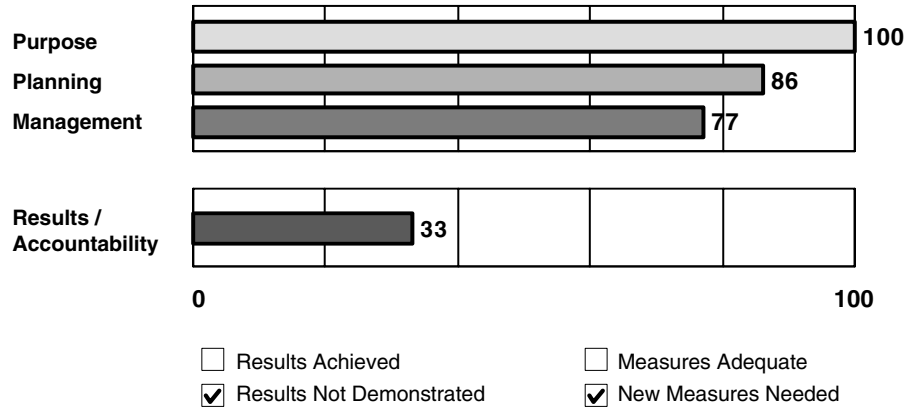


Program: Center for Drug Evaluation and Research

Agency: Department of Health and Human Services

Bureau: Food and Drug Administration



Key Performance Measures

Year Target Actual

Measure	Year	Target	Actual
Long-term Measure: Measures under development			
Annual Measure: Percentage of new drug applications "reviewed and acted on" within 10 months of receipt	1999	30%	66%
	2000	50%	79%
	2004	90%	
Annual Measure: Percentage of human drug manufacturing establishments inspected (Statutory target is 50%.)	1999	22%	26%
	2000	22%	22%
	2001	26%	19%
	2004	55%	

Rating: Results Not Demonstrated

Program Type: Regulatory

Program Summary:

The Center for Drug Evaluation and Research (CDER) regulates human drugs for safety and effectiveness.

Findings from the PART assessment include the following:

1. Accountability/Results was identified as a weakness. This would improve with the establishment of measurable long-term outcome goals.
2. CDER achieves solid performance in meeting annual performance benchmarks for the review of new drug applications.
3. CDER exhibits poor performance in inspection rates for drug manufacturing establishments. In 2001, CDER inspected only 19 percent of registered drug manufacturing establishments. Inspections are targeted to high priority establishments.
4. CDER uses performance data to recommend improvements. Financial management is sound, and managers take meaningful steps to address management weaknesses.
5. CDER created a new annual performance measure for improving the efficiency of the pre-market review process through enhanced use of information technology.
6. CDER achieved a relatively high score for their Planning efforts. CDER's list of annual performance goals allows for measurement of performance results. Long-term outcome goals would improve strategic planning at CDER.

In response to these findings, the Administration will:

1. Establish new, measurable long term performance goals for CDER.
2. Increase funding to support the timely review of new drugs through increases in prescription drug user fee collection levels.

Program Funding Level (in millions of dollars)

<u>2002 Actual</u>	<u>2003 Estimate</u>	<u>2004 Estimate</u>
367	426	454