that began in 2002. The increased median approval times in years 2008 and 2009 overlap with the implementation of FDAAA as disussed on the previous page. Years 2007 and later are based on estimates, as footnoted below the graph, because some applications for drugs submitted during these years have not yet been approved.

CDER NME Median Approval Times

(by fiscal year of receipt)



CDER data as of 12/31/2011

*Estimated median approval time. These figures are based on NME approvals by date, elapsed time of NMEs in process, and the historic approval rate of 75-80% of NMEs filed in a given year that eventually gain FDA approval.

FIRST CYCLE APPROVALS

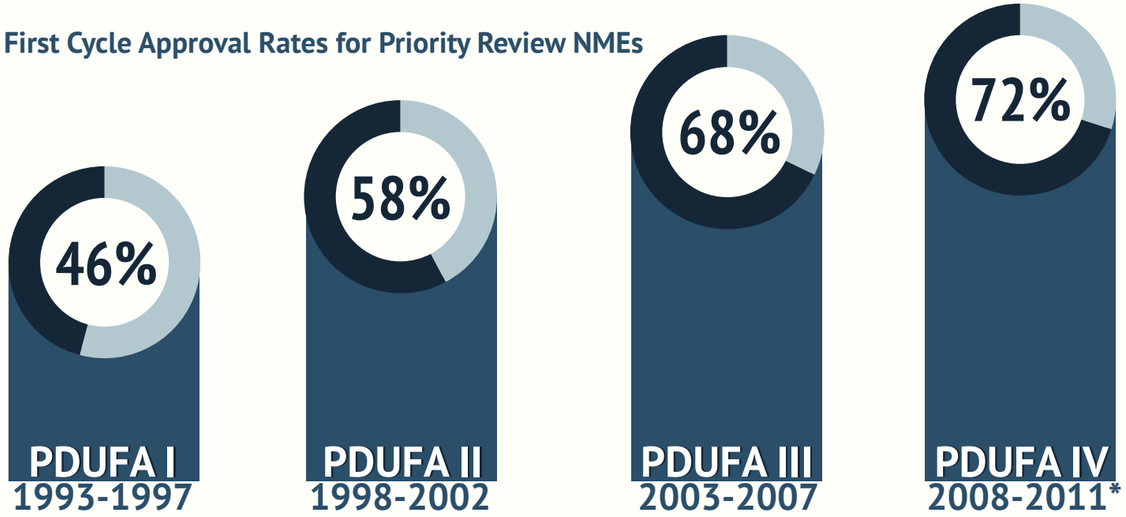
First cycle approvals for *priority* review NMEs

Drugs approved after initial review are said to be approved by CDER on the "first cycle." Alternatively, after an initial review is completed, CDER may issue the drug's sponsor a Complete Response (CR) letter, informing the sponsor the drug has not been approved; this requires at least another review cycle and therefore a delay in bringing the drug to market. First cycle approval brings drugs to patients faster, and is therefore an important measure of CDER's review efficiency.

The graph below shows CDER's percentage of first cycle approvals for priority review NMEs since 1993. Priority review drugs are designated by CDER as having the potential for contributing significant advances over existing therapies. When weighing benefits against risks in deciding to approve new drugs, CDER may accept more risk associated with a priority review drug because of its potential benefits. Note: every five years Congress must re-authorize PDUFA for continued funding. The graph below shows CDER's performance during each five-year PDUFA cycle. During PDUFA IV, the most recent PDUFA cycle, CDER's percentage of priority review new molecular entities (NMEs) approved after only one cycle of review was higher than all previous PDUFA cycles.

Priority review drugs are designated by CDER as having the potential for contributing significant advances over existing therapies.

First Cycle Approval Rates for Priority Review NMEs



CDER NME and new BLA actions as of 12/31/2011. Ten FY 2011 priority NMEs/NBEs have reached a regulatory action to date, with four currently pending first-cycle review.

