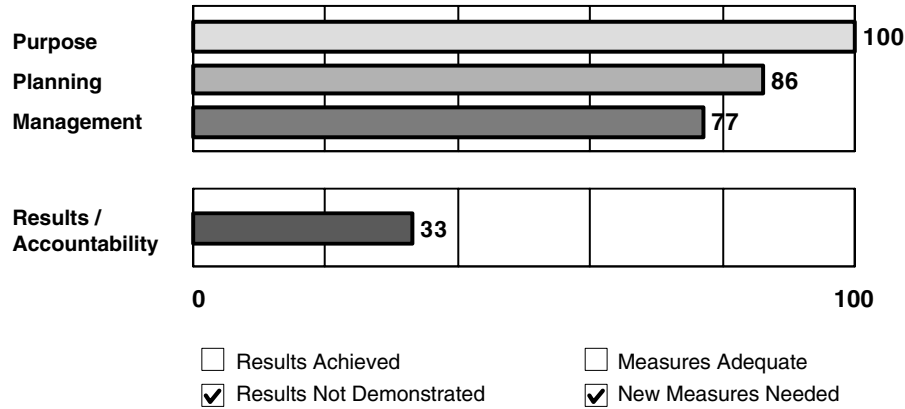


**Program:** *Center for Biologics Evaluation and Research*

**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 pre-market reviews reviewed and acted on within 10 months of receipt	1999	30%	100%
	2000	50%	100%
	2004	90%	
Annual Measure: Percentage of pre-market applications submitted to CBER via electronic application (New measure)	2004	85%	

**Rating:** *Results Not Demonstrated*

**Program Type:** *Regulatory*

**Program Summary:**

The Center for Biologics Evaluation and Research (CBER) regulates biological products, such as blood and vaccines. CBER reviews new biological products for safety and effectiveness, and ensures that products available to the public remain safe and effective.

Findings from the PART assessment include the following:

1. CBER uses performance data to recommend improvements.
2. Financial management is sound, and managers take meaningful steps to address management problems.
3. CBER created a new annual performance measure for improving the efficiency of the pre-market product reviews through increased use of information technology. Data for this measure is forthcoming.
4. CBER achieved a relatively high score for their Planning efforts. CBER's comprehensive list of annual performance goals allows for annual measurement of performance results. Long-term outcome goals would improve strategic planning at CBER.
5. Long-term measures don't currently exist. Therefore, the program cannot demonstrate the impact it is having on the public.
6. CBER achieves solid performance in meeting current annual performance goals.

In response to these findings, the Administration will:

1. Establish new, measurable long term outcome goals for CBER.
2. Increase funding for CBER pre-market reviews through increases in prescription drug review user fees.

**Program Funding Level (in millions of dollars)**

<u>2002 Actual</u>	<u>2003 Estimate</u>	<u>2004 Estimate</u>
176	200	203