

Program: Food and Drug Administration

Agency: Department of Health and Human Services

Bureau: Food and Drug Administration

Rating: Moderately Effective

Program Type: Regulatory

Program Summary:

The Food and Drug Administration (FDA) regulates the safety and effectiveness of human and animal drugs, medical devices, vaccines, and animal feeds; and the safety of food (except meat, poultry, and certain egg products). FDA accomplishes this task through pre-market review of new products and continued safety surveillance of products already available to consumers. FDA-regulated products account for almost 20 cents of every dollar spent by American consumers.

For FY 2004, a PART assessment was conducted for each of the five FDA product Centers. Due to the agency-wide centralization of planning efforts, each Center achieved a very similar score. The FY 2005 FDA PART evaluates the entire FDA through one PART format.

The FY 2005 PART assessment resulted in the creation of a challenging set of long-term outcome goals at the FDA. The new long-term outcome goals address a variety of FDA programs throughout the agency. The PART assessment found:

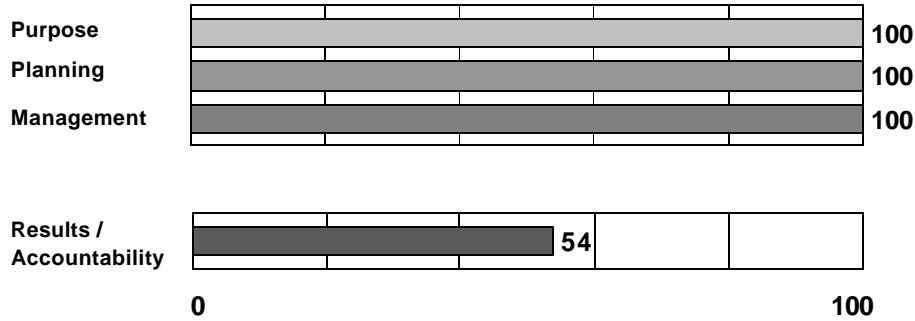
- FDA has a clear mission and a unique Federal role in protecting public health.
- FDA is well managed, and has a strong and comprehensive strategic planning process.
- FDA's annual performance goals allow for measurement of performance results. FDA generally meets most annual performance goals.
- Financial management at FDA is sound; FDA has received a clean audit free of internal material control weaknesses for five consecutive years.
- FDA is improving collaborative efforts with stakeholders and other Federal agencies.

In response to these findings from the FY 2005 consolidated FDA PART, the Administration:

1. Will track FDA performance on new long-term outcome goals.
2. Is requesting additional food defense resources to support the achievement of FDA's lab surge capacity targets.

Program Funding Level (in millions of dollars)

<u>2003 Actual</u>	<u>2004 Estimate</u>	<u>2005 Estimate</u>
1,652	1,695	1,845



Key Performance Measures *Year* *Target* *Actual*

Long-term Measure: Percentage of medical device submissions that will receive final decisions within 320 review days.	2001		72%
	2006	80%	
	2007	90%	
Long-term Measure: Increase by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. (Baseline data under development)			
Long-term Measure: Number of labs to address surge capacity in the event of terrorist attack on the food supply.	2004	10	10
	2005	25	
	2006	42	
	2007	60	