CDER User Fee Performance and New Drug Approvals, 2011

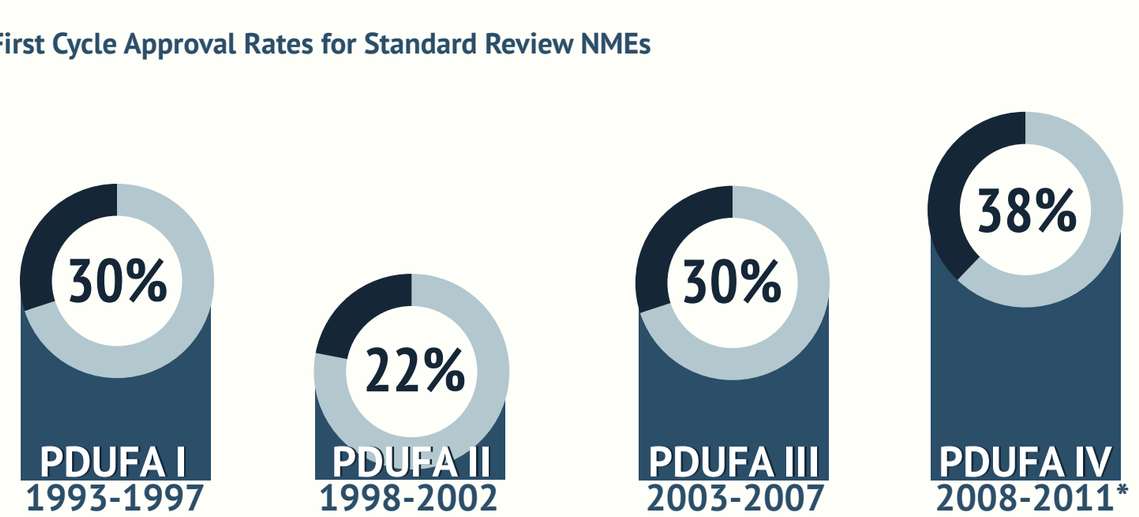
CDER may accept less risk or require more evidence of safety for standard review drugs.

First cycle approvals for *standard* review NMEs

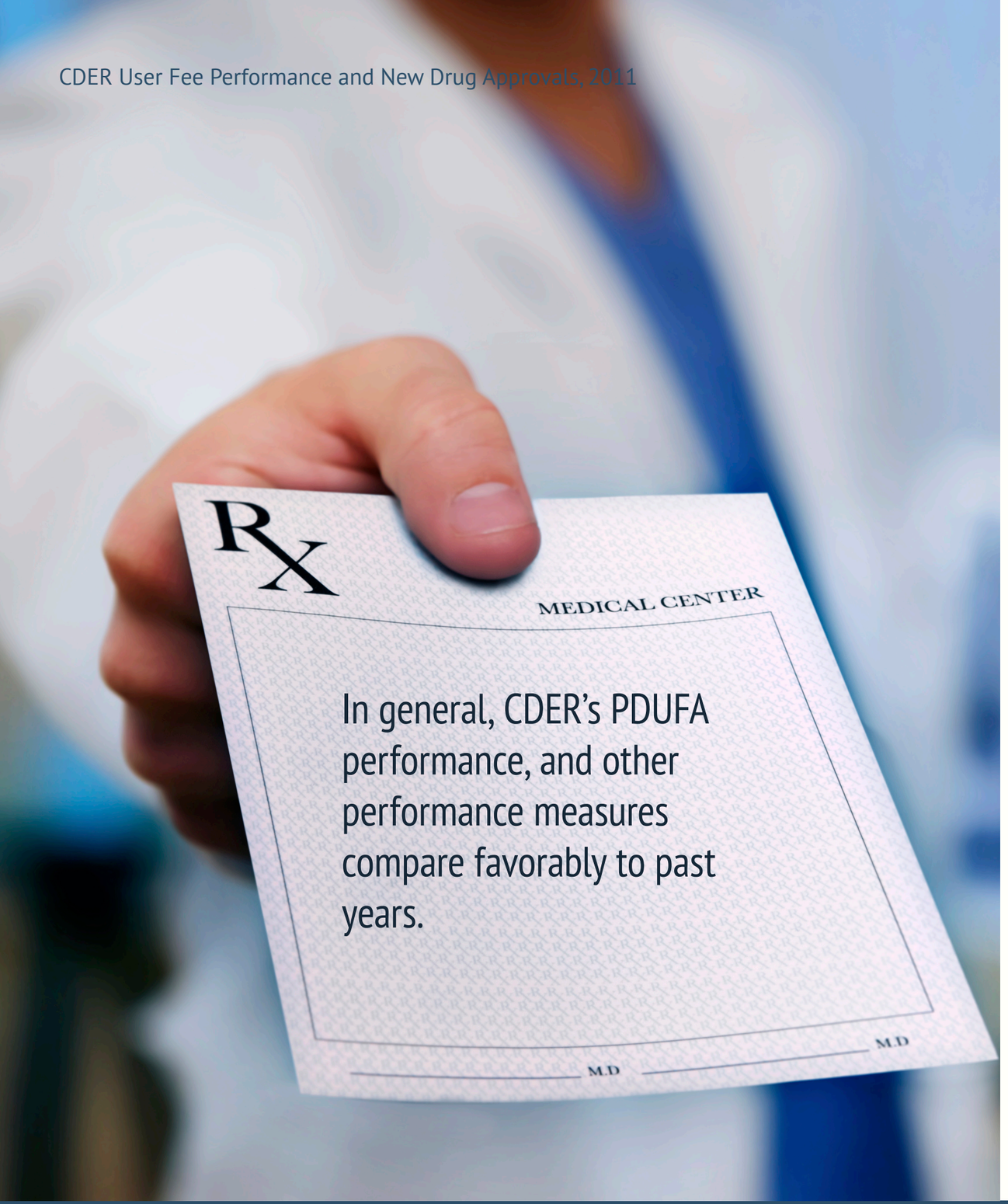
The graph below is similar to the previous graph, however, instead of measuring first cycle approval percentage for priority NMEs, it measures first cycle approval percentage for standard NMEs, which, unlike priority review drugs, are not designated by CDER as having the potential for contributing significant advances over existing therapies. For this reason, when weighing benefit to risk of a potential new drug, CDER may accept less risk or requires more evidence of safety for standard review drugs. This can lead to fewer first cycle approvals for standard review drugs compared to priority review drugs.

The graph below, as may be expected based on the discussion above, shows lower percentages of first cycle approvals for standard review drugs than the previous graph shows for priority review drugs. Although CDER recognizes room for improvement in first cycle approvals for standard review drugs, the graph also shows that during PDUFA IV, CDER's percentage of standard review NMEs approved on the first cycle is considerably higher than those of past PDUFA cycles.

First Cycle Approval Rates for Standard Review NMEs



CDER NME and new BLA actions as of 12/31/2011. Only 3 FY 2011 priority NMEs/NBEs have reached a regulatory action, with 14 currently pending first-cycle review.



In general, CDER's PDUFA performance, and other performance measures compare favorably to past years.

SUMMARY

These measures were achieved under PDUFA IV.

This document represents a broad overview of CDER's PDUFA performance and other key approval performance measures of 2011.

In general, the FDA's Center for Drug Evaluation and Research (CDER's) PDUFA performance, and other approval measures compare favorably to past years.

These measures were achieved under PDUFA IV, which expires September 31, 2012. As of the end of calendar year 2011, Congress is considering a proposal from FDA, based on agreement with industry, for new user fee requirements under PDUFA V.

To view the latest available detailed reports of CDER performance since 1995 visit: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/default.htm